2026 UnitedHealthcare Individual and Family Plan Clinical Criteria - Indiana
Effective 5.1.2026

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Vyndaqel, Vyndamax 1879
Vyvgart Hytrulo 1884
Wainua 1892
Wakix 1896
Wayrilz 1902
Wegovy 1906
Winrevair 1916
Xdemvy 1921
Xeljanz, Xeljanz XR 1925
Xenazine 1944
Xermelo 1948
Xifaxan 1951
Xolair 1957
Xolremdi 1976

Xospata 1980
Xphozah 1986
Xtandi 1990
Xyrem, Xywav, Lumryz 1995
Yonsa 2005
Yorvipath 2011
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Abirtega, Zytiga

Prior Authorization Guideline

Guideline ID	GL-375634
Guideline Name	Abirtega, Zytiga
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 05/21/2021 ; 09/15/2021 ; 05/20/2022 ; 09/21/2022 ; 05/25/2023 ; 05/17/2024 ; 04/16/2025 ; 05/16/2025 ; 9/25/2025

1 . Indications

Drug Name: Abirtega, Zytiga (abiraterone acetate)
Prostate cancer Indicated for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer and for high-risk metastatic castration-sensitive prostate cancer.

2 . Criteria

Product Name:Brand Abirtega, Brand Zytiga, generic abiraterone [a]	
Diagnosis	Prostate cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Disease is metastatic castration-resistant

AND

2.1.2 If the request is for BRAND Zytiga, ONE of the following:

- History of failure, contraindication or intolerance to Xtandi (enzalutamide)
- Provider attests that the patient is not an appropriate candidate for Xtandi (enzalutamide)

OR

2.2 BOTH of the following:

2.2.1 Disease is metastatic castration-sensitive

AND

2.2.2 If the request is for brand Zytiga, ONE of the following:

2.2.2.1 History of failure, contraindication or intolerance to BOTH of the following:

- Erleada (apalutamide)

- Xtandi (enzalutamide)

OR

2.2.2.2 Provider attests that the patient is not an appropriate candidate for BOTH of the following:

- Erleada (apalutamide)
- Xtandi (enzalutamide)

OR

2.3 BOTH of the following:

2.3.1 ONE of the following:

- Disease is regional node positive (Any T, N1, M0)
- Patient is in a very-high-risk group receiving radiation therapy

AND

2.3.2 ONE of the following:

- Life expectancy > 5 years
- Patient has symptomatic disease

OR

2.4 ALL of the following:

2.4.1 Disease is non-metastatic

AND

2.4.2 Life expectancy > 5 years

AND

2.4.3 ONE of the following:

- Positive pelvic persistence/recurrence after radical prostatectomy (RP)
- Lymph node metastases after RP
- Studies positive for regional lymph nodes after radiation therapy

AND

3 - Used in combination with prednisone

AND

4 - ONE of the following:

- Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]
- \Patient has had bilateral orchiectomy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Abirtega, Brand Zytiga, generic abiraterone [a]	
Diagnosis	Prostate cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Abirtega or Zytiga therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Abirtega, Brand Zytiga, generic abiraterone [a]	
Diagnosis	Salivary Gland Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of salivary gland tumor **AND** **2** - Used in combination with prednisone **AND** **3** - Androgen receptor positive recurrent disease	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Abirtega, Brand Zytiga, generic abiraterone [a]	
Diagnosis	Salivary Gland Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Abirtega or Zytiga therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Abirtega, Brand Zytiga, generic abiraterone [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Abirtega or Zytiga will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Abirtega, Brand Zytiga, generic abiraterone [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Abirtega or Zytiga therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background

Abiraterone acetate is a CPY17 inhibitor indicated for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer and for high-risk metastatic castration-sensitive prostate cancer. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently while taking abiraterone or should have had bilateral orchiectomy.

The National Comprehensive Cancer Network (NCCN) also recommends the use of abiraterone in combination with prednisone and androgen deprivation therapy (ADT) as initial therapy for patients without metastases yet with regional node positive disease if life expectancy is greater than 5 years or symptomatic. In combination with ADT and radiation therapy as initial therapy in patients in very-high-risk group if life expectancy is greater than 5 years or symptomatic. In combination with prednisone and ADT if life expectancy is greater than 5 years for patients with non-metastatic positive pelvic persistence/recurrence after prostatectomy, non-metastatic undetectable PSA after radical prostatectomy and non-metastatic PSA recurrence or positive digital rectal exam. The NCCN also recommends the use of abiraterone in salivary gland tumors useful in certain circumstances as single-agent systemic therapy (used in combination with prednisone) for androgen receptor positive recurrent disease.

Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
  Supply limits may be in place.

4 . References

1. Zytiga [package insert]. Horsham, PA: Janssen Biotech Inc.; November 2024.
2. Abirtega [package insert]. Lehi, UT: CivicaScript, LLC. February 2025.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 4, 2025.

5 . Revision History

Date	Notes
8/29/2025	Annual review. Updated step therapy language for brand Zytiga to br eak out between metastatic castration-sensitive and metastatic castr ation-resistant and updated step therapy logic in accordance with pro ducts that share indications. Updated criteria for prostate cancer per NCCN, updated references.

Actimmune

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-285255
Guideline Name	Actimmune
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	06/17/2020 ; 02/19/2021 ; 06/16/2021 ; 06/15/2022 ; 06/21/2023 ; 06/17/2024 ; 6/18/2025

1 . Indications

Drug Name: Actimmune (interferon gamma-1b)
Chronic granulomatous disease Indicated for the treatment of chronic granulomatous disease to reduce the frequency and severity of serious infections. **Osteopetrosis** Indicated in the treatment of severe, malignant osteopetrosis to delay the time to progression. **Other Uses:** The National Cancer Comprehensive Network (NCCN) recommends use of Actimmune in mycosis fungoides (MF) and Sezary syndrome (SS).

2 . Criteria

Product Name:Actimmune [a]	
Diagnosis	Chronic Granulomatous Disease (CGD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic granulomatous disease	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Actimmune [a]	
Diagnosis	Chronic Granulomatous Disease (CGD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Actimmune	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Actimmune [a]	
Diagnosis	Osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe, malignant osteopetrosis	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Actimmune [a]	
Diagnosis	Osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Actimmune	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Actimmune [a]	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has ONE of the following diagnoses:	

• Mycosis fungoides (MF) • Sezary syndrome (SS)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Actimmune [a]	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Actimmune	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Actimmune [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Actimmune will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Actimmune [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Actimmune therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Actimmune (interferon gamma-1b) is indicated for reducing the frequency and severity of serious infections associated with chronic granulomatous disease (CGD). It is also indicated for delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO). The National Cancer Comprehensive Network (NCCN) recommends use of Actimmune in mycosis fungoides (MF) and Sézary syndrome (SS). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class

- Supply limits may apply.

4 . References

1. Actimmune [Package Insert]. Deerfield, IL: Horizon Therapeutics USA Inc.; December 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 28, 2025.

5 . Revision History

Date	Notes
6/2/2025	Annual review with no changes to coverage criteria. Updated references.

Adalimumab

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-533192
Guideline Name	Adalimumab
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	05/21/2021 ; 05/20/2022 ; 09/21/2022 ; 01/18/2023 ; 06/21/2023 ; 08/18/2023 ; 12/13/2023 ; 04/17/2024 ; 01/15/2025 ; 06/18/2025 ; 10/15/2025 ; 2/20/2026

1 . Indications

Drug Name: Adalimumab
Rheumatoid Arthritis Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. **Polyarticular Juvenile Idiopathic Arthritis** Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 2 years of age and older. **Psoriatic Arthritis** Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. **Ankylosing Spondylitis** Indicated for reducing signs and symptoms in adult patients with

active ankylosing spondylitis.

Crohn's Disease Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years and older.

Ulcerative Colitis Indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years and older.

Plaque Psoriasis Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

Hidradenitis Suppurativa Indicated for the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.

Uveitis Indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult and pediatric patients 2 years of age and older.

2 . Criteria

Product Name:Adalimumab [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - ONE of the following:

2.1 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at the maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

OR

2.3 BOTH of the following:

- Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of adalimumab*

AND

3 - If the request is for a non-formulary adalimumab product, the patient has a history of failure to all formulary adalimumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary adalimumab product (please document reason/special circumstances) [b]

AND

4 - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator. [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to adalimumab therapy **AND** **2** - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator. [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

	NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - If the request is for a non-formulary adalimumab product, the patient has a history of failure to all formulary adalimumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary adalimumab product (please document reason/special circumstances) [b]

AND

3 - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may ap

	ply. [b] For a list of preferred adalimumab products please reference drug coverage tools. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to adalimumab therapy **AND** **2** - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]

Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - ONE of the following:

2.1 History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

OR

2.3 BOTH of the following:

- Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of adalimumab*

AND

3 - If the request is for a non-formulary adalimumab product, the patient has a history of failure to all formulary adalimumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary adalimumab product (please document reason/special circumstances) [b]

AND

4 - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. [b] For a list of preferred adalimumab products please reference drug coverage tools. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Psoriatic Arthritis (PsA)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to adalimumab therapy

AND

2 - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

2.1.2 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Coal tar

AND

2.1.3 History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

OR

2.3 BOTH of the following:

- Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of adalimumab*

AND

3 - If the request is for a non-formulary adalimumab product, the patient has a history of failure to all formulary adalimumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary adalimumab product (please document reason/special circumstances) [b]

AND

4 - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab produc

	t, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary ad alimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to adalimumab therapy **AND** **2** - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - ONE of the following:

2.1 History of failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

OR

2.3 BOTH of the following:

- Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of adalimumab*

AND

3 - If the request is for a non-formulary adalimumab product, the patient has a history of failure to all formulary adalimumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary adalimumab product (please document reason/special circumstances) [b]

AND **4** - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication. **AND** **5** - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to adalimumab therapy

AND

2 - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - ONE of the following:

2.1 History of failure to ONE of the following conventional therapies at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of Crohn's disease as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), ustekinumab]

OR

2.3 BOTH of the following:

- Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of adalimumab*

AND

3 - If the request is for a non-formulary adalimumab product, the patient has a history of failure to all formulary adalimumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary adalimumab product (please document reason/special circumstances) [b]

AND

4 - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with a gastroenterologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to adalimumab therapy **AND** **2** - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply. NOTE: If the member meets the medical necessity authorization criteri a requirements for treatment with a non-formulary adalimumab produc t, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary ad alimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - ONE of the following:

2.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission medical records (Document drug, date, and duration of therapy) [e.g., Simponi (golimumab), ustekinumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

OR

2.3 BOTH of the following:

- Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of adalimumab*

AND

3 - If the request is for a non-formulary adalimumab product, the patient has a history of failure to all formulary adalimumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary adalimumab product (please document reason/special circumstances) [b]

AND

4 - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with a gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary

	denial should be issued and a 12 month authorization for formulary ad alimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to adalimumab therapy **AND** **2** - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

AND

2 - ONE of the following:

2.1 History of failure to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

OR

2.2 BOTH of the following:

- Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of adalimumab*

AND

3 - If the request is for a non-formulary adalimumab product, the patient has a history of failure to all formulary adalimumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary adalimumab product (please document reason/special circumstances) [b]

AND

4 - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

AND **5** - Prescribed by or in consultation with a dermatologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to adalimumab therapy **AND** **2** - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab),	

Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-infectious uveitis

AND

2 - Uveitis is classified as ONE of the following:

- intermediate
- posterior
- panuveitis

AND

3 - ONE of the following:

3.1 BOTH of the following:

- History of failure to at least ONE corticosteroid (e.g., prednisolone, prednisone) at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)
- History of failure to at least ONE systemic non-biologic immunosuppressant (e.g., methotrexate, cyclosporine, azathioprine, mycophenolate) at up to a maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

OR

3.2 BOTH of the following:

- Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of adalimumab*

AND

4 - If the request is for a non-formulary adalimumab product, the patient has a history of failure to all formulary adalimumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary adalimumab product (please document reason/special circumstances) [b]

AND

5 - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

AND

6 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Ophthalmologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary adalimumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary adalimumab products should be provided at GPI 66270015******.

Product Name:Adalimumab [a]	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to adalimumab therapy **AND** **2** - Patient is not receiving adalimumab in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

	NOTE: If the member meets the medical necessity authorization criteri a requirements for treatment with a non-formulary adalimumab produc t, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary ad alimumab products should be provided at GPI 66270015******.

3 . Background

Clinical Practice Guidelines
Medication: Humira® (adalimumab), Abrilada™ (adalimumab-afzb), Adalimumab-aacf (unbranded Idacio), Adalimumab-aaty (unbranded Yuflyma), Adalimumab-adaz (unbranded Hyrimoz), Adalimumab-adbm (unbranded Cyltezo), Adalimumab-bwwd (unbranded Hadlima), Adalimumab-fkjp (unbranded Hulio), Adalimumab-ryvk (unbranded Simlandi), Amjevita™ (adalimumab-atto), Cyltezo®, (adalimumab-adbm), Hadlima™ (adalimumab-bwwd), Hulio® (adalimumab-fkjp), Hyrimoz® (adalimumab-adaz), Idacio® (adalimumab-aacf), Simlandi® (adalimumab-ryvk), Yuflyma® (adalimumab-aaty), Yusimry™ (adalimumab-aqvh)
Benefit/Coverage/Program Information
Background: Adalimumab is a tumor necrosis factor (TNF) blocker indicated for: • Rheumatoid Arthritis (RA): reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. Adalimumab can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs). • Juvenile Idiopathic Arthritis (JIA): reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older. Adalimumab can be used alone or in combination with methotrexate. • Psoriatic Arthritis (PsA): reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA. • Ankylosing Spondylitis (AS): reducing signs and symptoms in adult patients with active AS. Adalimumab can be used alone or in combination with non-biologic DMARDs.

• Crohn's Disease (CD): treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.

• Ulcerative Colitis (UC): treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older.

• Plaque Psoriasis (Ps): treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

• Hidradenitis Suppurativa (HS): treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.

• Uveitis (UV): treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older.

In ulcerative colitis, effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

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19. Cyltezo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2023
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21. Hadlima [package insert]. Jersey City, NJ: Organon & Co.; July 2023.
22. Hulio [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; December 2023.
23. Yusimry [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; September 2023.
24. Yuflyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; December 2023.
25. Idacio [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC.; October 2023.
26. Abrilada [package insert]. New York, NY: Pfizer, Inc. January 2024.
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5 . Revision History

Date	Notes
2/25/2026	Added Adalimumab-bwwd (unbranded Hadlima) to policy.

Adbry

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-405334
Guideline Name	Adbry
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	2/18/2022
P&T Revision Date:	03/16/2022 ; 07/20/2022 ; 03/15/2023 ; 03/20/2024 ; 03/19/2025 ; 04/16/2025 ; 10/15/2025

1 . Indications

Drug Name: Adbry (tralokinumab-ldrm)
Atopic Dermatitis Indicated for the treatment of moderate to severe atopic dermatitis in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

2 . Criteria

Product Name:Adbry [a]	
Diagnosis	Atopic Dermatitis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderate-to-severe chronic atopic dermatitis

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to BOTH of the following therapeutic classes of topical therapies (document drug, date of trial, and/ or contraindication to medication)^:

- Medium, high, or very-high potency topical corticosteroids [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]
- Topical calcineurin inhibitor [e.g., tacrolimus (generic Protopic)]

OR

2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of atopic dermatitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Opzelura (ruxolitinib), Rinvoq (upadacitinib)].

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to Dupixent (dupilumab) (document date and duration of trial)

OR

3.2 BOTH of the following:

3.2.1 Patient is currently on Adbry therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

AND

3.2.2 Patient has not received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Leo Pharma dermatology patient access program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Adbry*

AND

4 - Patient is NOT receiving Adbry in combination with EITHER of the following:

- Biologic immunomodulator [e.g., Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemoli-zumab-ilto)]
- Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]

AND

5 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Leo Pharma dermatology patient access program shall be required to meet initial authorization criteria as if patient were new to therapy. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Adbry [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Adbry therapy

AND

2 - Patient is NOT receiving Adbry in combination with EITHER of the following:

- Biologic immunomodulator [e.g., Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemoli-zumab-ilto)]
- Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Adbry (tralokinumab-ldrm) is an interleukin-13 antagonist indicated for the treatment of moderate to severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry can be used with or without topical corticosteroids.

Table 1: Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05

	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.

4 . References

1. Adbry [package insert]. Madison, NJ: Leo Pharma Inc.; June 2024.
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5 . Revision History

Date	Notes
9/29/2025	Removed step through Rinvoq.

Administrative Off-Label



Prior Authorization Guideline

Guideline ID	GL-424273
Guideline Name	Administrative Off-Label
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	
P&T Revision Date:	10/20/2021 ; 05/25/2023

Note:

Technician Note: ***Link to Exclusions and Limitations Grid: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x01200027C80175A8369D44AC45A99A99328B80&View=%7B4B6D25AD%2D6A95%2D496D%2D9937%2D65CECD43AFE7%7D&viewid=c2ad0afa%2D814c%2D499e%2Dbf25%2D3411fac9171f&id=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FUHCGP%20Exchange

1 . Criteria

Product Name:Medications requested for off-label indications	
Approval Length	12 month(s)
Guideline Type	Administrative Off-Label

Approval Criteria

1 - A request for an off-label indication will be approved based on one of the following:

1.1 The diagnosis is supported in DRUGDEX and one of the following:

1.1.1 The drug has a Strength of Recommendation in the FDA Uses/Non-FDA Uses section rating of Class I, Class IIa, or Class IIb (see DRUGDEX Strength of Recommendation table in Background section)

OR

1.1.2 Both of the following:

- The drug has a Strength of Recommendation of III or Class Indeterminate (see DRUGDEX Strength of Recommendation table in Background section)
- Efficacy is rated as "Effective" or "Evidence Favors Efficacy" (see DRUGDEX Efficacy Rating and Prior Authorization Approval Status table in Background section)

OR

1.1.3 The diagnosis is supported in any other section in DRUGDEX. (Note: Supported use is considered to mean positive language in any section of the compendia that clearly indicates the drug has efficacy or is beneficial for an off-label use. If there is conflicting evidence, [e.g., use is not supported in the FDA Uses/Non-FDA Uses sections of DRUGDEX but has favorable support elsewhere within DRUGDEX] the favorable support would take precedence and the use would be accepted as a supported use)

OR

1.2 The diagnosis is supported as a use in Clinical Pharmacology

OR

1.3 The diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI)

OR

1.4 The diagnosis is supported as a use in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section)

OR

1.5 The diagnosis is supported as a use in United States Pharmacopoeia-National Formulary (USP-NF)

OR

1.6 The diagnosis is supported as a use in Drug Facts and Comparisons

OR

1.7 The diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs

OR

1.8 The diagnosis is supported in published practice guidelines and treatment protocols

OR

1.9 The diagnosis is supported in peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

AND

2 - The use is not excluded as documented in the limitations and exclusions section of the certificate of coverage (see technician note for the Exclusions and Limitations Grid URL).

Notes	NOTE: Off-label use may be reviewed for medical necessity and denied as such if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

2 . Background

Clinical Practice Guidelines

DRUGDEX Strength of Recommendation [1]

Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been proven useful and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test or treatment is not useful, and should be avoided
Class Indeterminate	Evidence Inconclusive	

DRUGDEX Efficacy Rating and Prior Authorization Approval Status [1]

Efficacy Rating	Prior Authorization Status
Effective	Approvable
Evidence favors Efficacy	Approvable
Evidence is inconclusive	Not approvable
Ineffective	Not approvable

NCCN Categories of Evidence and Consensus [2]

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus tha intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus th intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement intervention is appropriate.

Benefit/Coverage/Program Information

BACKGROUND:

This program is to be administered to medications of various formulary statuses where the requested use is not FDA approved. This policy is intended to ensure that medications subject to prior authorization, including those not listed on the Plan Formulary/PDL, are utilized in accordance with FDA indications and uses found in the compendia of current literature. This policy aims to foster cost-effective, first-line use of available formulary/PDL medications.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

3 . References

1. Micromedex Healthcare Series. Recommendation, Evidence and Efficacy Ratings. https://www.micromedexsolutions.com/home/dispatch/CS/F09729/PFActionId/pf.HomePage. Accessed July 28, 2025.
2. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines. Accessed July 28, 2025.

4 . Revision History

Date	Notes
10/22/2025	Annual Review. Updated references.

Administrative Transition of Care (TOC) For Members New to Plan



Prior Authorization Guideline

Guideline ID	GL-163280
Guideline Name	Administrative Transition of Care (TOC) For Members New to Plan
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	3/1/2025
P&T Approval Date:	1/15/2025
P&T Revision Date:	

Note:

Note: Policy is to be applied if drug specific criteria are not met.

1 . Criteria

Product Name:All Formulary and Non-Formulary Medications*	
Approval Length	30 Day(s)
Guideline Type	Administrative
Approval Criteria	

1 - Member is new to plan (within first 90 days of eligibility with the plan)**

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Requested drug is FDA-approved for the condition being treated
- Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g.: first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

2.2 Meets Off-Label Administrative guideline criteria

AND

3 - Provider attestation to use of the requested medication prior to enrollment in the plan

Notes	*Note: Policy is to be applied if drug specific criteria are not met. **New to plan includes new members within the first 90 days of cover age, existing members who moved to a new state and are within the fi rst 90 days of coverage under their new state IFP plan, and members had a lapse in coverage/re-enrolled and are within the first 90 days of coverage under their most recent enrollment.

2 . Background

Benefit/Coverage/Program Information
Background: This program is to be administered to members who are new to plan (within the past 90 days) and who have an authorization from a prior plan to allow a transitional fill for continuation of therapy.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

3 . Revision History

Date	Notes
1/8/2025	New Program

Afinitor, Torpenz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-244329
Guideline Name	Afinitor, Torpenz
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	1/20/2021
P&T Revision Date:	05/21/2021 ; 09/15/2021 ; 05/20/2022 ; 10/19/2022 ; 05/25/2023 ; 08/18/2023 ; 05/17/2024 ; 08/16/2024 ; 5/16/2025

1 . Indications

Drug Name: Afinitor (everolimus)
Advanced renal cell carcinoma Indicated for adults with advanced renal cell carcinoma (RCC) after failure of treatment with Sutent (sunitinib) or Nexavar (sorafenib). [1] **Subependymal giant cell astrocytoma (SEGA)** Indicated for treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. [1] **Progressive neuroendocrine tumors of pancreatic origin (PNET)** Indicated for adults with progressive neuroendocrine tumors of pancreatic origin (PNET) and adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. [1] **Renal angiomyolipoma and tuberous sclerosis complex (TSC)** Indicated for adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate

surgery. [1]

Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer (Advanced HR+ BC) Indicated for postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with Aromasin (exemestane) after failure of treatment with Femara (letrozole) or Arimidex (anastrozole).

Tuberous Sclerosis Complex (TSC) Indicated for the adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC associated partial-onset seizures.

Drug Name: Torpenz (everolimus)

Hormone Receptor-Positive, HER2-Negative Breast Cancer Indicated for postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole

Tuberous Sclerosis Complex (TSC)-Associated Renal Angiomyolipoma Indicated for adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery

Tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA) Indicated in adult and pediatric patients aged 1 year and older with TSC for the treatment of SEGA that requires therapeutic intervention but cannot be curatively resected.

2 . Criteria

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Neuroendocrine Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of ONE of the following:

- Neuroendocrine tumors of gastrointestinal origin
- Neuroendocrine tumors of lung origin

- Neuroendocrine tumors of thymic origin

AND

1.2 ONE of the following:

- Disease is unresectable
- Disease is locally advanced
- Disease is metastatic

OR

2 - BOTH of the following:

2.1 Diagnosis of neuroendocrine tumors of pancreatic origin

AND

2.2 ONE of the following:

- Used for the management of recurrent, locoregional advanced and/or metastatic disease
- Used for management to stabilize glucose levels of locoregional insulinoma

OR

3 - ALL of the following:

3.1 Diagnosis of well-differentiated, grade 3 neuroendocrine tumor

AND

3.2 ONE of the following:

- Disease is unresectable
- Disease is locally advanced
- Disease is metastatic

AND **3.3** Tumor has favorable biology (e.g., relatively low Ki-67 [

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Neuroendocrine Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - BOTH of the following: • Diagnosis of kidney cancer	

- Disease is relapsed or stage IV

OR

2 - Diagnosis of tuberous sclerosis complex (TSC)-associated renal cell carcinoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of subependymal giant cell astrocytoma (SEGA)
- Used as adjuvant treatment

OR

2 - ALL of the following:

2.1 Diagnosis of meningioma

AND

2.2 Disease is recurrent or progressive

AND

2.3 Surgery and/or radiation is not possible

AND

2.4 ONE of the following:

- Used in combination with bevacizumab (Avastin, Mvasi, etc.)
- Used in combination with octreotide acetate LAR

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Waldenstroms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Waldenstroms macroglobulinemia
- Lymphoplasmacytic lymphoma

AND

2 - ONE of the following:

- Disease is non-responsive to primary treatment
- Disease is progressive
- Disease has relapsed

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]

Diagnosis	Waldenstroms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - ONE of the following:

- Disease is recurrent
- Disease is metastatic

AND

3 - ONE of the following:

- Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)]
- Breast cancer is considered inflammatory

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - ONE of the following:

5.1 Patient is a postmenopausal woman

OR

5.2 BOTH of the following

- Patient is a premenopausal woman
- Patient is being treated with ovarian ablation/suppression

OR

5.3 Patient is male

AND

6 - Used in combination with one of the following:

- Exemestane if progressed within 12 months or on a non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)]
- Fulvestrant
- Tamoxifen

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may ap

	ply. ^Tried/failed alternative(s) are supported by FDA labeling and/or NCC N guidelines.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of classic Hodgkin lymphoma **AND** **2** - Disease is relapsed or refractory	

AND **3** - Patient is not a candidate for autologous stem cell rescue/high-dose therapy (ASCR/HDT)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following soft tissue sarcoma subtypes:	

• Locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa) • Recurrent angiomyolipoma • Lymphangioleiomyomatosis

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Thymomas and Thymic Carcinomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following:	

- Diagnosis of thymic carcinoma
- Diagnosis of thymoma

AND

2 - ONE of the following:

- First-line therapy as a single agent for those who cannot tolerate first-line combination regimens
- Second-line therapy as a single agent

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Thymomas and Thymic Carcinomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

AND

2 - ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

3 - ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of endometrial carcinoma
- Used in combination with letrozole

OR

2 - ALL of the following:

- Diagnosis of Uterine Sarcoma
- Disease is perivascular epithelioid cell tumor (PEComa)
- Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Tuberous Sclerosis Complex associated Partial-onset Seizures
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of tuberous sclerosis complex associated partial-onset seizures **AND** **2** - Used as adjunctive therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Tuberous Sclerosis Complex associated Partial-onset Seizures
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Bone Cancer - Osteosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of osteosarcoma

AND

2 - Disease is ONE of the following:

- Relapsed/Refractory
- Metastatic

AND

3 - Used as second-line therapy

AND

4 - Used in combination with Nexavar (sorafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Bone Cancer - Osteosarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Rosai-Dorfman Disease
- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease

AND

2 - Presence of phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha (PIK3CA) mutation	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Gastrointestingal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Gastrointestinal Stromal Tumor (GIST) **AND**	

2 - Disease is ONE of the following:

- Unresectable primary
- Recurrent/metastatic
- Gross residual (R2 resection)
- Tumor rupture

AND

3 - Disease has progressed after single agent therapy with ALL of the following^:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)
- Stivarga (regorafenib)
- Qinlock (ripretinib)

AND

4 - Used in combination with ONE of the following:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)
- Stivarga (regorafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	Gastrointestingal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Afinitor, generic everolimus, Torpenz [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Afinitor® (everolimus) is a kinase inhibitor indicated for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with Aromasin® (exemestane) after failure of treatment with Femara® (letrozole) or Arimidex® (anastrozole); in adults with progressive neuroendocrine tumors of pancreatic origin (PNET) and adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic; adults with advanced renal cell carcinoma (RCC) after failure of treatment with Sutent® (sunitinib) or Nexavar® (sorafenib); adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery; treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected; and for the adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC associated partial-onset seizures.[1] Torpenz is indicated for postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole, for adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery, and for adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. Afinitor is not indicated for the treatment of patients with functional carcinoid tumors. The National Cancer Comprehensive Network (NCCN) also recommends use of Afinitor in invasive and inflammatory breast cancer, Waldenström's macroglobulinemia / lymphoplasmacytic lymphoma, neuroendocrine tumors, kidney cancer, soft tissue sarcomas, osteosarcomas, gastrointestinal stromal tumors, thymomas and thymic carcinomas, Hodgkin lymphoma, follicular, oncocytic, and papillary thyroid carcinomas, subependymal giant cell astrocytoma (SEGA), meningioma, histiocytic neoplasms, and endometrial carcinoma.[2]

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Afinitor [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2022.
2. Torpenz [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC.; June 2024.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. April 9, 2025

5 . Revision History

Date	Notes
4/28/2025	Annual review. Updated criteria for neuroendocrine tumors, breast cancer, Hodgkin lymphoma, thyroid cancer, and gastrointestinal stromal tumors per NCCN guidelines. Updated section on endometrial carcinoma and renamed uterine neoplasms. Consolidated sections for meningioma and subependymal giant cell astrocytoma (SEGA) and renamed central nervous system cancer. Consolidated sections for tuberous sclerosis complex (TSC)-associated renal cell carcinoma and advanced renal cell carcinoma and renamed kidney cancer.

Agamree

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412195
Guideline Name	Agamree
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	7/17/2024
P&T Revision Date:	10/16/2024 ; 10/15/2025

1 . Indications

Drug Name: Agamree (vamorolone)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older

2 . Criteria

Product Name:Agamree [a]	
Diagnosis	Duchenne Muscular Dystrophy (DMD)
Guideline Type	Non Formulary

Approval Criteria **1** - Published clinical evidence shows Agamree is likely to produce equivalent therapeutic results as other available corticosteroids (e.g., prednisone); therefore, Agamree is not medically necessary for treatment of Duchenne muscular dystrophy.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Agamree (vamorolone) is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older. [1] The UnitedHealthcare Pharmacy and Therapeutics Committee has determined that Agamree is Therapeutically Equivalent to prednisone in the treatment of DMD. While adverse effect profiles may differ among glucocorticoids, vamorolone does not offer a clear advantage over other glucocorticoids for DMD with respect to efficacy and overall safety. [2-5] **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Agamree [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; June 2024.

2. Dang UJ, Damsker JM, Guglieri M, et al. Efficacy and Safety of Vamorolone Over 48 Weeks in Boys With Duchenne Muscular Dystrophy: A Randomized Controlled Trial. Neurology. 2024;102(5):e208112.
3. Guglieri M, Clemens PR, Perlman SJ, et al. Efficacy and Safety of Vamorolone vs Placebo and Prednisone Among Boys With Duchenne Muscular Dystrophy: A Randomized Clinical Trial. JAMA Neurol. 2022;79(10):1005-1014.
4. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. Lancet Neurol. 2018;17(3):251-267.

5 . Revision History

Date	Notes
10/6/2025	Annual review with no changes to criteria. Updated background and r eferences.

Alecensa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-276240
Guideline Name	Alecensa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	8/18/2023
P&T Revision Date:	06/17/2024 ; 6/18/2025

1 . Indications

Drug Name: Alecensa (alectinib)
Adjuvant Treatment of Resected ALK-Positive Non-Small Cell Lung Cancer (NSCLC) Indicated as adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive), as detected by an FDA-approved test **Treatment of Metastatic ALK-Positive NSCLC** Indicated for the treatment of adult patients with ALK-positive metastatic NSCLC as detected by an FDA-approved test

2 . Criteria

Product Name:Alecensa [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is anaplastic lymphoma kinase (ALK)-positive

AND

3 - ONE of the following:

3.1 Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

OR

3.2 Used as adjuvant treatment following tumor resection

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Alecensa [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic Erdheim-Chester Disease

AND

2 - Used as targeted therapy ALK-fusion

AND

3 - Disease is ONE of the following:

- Relapsed
- Refractory

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Alecensa [a]	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma (ALCL)

AND

2 - Used as initial palliative intent therapy or second-line and subsequent therapy

AND

3 - Disease is ONE of the following:

- Relapsed
- Refractory

AND

4 - Anaplastic lymphoma kinase (ALK)-positive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Alecensa [a]	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of large B-Cell lymphoma

AND

2 - Disease is ONE of the following:

- Relapsed
- Refractory

AND

3 - Anaplastic lymphoma kinase (ALK)-positive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Alecensa [a]	
Diagnosis	Central Nervous System (CNS) Cancers/ Pediatric Central Nervous System Cancers - Pediatric Diffuse
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Diagnosis of metastatic brain cancer from NSCLC
- Diagnosis of pediatric diffuse high-grade glioma

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Alecensa [a]	
Diagnosis	Soft Tissue Sarcoma/Uterine Neoplasms

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)

AND

2 - Presence of ALK translocation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Alecensa [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Histiocytic Neoplasms, T-Cell Lymphomas, B-Cell Lymphomas, CNS Cancers/ Pediatric Central Nervous System Cancers - Pediatric Diffuse, Soft Tissue Sarcoma/Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Alecensa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Alecensa [a]

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Alecensa will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Alecensa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background:

Alecensa® (alectinib) is a kinase inhibitor indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test and for adjuvant treatment in adult patients following tumor resection of ALK-positive NSCLC (tumors ≥ 4 cm or node positive) as detected by an FDA-approved test. The NCCN also recommends Alecensa for ALK-fusion targeted relapsed/refractory, symptomatic Erdheim-Chester Disease, as second-line or initial palliative intent therapy and subsequent therapy for relapsed/refractory ALK+ anaplastic large cell lymphoma (ALCL), relapsed or refractory ALK-positive large B-Cell lymphoma, ALK-positive metastatic brain cancer from NSCLC, ALK-rearrangement positive pediatric diffuse high-grade glioma, and inflammatory myofibroblastic tumors with ALK translocation.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Alecensa [package insert]. South San Francisco, CA: Genentech USA, Inc.; April 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/. Accessed May 9, 2025.

5 . Revision History

Date	Notes
5/27/2025	Annual review. Added criteria for pediatric diffuse high-grade gliomas per NCCN guidelines. Updated background and references.

Ampyra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136026
Guideline Name	Ampyra
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	9/16/2020
P&T Revision Date:	05/21/2021 ; 09/15/2021 ; 05/20/2022 ; 05/25/2023 ; 11/17/2023

1 . Indications

Drug Name: Ampyra (dalfampridine)
Multiple sclerosis (MS) Indicated to improve walking in patients with multiple sclerosis (MS).

2 . Criteria

Product Name:Brand Ampyra, generic dalfampridine [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of multiple sclerosis **AND** **2** - Physician confirmation that patient has difficulty walking (e.g., timed 25-foot walk)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Ampyra, generic dalfampridine [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Physician confirmation that the patient's walking improved with therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Additional Clinical Programs: • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

Background

Ampyra (dalfampridine) is a potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.[1]

4 . References

1. Ampyra [package insert]. Acorda Therapeutics: Ardsley, NY. June 2022

5 . Revision History

Date	Notes
11/7/2023	Updated initial authorization period from 6 months to 12 months and added SML.

Ancillary Charge Adjustment

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-424268
Guideline Name	Ancillary Charge Adjustment
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026

1 . Criteria

Product Name:New York	
Approval Length	Authorization will be issued for 12 months.*
Therapy Stage	Initial Authorization
Guideline Type	Administrative

Approval Criteria

1 - The brand medication with ancillary charge will be approved without ancillary charge based on ALL of the following criteria:

1.1 Submission of medical records documenting patient has experienced a life-threatening, potentially life-threatening or severe adverse reaction to the generic medication which did not

happen on the branded product (e.g. anaphylaxis, break-through or an increase in seizures, hospitalization from worsening symptoms based on switch to the generic and not attributed to other factors [adherence or change in disease state]) **AND** **1.2** Submission of medical records documenting a switch to an alternative preferred agent could lead to deterioration of the patient's condition requiring emergent medical care (e.g., increased seizures with generic anticonvulsants, rejection of transplant with generic transplant medications)

Notes	*If approved, remove the tier from the authorization.

Product Name:New York	
Approval Length	Authorization will be issued for 12 months.*
Therapy Stage	Reauthorization
Guideline Type	Administrative

Approval Criteria

1 - The brand medication with ancillary charge will be approved without ancillary charge based on the following criteria:

1.1 Member still requires treatment with previously requested brand medication and continues to use requested medication (as evidenced by claims in the past 120 days).

Notes	*If approved, remove the tier from the authorization.

Product Name:Washington	
Approval Length	Authorization will be issued for 12 months.*
Therapy Stage	Initial Authorization
Guideline Type	Administrative

Approval Criteria

1 - Upon request, the brand medication with ancillary charge will be approved without ancillary charge based on ALL of the following criteria:

1.1 Provider is requesting the brand be dispensed as written (i.e., DAW1)

AND

1.2 Submission of medical records documenting patient has experienced a life-threatening, potentially life-threatening or severe adverse reaction to the generic medication which did not happen on the branded product (e.g. anaphylaxis, break-through or an increase in seizures, hospitalization from worsening symptoms based on switch to the generic and not attributed to other factors [adherence or change in disease state])

AND

1.3 Submission of medical records documenting a switch to an alternative preferred agent could lead to deterioration of the patient's condition requiring emergent medical care (e.g., increased seizures with generic anticonvulsants, rejection of transplant with generic transplant medications)

AND

1.4 Submission of medical records documenting ancillary charge would lead to abandonment of therapy and potential increased utilization of other healthcare resources.

Notes	*If approved, remove the tier from the authorization.

Product Name:Washington	
Approval Length	Authorization will be issued for 12 months.*
Therapy Stage	Reauthorization
Guideline Type	Administrative

Approval Criteria

1 - Upon request, the brand medication with ancillary charge will be approved without ancillary charge based on BOTH of the following criteria:

1.1 Provider is requesting the brand be dispensed as written (i.e., DAW1)

AND **1.2** Member still requires treatment with previously requested brand medication and continues to use requested medication (as evidenced by claims in the past 120 days).
Notes | *If approved, remove the tier from the authorization.

2 . Background

Benefit/Coverage/Program Information
Background: Some UnitedHealthcare pharmacy benefits include an ancillary charge requirement. An ancillary charge is a charge in addition to the copayment and/or coinsurance that is applied when a brand medication is selected, and there is an FDA approved generic equivalent covered under the benefit that is chemically and therapeutically equivalent. This document provides benefit exception criteria for the review of brand medications for New York and Washington members subjected to ancillary charges to determine if a benefit exception should be made to waive the ancillary charge. **Additional Clinical Programs:** • Supply limits may also apply • Prior Authorization may also apply • Step Therapy may also apply

3 . Revision History

Date	Notes
10/21/2025	New program

Andembry

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436490
Guideline Name	Andembry
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	11/21/2025
P&T Revision Date:	

1 . Indications

Drug Name: Andembry (garadacimab-gxii)
Hereditary angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older.

2 . Criteria

Product Name:Andembry [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - ALL of the following:

- Prescribed for the prophylaxis of HAE attacks
- Not used in combination with other approved products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Takhzyro)
- Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Andembry

AND

3 - Prescribed by ONE of the following:

- Immunologist

- Allergist

AND

4 - Submission of medical records documenting a history of failure, contraindication, or intolerance to Haegarda (C1 esterase inhibitor, human)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Andembry [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Andembry therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest), as confirmed by claims history or submission of medical records, while on Andembry therapy

AND

3 - BOTH of the following:

- Prescribed for the prophylaxis of HAE attacks
- Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Takhzyro)

AND

4 - Prescribed by ONE of the following: • Immunologist • Allergist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3 . Background

Benefit/Coverage/Program Information
Background: Andembry is an activated Factor XII (FXIIa) inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Andembry [package insert]. King of Prussia, PA: CSL Behring LLC.; June 2025.
2. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2025.
3. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2021 revision and update. Allergy. 2022;77(7):1961-1990. doi:10.1111/all.15214

5 . Revision History

Date	Notes
11/3/2025	New Program

Anticonvulsants

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-558193
Guideline Name	Anticonvulsants
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	4/15/2026
P&T Approval Date:	8/15/2020
P&T Revision Date:	07/21/2021 ; 09/15/2021 ; 08/19/2022 ; 08/18/2023 ; 11/17/2023 ; 12/13/2023 ; 02/16/2024 ; 08/16/2024 ; 10/01/2024 ; 02/20/2025

1 . Indications

Drug Name: Aptiom (eslicarbazepine acetate), Briviact (brivaracetam), Xcopri (cenobamate)
Partial-onset seizures Indicated in the treatment of partial-onset seizures.
Drug Name: Vimpat (lacosamide)
Partial-onset seizures Indicated in the treatment of partial-onset seizures. **Primary Generalized Tonic-Clonic Seizures** Indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures.
Drug Name: Banzel (rufinamide), Onfi (clobazam), Sympazan (clobazam)

Seizures associated with Lennox-Gastaut syndrome (LGS) Indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS). There is some clinical evidence to support the use of Onfi for refractory partial onset seizures.
Drug Name: Diacomit (stripentol)
Seizures Indicated for seizures associated with Dravet syndrome in patients taking clobazam.
Drug Name: Epidiolex (cannabadiol)
Seizures Indicated for seizures associated with Lennox-Gastaut syndrome, Dravet syndrome or tuberous sclerosis complex.
Drug Name: Fintepla (fenfluramine)
Lennox-Gastaut syndrome and Dravet syndrome Indicated for seizures associated with Lennox-Gastaut syndrome and Dravet syndrome.
Drug Name: Fycompa (perampanel)
Partial-onset seizures Indicated for the treatment of partial-onset seizures with or without secondarily generalized seizures **Primary generalized tonic-clonic seizures** Indicated as adjunctive therapy for the treatment of primary generalized tonic-clonic seizures.
Drug Name: Motpoly XR (lacosamide)
Partial-onset seizures Indicated for the treatment of partial-onset seizures in adults and in pediatric patients weighing at least 50 kg. **Primary Generalized Tonic-Clonic Seizures** Indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and in pediatric patients weighing at least 50 kg.
Drug Name: Nayzilam (midazolam)
Seizures Indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern.
Drug Name: Sabril (vigabatrin), Vigadrone (vigabatrin), Vigafyde (vigabatrin), Vigpoder (vigabatrin)
Refractory complex partial seizures Indicated as adjunctive therapy for refractory complex partial seizures in patients who have inadequately responded to several alternative treatments and for infantile spasms for whom the potential benefits outweigh the risk of vision loss.

2 . Criteria

Product Name:Brand Aptiom, generic eslicarbazepine, Brand Briviact, generic brivaracetam, Xcopri [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following: • Diagnosis of partial-onset seizures • For continuation of prior therapy for a seizure disorder	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Banzel, generic rufinamide [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ALL of the following: • Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) • Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment) • Not used as primary treatment	

OR

2 - For continuation of prior therapy for a seizure disorder

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Fycompa, generic perampanel [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of partial-onset seizures with or without secondarily generalized seizures

OR

1.2 ALL of the following:

- Diagnosis of primary generalized tonic-clonic seizures
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

OR

2 - For continuation of prior therapy for a seizure disorder

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Onfi, generic clobazam, Sympazan [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

- Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)
- Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)
- Diagnosis of Dravet syndrome

AND

1.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

OR

2 - For continuation of prior therapy for a seizure disorder

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sabril, generic vigabatrin, Brand Vigadrone, Vigafyde, generic vigpoder [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Diagnosis of partial-onset seizures
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment
- Patient has had inadequate response to several (at least three) alternative anticonvulsants

OR

2 - Diagnosis of infantile spasms

OR

3 - For continuation of prior therapy for a seizure disorder

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Diacomit [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Dravet syndrome and currently taking clobazam

OR

2 - For continuation of prior therapy for a seizure disorder

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Epidiolex [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex

OR

2 - For continuation of prior therapy for a seizure disorder

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Vimpat soln/tabs, generic lacosamide solution [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of partial-onset seizures

OR

2 - ALL of the following:

- Diagnosis of primary generalized tonic-clonic seizures
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

OR

3 - For continuation of prior therapy for a seizure disorder

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Motpoly XR	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Diagnosis of partial-onset seizures
- Patient weighs at least 50 kg or more

OR

2 - ALL of the following:

- Diagnosis of primary generalized tonic-clonic seizures
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)

• Not used as primary treatment **OR** **3** - For continuation of prior therapy for a seizure disorder

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nayzilam [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizure clusters or acute repetitive seizures that are distinct from the patient's usual seizure pattern

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Fintepla [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Lennox-Gastaut syndrome or Dravet syndrome

OR **2** - For continuation of prior therapy for a seizure disorder

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Aptiom, generic eslicarbazepine, Brand Banzel, generic rufinamide, Brand Briviact, generic brivaracetam, Diacomit, Epidiolex, Fintepla, Brand Fycompa, generic perampanel, Motpoly XR, Nayzilam, Brand Onfi, generic clobazam, Brand Sabril, generic vigabatrin, Sympazan, Brand Vigadrone, Vigafyde, generic vigpoder, Brand Vimpat soln/tabs, generic lacosamide solution, Xopri [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Aptiom (eslicarbazepine acetate), Briviact (brivaracetam), Vimpat (lacosamide) and Xcopri (cenobamate) are indicated in the treatment of partial-onset seizures. Vimpat is also indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures.

Banzel (rufinamide), Onfi (clobazam) and Sympazan (clobazam) are indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS). There is some clinical evidence to support the use of clobazam for refractory partial onset seizures.

Diacomit (stiripentol) is indicated for seizures associated with Dravet syndrome in patients taking clobazam.

Epidiolex (cannabidiol solution) is indicated for seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex.

Fintepla (fenfluramine) is indicated for seizures associated with Lennox-Gastaut syndrome and Dravet syndrome.

Fycompa (perampanel) is indicated for the treatment of partial-onset seizures with or without secondarily generalized seizures and as adjunctive therapy for the treatment of primary generalized tonic-clonic seizures.

Motpoly XR is indicated for the treatment of partial-onset seizures and as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and in pediatric patients weighing at least 50 kg.

Nayzilam (midazolam) is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern.

Sabril (vigabatrin), Vigadone (vigabatrin), Vigafyde (vigabatrin) and Vigpoder (vigabatrin) are indicated as adjunctive therapy for refractory complex partial seizures in patients who have inadequately responded to several alternative treatments and for infantile spasms for whom the potential benefits outweigh the risk of vision loss.

Adjunctive therapy is defined as treatment administered in addition to another therapy. Coverage will not be provided for Banzel as primary treatment.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Banzel [package insert]. Nutley, NJ: Eisai, Inc; December 2022.
2. Vimpat [package insert]. Smyma, GA: UCB, Inc; October 2023.
3. Fycompa [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc. ; June 2023.
4. Aptiom [package insert]. Marlborough, MA; Sunovion Pharmaceuticals Inc; March 2019.
5. Onfi [package insert]. Deerfield, IL: Lundbeck; January 2023.
6. Sabril [package insert]. Deerfield, IL: Lundbeck; October 2021.
7. Koeppen, D. et al. Clobazam in therapy-resistant patients with partial epilepsy: A double-blind placebo-controlled crossover study. Epilepsia 28(5);495-506. October 1987.
8. Micahel, B. Clobazam as an add-on in the management of refractory epilepsy. Cochrane Database of Systemic Reviews 2008.
9. Diacomit [package insert]. San Mateo, CA: Biocodex Inc; July 2022.
10. Epidiolex [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc. ; January 2023.
11. Vigadrone [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; March 2023.
12. Motpoly XR [package insert]. Piscataway, NJ: Aucta Pharmaceuticals, Inc.; June 2024.
13. Vigoder [package insert]. Parsippany, NJ: Pyros Pharmaceuticals, Inc.; July 2023.
14. Nayzilam [package insert]. Smyrna, GA: UCB, Inc; January 2023.
15. Xcopri [package insert]. Paramus, NJ: SK Life Science, Inc; April 2024.
16. Fintepla [package insert]. Smyrna, GA: UCB, Inc; December 2023.
17. Sympazan [package insert]. Warren, NJ: Aquestive Therapeutics; March 2024.
18. Briviact [package insert]. Smyrna, GA: UCB, Inc; May 2023.
19. Vigafyde [package insert]. Parsippany, NJ: Pyros Pharmaceuticals, Inc.; August 2024.

5 . Revision History

Date	Notes
3/25/2026	added brivaracetam

Anzupgo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-493405
Guideline Name	Anzupgo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	1/21/2026
P&T Revision Date:	

1 . Indications

Drug Name: Anzupgo (delgocitinib)
Chronic Hand Eczema Indicated for the topical treatment of moderate to severe chronic hand eczema (CHE) in adults who have had an inadequate response to, or for whom topical corticosteroids are not advisable.

2 . Criteria

Product Name:Anzupgo [a]	
Diagnosis	Chronic Hand Eczema
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderate to severe chronic hand eczema

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to BOTH of the following therapeutic classes of topical therapies:

- One topical corticosteroid of at least medium- to high-potency (e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]

OR

2.2 BOTH of the following:

- Patient is currently on Anzupgo therapy
- Patient has not received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the LEO Pharma sponsored Anzupgo Let's GO program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Anzupgo¥

AND

3 - Patient is NOT receiving Anzupgo in combination with a biologic medication or JAK inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), Rinvoq (upadacitinib)]

AND

4 - Patient is NOT receiving Anzupgo in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ¥ Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the LEO Pharma sponsored Anzupgo Let's GO program program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Anzupgo [a]	
Diagnosis	Chronic Hand Eczema
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to therapy **AND** **2** - Patient is NOT receiving Anzupgo in combination with a biologic medication or JAK inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), Rinvoq (upadacitinib)] **AND** **3** - Patient is not receiving Anzupgo in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Anzupgo® (delgocitinib) is a Janus kinase (JAK) inhibitor indicated for the topical treatment of moderate to severe chronic hand eczema (CHE) in adults who have had an inadequate response to, or for whom topical corticosteroids are not advisable. Use of Anzupgo in combination with other JAK inhibitors or potent immunosuppressants is not recommended. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Anzupgo [package insert]. Madison, WI: Leo Pharma Inc; July 2025.
2. Sheehan MP. Chronic hand ezema: Management. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com. Accessed on December 5, 2025.
3. Supplement to: Bissonnette R, Warren RB, Pinter A, et al. Efficacy and safety of delgocitinib cream in adults with moderate to severe chronic hand eczema (DELTA 1 and DELTA 2): results from multicentre, randomised, controlled, double-blind, phase 3 trials. Lancet 2024; published online July 18. https://doi.org/10.1016/S0140- 6736(24)01027-4
4. Ghezzi G, Falcidia C, Paolino G, et al. Chronic Hand Eczema (CHE): A Narrative Review. Dermatol Ther (Heidelb). 2025;15(4):771-795. doi:10.1007/s13555-025-01365-7

5 . Revision History

Date	Notes

1/9/2026	New program.

Aqneursa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-405335
Guideline Name	Aqneursa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	11/22/2024
P&T Revision Date:	01/15/2025 ; 01/15/2025 ; 03/19/2025 ; 10/15/2025

1 . Indications

Drug Name: Aqneursa (levacetylleucine)
Niemann-Pick disease type C (NPC) Indicated for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥15 kg.

2 . Criteria

Product Name:Aqneursa [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - BOTH of the following:

- Diagnosis of Niemann-Pick disease type C (NPC)
- Diagnosis has been genetically confirmed by mutation analysis of NPC1 and NPC2 genes

AND

2 - Aqneursa is being used to treat neurological manifestations of NPC

AND

3 - Patient is not receiving Aqneursa in combination with Miplyffa (arimoclomol)

AND

4 - Aqneursa is prescribed by or in consultation with a provider with expertise in the treatment of NPC

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Aqneursa [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Aqneursa therapy (e.g., slowed disease progression from baseline based on assessment with NPC–specific scales) **AND** **2** - Patient is not receiving Aqneursa in combination with Miplyffa (arimoclomol) **AND** **3** - Aqneursa is prescribed by or in consultation with a provider with expertise in the treatment of NPC	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Aqneursa (levacetylleucine) is indicated for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥15 kg. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Aqneursa [package insert]. Austin TX: IntraBio Inc.; September 2024.

2. Geberhiwot T, Moro A, Dardis A, et al. Consensus clinical management guidelines for Niemann-Pick disease type C. Orphanet J Rare Dis. 2018;13(1):50. Published 2018 Apr 6. doi:10.1186/s13023-018-0785-7

5 . Revision History

Date	Notes
9/29/2025	Removed requirement for combination therapy or failure, contraindication, or intolerance to miglustat.

Arikayce

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523251
Guideline Name	Arikayce
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 02/18/2022 ; 02/17/2023 ; 02/16/2024 ; 02/20/2025 ; 2/20/2026

1 . Indications

Drug Name: Arikayce (amikacin liposome inhalation suspension)
Mycobacterium avium complex (MAC) lung disease Indicated in adults who have limited or no alternative treatment options, for the treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy.

2 . Criteria

Product Name:Arikayce [a]

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of refractory Mycobacterium avium complex (MAC) lung disease

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting respiratory cultures positive for MAC within the previous 6 months.

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

3.1 Patient has been receiving a multidrug background regimen containing AT LEAST TWO of the following agents for a minimum of 6 consecutive months within the past 12 months:

- Macrolide antibiotic [e.g., azithromycin, clarithromycin]
- Ethambutol
- Rifamycin antibiotic [e.g., rifampin, rifabutin]

AND

4 - Patient will continue to receive a multidrug background regimen

AND

5 - Documentation that the patient has not achieved negative sputum cultures after receipt of a multidrug background regimen for a minimum of 6 consecutive months

AND

6 - In vitro susceptibility testing of recent (within 6 months) positive culture documents that the MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of less than or equal to 64 mcg/mL

AND

7 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Arikayce [a]	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Documentation that the patient has achieved negative respiratory cultures

OR

1.2 All of the following:

1.2.1 Patient has not achieved negative respiratory cultures while on Arikayce

AND

1.2.2 Physician attestation that patient has demonstrated clinical benefit while on Arikayce

AND

1.2.3 In vitro susceptibility testing of most recent (within 6 months) positive culture with available susceptibility testing documents that the MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of < 64 mcg/mL

AND

1.2.4 Patient has NOT received greater than 12 months of Arikayce therapy with continued positive respiratory cultures

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient continues to receive a multidrug background regimen containing at least two of the following agents [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

- Macrolide antibiotic [e.g., azithromycin, clarithromycin]
- Ethambutol
- Rifamycin antibiotic [e.g., rifampin, rifabutin]

AND

3 - Prescribed by, or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background Arikayce is an aminoglycoside antibacterial indicated in adults who have limited or no alternative treatment options, for the treatment of *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. As only limited clinical safety and effectiveness data for Arikayce are currently available, reserve Arikayce for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients. This indication is approved under accelerated approval based on achieving sputum culture conversion (defined as 3 consecutive negative monthly sputum cultures) by Month 6. Clinical benefit has not yet been established. Arikayce has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of Arikayce is not recommended for patients with non-refractory MAC lung disease. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Arikayce [package insert]. Bridgewater, NJ: Insmed; December 2025.

2. Haworth CS, Banks J, Capstick T, et al. British thoracic society guidelines for the management of non-tuberculous mycobacterial pulmonary disease. Thorax. 2017;72:ii1-ii64.
3. Griffith DE, Eagle G, Thomson R, et al. Amikacin liposome inhalation suspension for treatment-refractory lung disease caused by mycobacterium avium complex (CONVERT): a prospective, open-label, randomized study. Am J Respir Crit Care Med. 2018; Sep 14. doi: 10.1164/rccm.201807-1318OC. [Epub ahead of print]
4. Kasperbauer S, Daley CL. Treatment of Mycobacterium avium complex lung infection in adults. Bloom A (Ed). UpToDate . Waltham MA: UpToDate Inc. http://www.uptodate.com. Accessed January 7, 2026.
5. Winthrop KL, Morimoto K, Castellotti PK, et al. An open-label extension study of amikacin liposome inhalation suspension (ALIS) for treatment-refractory lung disease caused by mycobacterium avium complex (MAC). Slides presented at: American College of Chest Physicians Annual Meeting; October 19-23, 2019; New Orleans, Louisiana.
6. Daley CL, Iaccarino Jr JM, Lange C, et al. Treatment of Nontuberculous Mycobacterial Pulmonary Disease: An Official ATS/ERS/ESCMID/IDSA Clinical Practice Guideline. Clinical Infectious Diseases. 2020; 71(11):3023.

5 . Revision History

Date	Notes
2/19/2026	Annual review with no change to coverage criteria. Updated referenc es.

Attruby

Prior Authorization Guideline

Guideline ID	GL-500233
Guideline Name	Attruby
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	1/15/2025
P&T Revision Date:	1/21/2026

1 . Indications

Drug Name: Attruby (acoramidis)
Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM) Indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization.

2 . Criteria

Product Name:Attruby [a]

Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)

AND

2 - ONE of the following:

2.1 Documentation that the patient has a pathogenic TTR mutation (e.g., V30M)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits

OR

2.3 ALL of the following:

- Echocardiagram or cardiac magnetic resonance imaging suggestive of amyloidosis
- Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake*
- Absence of light chain amyloidosis

AND

3 - Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

4 - Physician attests that the patient has an N-terminal pro-B-type natriuretic peptide (NT-proBNP) level that, when combined with signs and symptoms, is considered definitive for a diagnosis of ATTR-CM

AND

5 - ONE of the following:

- History of heart failure, with at least one prior hospitalization for heart failure
- Presence of signs and symptoms of heart failure (e.g., dyspnea, edema)

AND

6 - Prescribed by or in consultation with a cardiologist

AND

7 - Patient is not receiving Attruby in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Onpattro (patisiran), Tegsedi (inotersen), Vyndaqel/Vyndamax (tafamadis), or Wainua (eplontersen)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *May require prior authorization and notification

Product Name:Attruby [a]	
Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation that the patient has experienced a positive clinical response to Attruby (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

AND

2 - Documentation that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

3 - Prescribed by or in consultation with a cardiologist

AND

4 - Patient is not receiving Attruby in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Onpattro (patisiran), Tegsedi (inotersen), Vyndaqel/Vyndamax (tafamadis), or Wainua (eplontersen)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Attruby is a transthyretin stabilizer indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Attruby [package insert]. BridgeBio Pharma, Inc: Palo Alto, CA; August 2025.
2. Fontana, M. Cardiac amyloidosis: Epidemiology, clinical manifestations, and diagnosis. UpToDate. Dardas, T: UpToDate Inc. https://www.uptodate.com (Accessed on November 17, 2025).
3. Fontana, M. Cardiac amyloidosis: Treatment and prognosis. UpToDate. Dardas, T: UpToDate Inc. https://www.uptodate.com (Accessed on November 17, 2025).
4. Ruberg FL, Maurer MS. Cardiac Amyloidosis Due to Transthyretin Protein: A Review. JAMA 2024; 331:778.
5. Kittleson, M, Ruberg, F. et al. 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis: A Report of the American College of Cardiology Solution Set Oversight Committee. JACC. 2023 Mar, 81 (11) 1076–1126.

5 . Revision History

Date	Notes
1/20/2026	Annual review with no changes to coverage criteria. Updated referen ces.

Austedo, Austedo XR

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-232244
Guideline Name	Austedo, Austedo XR
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	6/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 02/18/2022 ; 02/17/2023 ; 06/21/2023 ; 04/17/2024 ; 4/16/2025

1 . Indications

Drug Name: Austedo (deutetrabenazine) or Austedo® XR (deutetrabenazine)
Chorea associated with Huntington's disease Indicated for the treatment of chorea associated with Huntington’s disease. **Tardive dyskinesia** Indicated for the treatment of adults with tardive dyskinesia.

2 . Criteria

Product Name:Austedo, Austedo XR [a]

Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia

AND

2 - ONE of the following:

- Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication
- Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with ONE of the following:

- Neurologist
- Psychiatrist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Austedo, Austedo XR [a]	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Austedo, Austedo XR [a]	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea associated with Huntington's disease

AND

2 - Prescribed by or in consultation with ONE of the following:

- Neurologist
- Psychiatrist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Austedo, Austedo XR [a]	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Austedo and Austedo XR are a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated in adults for the treatment of chorea associated with Huntington's disease and for the treatment of tardive dyskinesia. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Austedo – Austedo XR [package insert]. Parsippany, NJ: Teva Pharmaceuticals Inc. February 2025.

5 . Revision History

Date	Notes
4/4/2025	Annual review with no change to clinical criteria. References updated .

Azole Antifungals

Prior Authorization Guideline

Guideline ID	GL-500234
Guideline Name	Azole Antifungals
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	10/1/2024
P&T Revision Date:	1/21/2026

1 . Indications

Drug Name: Cresemba (isavuconazonium)
Invasive aspergillosis and invasive mucormycosis Indicated for the treatment of invasive aspergillosis and invasive mucormycosis and for patients 6 years of age and older who weigh 16 kg and greater.

2 . Criteria

Product Name:Cresemba [a]	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - BOTH of the following: • Diagnosis of invasive aspergillosis • History of failure, contraindication, or intolerance to voriconazole (generic Vfend) as confirmed by claims history or submission of medical records **OR** **2** - Diagnosis of invasive mucormycosis	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Cresemba (isavuconazonium) is indicated for the treatment of invasive aspergillosis and invasive mucormycosis and for patients 6 years of age and older who weigh 16 kg and greater, for the treatment of invasive mucormycosis and invasive aspergillosis. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Cresemba [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; April 2025.
2. Patterson TF, Thompson GR, Denning DW, et al. Practice Guidelines for the Diagnosis and Management of Aspergillosis: 2016 Update by the Infectious Diseases Society of America. Clin Infect Dis. 2016;63(4):1-60.

5 . Revision History

Date	Notes
1/20/2026	Annual review with no changes to coverage criteria. Updated references.

Belbuca_Butrans



Prior Authorization Guideline

Guideline ID	GL-375637
Guideline Name	Belbuca_Butrans
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	12/16/2020
P&T Revision Date:	05/21/2021 ; 09/15/2021 ; 12/14/2022 ; 10/18/2023 ; 10/01/2024 ; 12/18/2024 ; 9/25/2025

1 . Indications

Drug Name: Belbuca (buprenorphine) buccal film, Butrans (buprenorphine) transdermal patch
Pain Indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate.

2 . Criteria

Product Name:Belbuca, Brand Butrans, generic buprenorphine [a]	
Diagnosis	Cancer/Sickle Cell/Hospice/End of Life related pain
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is being treated for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance). Sickle Cell Disease related pain, hospice or end of life related pain

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name:Belbuca, Brand Butrans, generic buprenorphine [a]	
Diagnosis	Non-cancer pain/Non-sickle cell/Non-hospice/Non-end of life care pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to BOTH of the following:

- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

AND

2 - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

AND

3 - Patient has been screened for underlying depression and/or anxiety. If applicable, any underlying conditions have been or will be addressed

AND

4 - ONE of the following:

- The patient has a history of failure, contraindication or intolerance to a trial of tramadol IR, unless the patient is already receiving chronic opioid therapy prior to surgery for postoperative pain, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time
- Patient is new to plan and currently established on Belbuca or Butrans for at least the past 30 days

AND

5 - If the request for neuropathic pain (examples of neuropathic pain include neuralgias or neuropathies), ONE of the following:

5.1 BOTH of the following:

- Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose. (Document date of trial)
- Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug and date of trial)

OR

5.2 The patient is new to the plan and is currently established on the requested long-acting opioid therapy for at least the past 30 days

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply. If the member is currently taking the requested long-acting opioid for a

	t least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name:Belbuca, Brand Butrans, generic buprenorphine [a]	
Diagnosis	Non-cancer pain/Non-sickle cell/Non-hospice/Non-end of life care pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented meaningful improvement in pain and function when assessed against treatment goals (Document improvement in function or pain score improvement).

AND

2 - Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

AND

3 - Prescriber attest to BOTH of the following:

- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be i

	ssued and a maximum 60-day authorization may be authorized one ti me for the requested drug/strength combination up to the requested q uantity for transition to an alternative treatment.

3 . Background

Benefit/Coverage/Program Information
Additional Clinical Rules: • Supply limits may be in place. • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. **Background:** Buprenorphine is a partial opioid agonist. Belbuca and Butrans are buprenorphine products indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate. Similar to other long-acting opioids, the use of Butrans and Belbuca should be reserved for use in patients for whom alternative treatment options (e.g. non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or inadequate to provide sufficient management of pain. Belbuca and Butrans are not indicated as as-needed (prn) analgesics. UnitedHealthcare employs opioid safety edits at point-of-sale (POS) to prompt prescribers and pharmacists to conduct additional safety reviews to determine if the member's opioid use is appropriate and medically necessary. Development of opioid safety edit specifications, to include cumulative MME thresholds, are determined by the plan taking into consideration clinical guidelines, regulatory/state requirements, utilization and P&T Committee feedback.

4 . References

1. Belbuca [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc.; December 2023.
2. Butrans [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.

3. Franklin GM. Opioids for chronic noncancer pain. A position paper of the American Academy of Neurology. Neurology. 2014;83:1277-1284.
4. Rosenquist, R. Use of opioids in the management of chronic pain in adults. UptoDate. October 2024. https://www.uptodate.com/contents/use-of-opioids-in-the-management-of-chronic-pain-in-adults?search=overview%20of%20the%20treatment%20of%20chronic%20pain&source=search_result&selectedTitle=3%7E150&usage_type=default&display_rank=3Argoff CE, Silvershein DI. A Comparison of Long- and Short-Acting Opioids for the Treatment of Chronic Noncancer Pain: Tailoring Therapy to Meet Patient Needs. Mayo Clin Proc. 2009;84(7):602-612.
5. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. Published online March 15, 2016. Spatar, SB. Standardizing the use of mental health screening instruments in patients with pain. Fed Pract. 2019 Oct; 36 (Suppl 6): S28-S30
6. Sullivan MD. Depression effects on long-term prescription opioid use, abuse, and addiction. Clin J Pain. 2018 Sep;34(9):878-884.

5 . Revision History

Date	Notes
8/30/2025	Added bypass to neuropathic pain medication step therapy for patien ts who are new to plan.

Benlysta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-332216
Guideline Name	Benlysta
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	9/1/2025
P&T Approval Date:	2/18/2022
P&T Revision Date:	04/20/2022 ; 07/20/2022 ; 07/19/2023 ; 08/18/2023 ; 07/17/2024 ; 7/16/2025

Note:

*This program applies to the subcutaneous formulation of belimumab

1 . Indications

Drug Name: Benlysta (belimumab)
Systemic Lupus Erythematosus (SLE) Indicated for the treatment of patients aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy. **Lupus Nephritis** Indicated for the treatment of patients aged 5 years and older with active lupus nephritis who are receiving standard therapy.

2 . Criteria

Product Name:Benlysta [a]	
Diagnosis	Systemic Lupus Erythematosus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic lupus erythematosus

AND

2 - Patient is currently receiving standard immunosuppressive therapy [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

3 - Patient does NOT have severe active central nervous system lupus

AND

4 - Patient is not receiving Benlysta in combination with ANY of the following:

- Targeted Immunomodulator [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
- Lupkynis (voclosporin)
- Saphnelo (anifrolumab-fnia)

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Benlysta [a]	
Diagnosis	Systemic Lupus Erythematosus
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Benlysta therapy

AND

2 - Patient is not receiving Benlysta in combination with ANY of the following:

- Targeted Immunomodulator [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
- Lupkynis (voclosporin)
- Saphnelo (anifrolumab-fnia)

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Benlysta [a]	
Diagnosis	Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Patient is currently receiving standard immunosuppressive therapy for systemic lupus erythematosus [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

3 - Patient does NOT have severe active central nervous system lupus

AND

4 - Patient is not receiving Benlysta in combination with ANY of the following:

- Targeted Immunomodulator [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
- Lupkynis (voclosporin)
- Saphnelo (anifrolumab-fnia)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Benlysta [a]	
Diagnosis	Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Benlysta therapy

AND **2** - Patient is not receiving Benlysta in combination with ANY of the following: • Targeted Immunomodulator [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)] • Lupkynis (voclosporin) • Saphnelo (anifrolumab-fnia)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Benlysta is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of patients aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy and in patients aged 5 years and older with active lupus nephritis who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in this situation. This program applies to the subcutaneous formulation of belimumab. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits may be in place.

4 . References

1. Benlysta [package insert]. Durham, NC: GlaxoSmithKline; June 2024.

5 . Revision History

Date	Notes
7/16/2025	Annual review with no changes to coverage criteria. Updated reference.

Berinert

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399281
Guideline Name	Berinert
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 07/21/2021 ; 09/15/2021 ; 04/20/2022 ; 08/19/2022 ; 04/19/2023 ; 08/18/2023 ; 04/17/2024 ; 9/25/2025

1 . Indications

Drug Name: Berinert (C1 esterase inhibitor, human)
Hereditary angioedema (HAE) Indicated for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adult and pediatric patients. The safety and efficacy of Berinert for prophylactic therapy have not been established.

2 . Criteria

Product Name:Berinert [a]	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - BOTH of the following:

- Prescribed for the acute treatment of HAE attacks
- Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Firazyr, Ruconest)

AND

3 - Submission of medical records documenting a history of failure, contraindication, or intolerance to icatibant acetate (generic Firazyr)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Berinert [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Berinert therapy

AND

2 - BOTH of the following:

- Prescribed for the acute treatment of HAE attacks
- Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Firazyr, Ruconest)

AND

3 - Prescribed by ONE of the following:

- Immunologist

• Allergist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Berinert is a plasma-derived C1 esterase inhibitor (human) indicated for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adult and pediatric patients. The safety and efficacy of Berinert for prophylactic therapy has not been established. [1] **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; September 2021.
2. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018 Jan 10.
3. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2024.
4. Busse, P., Christiansen, S., Riedl, M., et. al. “US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema.” The Journal of Allergy and Clinical Immunology. 2020 September 05.

5. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2021 revision and update. Allergy. 2022;77(7):1961-1990. doi:10.1111/all.15214

5 . Revision History

Date	Notes
9/20/2025	Updating for 2026 implementation to remove Sajazir as a step therap y option. Sajazir moving to NF in 2026.

Besremi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412196
Guideline Name	Besremi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	10/18/2023
P&T Revision Date:	10/16/2024 ; 10/15/2025

1 . Indications

Drug Name: Besremi (ropeginterferon alfa-2b-njft)
Polycythemia Vera Besremi (ropeginterferon alfa-2b-njft) is an interferon alfa-2b indicated for the treatment of adults with polycythemia vera.

2 . Criteria

Product Name:Besremi [a]	
Diagnosis	Polycythemia Vera [a]
Approval Length	12 month(s)

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of polycythemia vera	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Besremi [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Besremi will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Besremi [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Besremi (ropeginterferon alfa-2b-njft) is an interferon alfa-2b indicated for the treatment of adults with polycythemia vera. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits and/or Step Therapy may be in place.

4 . References

1. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Accessed September 5, 2025 at http://www.nccn.org/professionals/drug_compendium/content/contents.asp
2. Besremi [package insert]. Burlington, MA: PharmaEssentia; April 2024.

5 . Revision History

Date	Notes

10/6/2025	Annual review with no changes to criteria. Updated references.

Bonsity, Forteo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-312208
Guideline Name	Bonsity, Forteo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	9/1/2025
P&T Approval Date:	1/20/2021
P&T Revision Date:	03/17/2021 ; 03/17/2021 ; 10/20/2021 ; 01/19/2022 ; 01/18/2023 ; 02/17/2023 ; 10/18/2023 ; 11/17/2023 ; 10/16/2024 ; 10/16/2024 ; 7/24/2025

1 . Indications

Drug Name: Bonsity (teriparatide), Forteo (teriparatide) and Teriparatide Injection (teriparatide)
Postmenopausal patients with osteoporosis at high risk of fracture Indicated for the treatment of postmenopausal patients with osteoporosis who are at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. **Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture** Indicated to increase bone mass in patients with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. **Glucocorticoid-induced osteoporosis at high risk for fracture** Indicated for the treatment

of patients with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name:Bonsity, Brand Forteo, generic teriparatide Injection [a]	
Diagnosis	Osteoporosis
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - ONE of the following diagnoses:

1.1 BOTH of the following:

- Patient is female
- Diagnosis of postmenopausal osteoporosis

OR

1.2 BOTH of the following:

- Patient is male
- Diagnosis of osteoporosis

AND

2 - ONE of the following:

- Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on

drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture is greater than 30%, hip fracture is greater than 4.5%)]
- Patient has a history of failure, intolerance or contraindication to other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate)

AND

3 - ONE of the following:

3.1 Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Bonsity, Teriparatide Injection, Forteo, Tymlos)

OR

3.2 BOTH of the following:

- Patient is currently or has previously been treated with parathyroid hormone analogs (e.g., Bonsity, Teriparatide Injection, Forteo, Tymlos)
- The prescriber attests that the patient remains at or has returned to having a high risk for fracture

AND

4 - Patient has a history of failure, intolerance or contraindication to Tymlos

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Bonsity, Brand Forteo, generic teriparatide Injection [a]	
Diagnosis	Osteoporosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Treatment duration of parathyroid hormones (e.g., Bonsity, Teriparatide injection, Forteo, Tymlos) has not exceeded a total of 24 months during the patient's lifetime

OR

2 - Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., Bonsity, Teriparatide injection, Forteo, Tymlos)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Bonsity, Brand Forteo, generic teriparatide Injection [a]	
Diagnosis	Osteoporosis Associated with Sustained Systemic Glucocorticoid Therapy
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - History of prednisone or its equivalent at a dose greater than or equal to 5 mg/day

AND

3 - ONE of the following:

- Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%)]
- Patient has a history of failure, intolerance or contraindication to other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate)

AND

4 - ONE of the following:

4.1 Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Bonsity, Teriparatide Injection, Forteo, Tymlos)

OR

4.2 BOTH of the following:

- Patient is currently or has previously been treated with parathyroid hormone analogs (e.g., Bonsity, Teriparatide Injection, Forteo, Tymlos)
- The prescriber attests that the patient remains at or has returned to having a high risk for fracture

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Bonsity, Brand Forteo, generic teriparatide Injection [a]	
Diagnosis	Osteoporosis Associated with Sustained Systemic Glucocorticoid Therapy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria **1** - Treatment duration of parathyroid hormones (e.g., Bonsity, Teriparatide injection, Forteo, Tymlos) has not exceeded a total of 24 months during the patient's lifetime **OR** **2** - Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., Bonsity, Teriparatide injection, Forteo, Tymlos)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Bonsity (teriparatide), Forteo (teriparatide) and Teriparatide Injection (teriparatide) are recombinant human parathyroid hormone with three FDA approved indications:[1-2,5]

Treatment of postmenopausal patients with osteoporosis at high risk of fracture:

Bonsity, Forteo and Teriparatide Injection are indicated for the treatment of postmenopausal patients with osteoporosis who are at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture:

Bonsity, Forteo and Teriparatide Injection are indicated to increase bone mass in patients with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Treatment of patients with glucocorticoid-induced osteoporosis at high risk for fracture:

Bonsity, Forteo and Teriparatide Injection are indicated for the treatment of patients with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Bonsity, Forteo and Teriparatide Injection for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture.[1-2,5]

The American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE) recommend the use of teriparatide be considered for patients unable to use oral therapy and as initial therapy for patients at very high fracture risk defined as the following: patients with a recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%) or other validated fracture risk algorithm to be at very high fracture risk.[3] Additionally, the AACE/ACE and Endocrine Society both recommend to limit treatment with teriparatide to 2 years.[3-4]

Coverage will be provided for members who meet the above criteria.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Forteo [package insert]. Indianapolis, IN: Eli Lilly, Inc.; July 2024.
2. Teriparatide Injection [package insert]. Morristown, NJ: Alvogen, Inc.; November 2023.
3. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis – 2020 Update. Endocr Pract. 2020;26(Supp1): 1-46. doi:10.4158/GL-2020-0524SUPPL
4. Shoback D, Rosen CJ, Black DM, Cheung AM, Murad MH, Eastell R. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update. J Clin Endocrinol Metab. 2020 Mar 1;105(3):dgaa048.
5. Bonsity [package insert]. Morristown, NJ: Alvogen, Inc.; December 2024.

5 . Revision History

Date	Notes
6/27/2025	Added Bonsity to policy.

Bosulif

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523257
Guideline Name	Bosulif
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 02/18/2022 ; 02/17/2023 ; 02/16/2024 ; 02/20/2025 ; 2/20/2026

1 . Indications

Drug Name: Bosulif (bosutinib)
Philadelphia-positive chronic myelogenous leukemia (Ph+CML) Inhibitor indicated for the treatment of adult and pediatric patients 1 year of age and older with chronic phase Philadelphia-positive chronic myelogenous leukemia (Ph+ CML), newly diagnosed or resistant or intolerant to prior therapy. Bosulif is also indicated for the treatment of adult patients with accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy.

2 . Criteria

Product Name:Bosulif [a]

Diagnosis	Chronic Myelogenous/Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myeloid leukemia

AND

2 - ONE of the following:

2.1 Patient is not a candidate for imatinib as attested by physician

OR

2.2 Patient is currently on Bosulif therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Bosulif [a]	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Bosulif therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Bosulif [a]	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Bosulif [a]	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Bosulif therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Bosulif [a]

Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis myeloid/lymphoid neoplasms with eosinophilia

AND

2 - Presence of ABL1 rearrangement

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Bosulif [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Bosulif therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Bosulif [a]	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Bosulif will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Bosulif [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Bosulif therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background:

Bosulif (bosutinib) is a kinase inhibitor indicated for the treatment of adult and pediatric patients 1 year of age and older with chronic phase Philadelphia-positive chronic myelogenous leukemia (Ph+ CML), newly diagnosed or resistant or intolerant to prior therapy. Bosulif is also indicated for the treatment of adult patients with accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy. [1]

The National Comprehensive Cancer Network (NCCN) recommends use of Bosulif in follow-up therapy in CML after primary treatment with asciminib, imatinib, dasatinib, or nilotinib. NCCN also recommends Bosulif as primary treatment of CML in accelerated phase as a single agent, in combination with induction chemotherapy for lymphoid blast phase or myeloid blast phase, in combination with steroids for CML in lymphoid blast phase if not a candidate for induction chemotherapy, for CML in myeloid blast phase as a single agent if not a candidate for induction chemotherapy, as maintenance therapy with consolidation chemotherapy for non-candidates for allogeneic hematopoietic stem cell transplant (HCT) in remission for BP-CML, for CML patients that are post-transplant experiencing a cytogenic or molecular relapse, for Philadelphia-positive acute lymphoblastic leukemia, and for treatment of myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Bosulif [package insert]. New York, NY: Pfizer, Inc. December 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org. Accessed on December 16, 2025.

5 . Revision History

Date	Notes
2/19/2026	Annual review with no changes to coverage criteria. Updated references.

Brexafemme

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-510401
Guideline Name	Brexafemme
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/19/2022
P&T Revision Date:	02/17/2023 ; 2/20/2026

1 . Indications

Drug Name: Brexafemme (ibrexafungerp)
Vulvovaginal candidiasis Indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC).

2 . Criteria

Product Name:Brexafemme [a]	
Diagnosis	Treatment of Vulvovaginal candidiasis (VVC)
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of vulvovaginal candidiasis (VVC)

AND

2 - ONE of the following:

2.1 Confirmed azole resistance demonstrated by culture and susceptibility testing

OR

2.2 BOTH of the following:

- Other causes (including but not limited to bacterial vaginosis or trichomoniasis) have been ruled out
- Failure of oral fluconazole therapy for the current episode of VVC

AND

3 - Prescribed by or in consultation with ONE of the following:

- Infectious disease physician
- Obstetrician/Gynecologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brexafemme [a]	
Diagnosis	Recurrent vulvovaginal candidiasis (RVVC)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of recurrent vulvovaginal candidiasis (RVVC)

AND

2 - ONE of the following:

2.1 Confirmed azole resistance demonstrated by culture and susceptibility testing

OR

2.2 BOTH of the following:

- Other causes (including but not limited to bacterial vaginosis or trichomoniasis) have been ruled out
- Failure of a maintenance course of oral fluconazole defined as 100-mg, 150-mg, or 200-mg taken weekly for 6 months

AND

3 - Prescribed by or in consultation with ONE of the following:

- Infectious disease physician
- Obstetrician/Gynecologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Brexafemme (ibrexafungerp) is indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC).

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Brexafemme [package insert]. Jersey City, NJ: Scynexis, Inc; November 2025.
2. Sexually Transmitted Infections Treatment Guidelines, 2021. Vulvovaginal Candidiasis (VVC). Centers for Disease Control and Prevention. https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm.

5 . Revision History

Date	Notes
2/5/2026	Annual review. Removed the 7-day trial requirement of fluconazole fo r treatment of vulvovaginal candidiasis based on CDC guidelines. Up dated references.

Brinsupri

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436493
Guideline Name	Brinsupri
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	11/21/2025
P&T Revision Date:	

1 . Indications

Drug Name: Brinsupri (brensocatib)
Non-cystic fibrosis bronchiectasis Indicated for the treatment of non-cystic fibrosis bronchiectasis in adult and pediatric patients 12 years of age and older.

2 . Criteria

Product Name:Brinsupri [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of non-cystic fibrosis bronchiectasis

AND

2 - ALL of the following signs and symptoms associated with bronchiectasis

- Cough most days of the week lasting greater than 3 months
- Production of mucopurulent sputum most days of the week lasting greater than 3 months
- Recurrent respiratory tract infections

AND

3 - Chest computed tomography (CT) is positive for bronchiectasis

AND

4 - Cystic fibrosis (CF) has been ruled out by ONE of the following:

- Sweat chloride test is negative
- Mutation analysis of the cystic fibrosis transmembrane conductance regulator (CFTR) gene is negative for CF

AND

5 - ONE of the following:

5.1 BOTH of the following:

- Patient is 12 – 17 years of age
- Patient has experienced one or more pulmonary exacerbation(s) requiring systemic antimicrobial therapy in the previous 12 months

OR

5.2 BOTH of the following:

- Patient is 18 years of age or older
- Has experienced two or more pulmonary exacerbations requiring systemic antimicrobial therapy in the previous 12 months

AND

6 - ONE of the following:

6.1 Patient does not have co-existing COPD or asthma

OR

6.2 For patients with co-existing COPD, the patient is currently being treated with ONE of the following therapies at maximally tolerated doses unless there is a contraindication or intolerance to these medications:

- Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., tiotropium, umeclidinium) and a long-acting beta agonist (LABA) (e.g., salmeterol, arformoterol, formoterol)
- Triple therapy [LAMA + LABA combined with an inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone propionate)]

OR

6.3 For patients with co-existing asthma, the patient is currently being treated with ONE of the following therapies at maximally tolerated doses unless there is a contraindication or intolerance to these medications:

- Inhaled corticosteroid (ICS) (e.g., fluticasone propionate)
- Dual therapy with a LABA (e.g., salmeterol, arformoterol, formoterol) and ICS (e.g., budesonide, fluticasone propionate)
- Triple therapy with a LAMA (e.g., tiotropium, umeclidinium) + LABA (e.g., salmeterol, arformoterol, formoterol) combined with an ICS (e.g., budesonide, fluticasone propionate)]

AND

7 - Prescribed by or in consultation with a pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brinsupri [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of a positive clinical response (e.g, the patient has not had an increase in the number of annual pulmonary exacerbations requiring treatment with systemic antibiotics, patient has not initiated therapy with long-term maintenance systemic or inhaled antibiotics since starting Brinsupri)

AND

2 - ONE of the following:

2.1 Patient does not have co-existing COPD or asthma

OR

2.2 For patients with co-existing COPD, the patient continues to be treated with ONE of the following therapies at maximally tolerated doses unless there is a contraindication or intolerance to these medications:

- Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., tiotropium, umeclidinium) and a long-acting beta agonist (LABA) (e.g., salmeterol, arformoterol, formoterol)

- Triple therapy [LAMA + LABA combined with an inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone propionate)]

OR

2.3 For patients with co-existing asthma, the patient continues to be treated with ONE of the following therapies at maximally tolerated doses unless there is a contraindication or intolerance to these medications:

- Inhaled corticosteroid (ICS) (e.g., fluticasone propionate)
- Dual therapy with a LABA (e.g., salmeterol, arformoterol, formoterol) and ICS (e.g., budesonide, fluticasone propionate)
- Triple therapy with a LAMA (e.g., tiotropium, umeclidinium) + LABA (e.g., salmeterol, arformoterol, formoterol) combined with an ICS (e.g., budesonide, fluticasone propionate)]

AND

3 - Prescribed by or in consultation with a pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Brinsupri is a dipeptidyl peptidase 1 (DPP1) inhibitor indicated for the treatment of non-cystic fibrosis bronchiectasis in adult and pediatric patients 12 years of age and older. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place

4 . References

1. Brinsupri™ [prescribing information]. Bridgewater, NJ: Insmed Incorporated; August 2025
2. Aliberti S, Goeminne PC, O'Donnell AE, et al. Criteria and definitions for the radiological and clinical diagnosis of bronchiectasis in adults for use in clinical trials: international consensus recommendations. Lancet Respir Med. 2022;10(3):298-306. doi:10.1016/S2213-2600(21)00277-0
3. Barker, A. Bronchiectasis in adults: Maintaining Lung Health. In: UpToDate, Lam, A (Ed), UpToDate, Waltham, MA, 2025.

5 . Revision History

Date	Notes
11/3/2025	New program.

Brukinsa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-510402
Guideline Name	Brukinsa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	5/16/2025
P&T Revision Date:	07/16/2025 ; 2/20/2026

1 . Indications

Drug Name: Brukinsa (zanubrutinib)
Mantle Cell Lymphoma Indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. **Waldenström's Macroglobulinemia** Indicated for the treatment of adult patients with Waldenström's macroglobulinemia (WM) **Marginal Zone Lymphoma** Indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti–CD20-based regimen. **Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma** Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) **Follicular Lymphoma** Indicated for the treatment of adult patients with relapsed or refractory

follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy.

2 . Criteria

Product Name:Brukinsa [a]	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Diagnosis of follicular lymphoma (FL)
- Disease is relapsed, refractory, or progressive
- Patient has received at least two or more lines of systemic therapy
- Brukinsa will be used in combination with obinutuzumab

OR

2 - ALL of the following:

2.1 Diagnosis of ONE of the following:

- Extranodal marginal zone lymphoma (EMZL) of the stomach
- Extranodal marginal zone lymphoma of nongastric sites (noncutaneous)
- Nodal marginal zone lymphoma

AND

2.2 Disease is relapsed, refractory, or progressive

AND

2.3 Patient has received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab)

OR

3 - ALL of the following:

- Diagnosis of splenic marginal zone lymphoma
- Disease is relapsed or refractory
- Patient has received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab)

OR

4 - Diagnosis of mantle cell lymphoma (MCL)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brukinsa [a]	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Brukinsa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brukinsa [a]	
Diagnosis	Waldenström's Macroglobulinemia (WM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Waldenström's macroglobulinemia (WM)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brukinsa [a]	
Diagnosis	Waldenström's Macroglobulinemia (WM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Brukinsa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brukinsa [a]	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brukinsa [a]	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Brukinsa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brukinsa [a]	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of hairy cell leukemia **AND** **2** - Disease is relapsed, refractory, or progressive	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brukinsa [a]	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Brukinsa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brukinsa [a]	
Diagnosis	Central Nervous System Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of primary central nervous system lymphoma **AND** **2** - Disease is relapsed or refractory

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brukinsa [a]	
Diagnosis	Central Nervous System Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Brukinsa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brukinsa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Brukinsa will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brukinsa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Brukinsa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Brukinsa (zanubrutinib) is a kinase inhibitor indicated for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy, relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen, and relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy. These indications are approved under accelerated approval based on overall response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial. Brukinsa is also indicated for the treatment of Waldenström's macroglobulinemia (WM) and chronic lymphocytic

leukemia (CLL) or small lymphocytic lymphoma (SLL).

NCCN recommends Brukinsa for relapsed/refractory hairy cell leukemia and primary central nervous system (CNS) lymphomas.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Brukinsa® [package insert]. Pennington, NJ: BeOne Medicines USA, Inc; June 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium ®). Available at NCCN Drugs and Biologics Compendium®. Accessed December 16, 2025.

5 . Revision History

Date	Notes
2/5/2026	Added coverage for progressive follicular lymphoma and primary CN S lymphoma. Updated background and references.

Buphenyl, Olpruva, Pheburane

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523259
Guideline Name	Buphenyl, Olpruva, Pheburane
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	09/15/2021 ; 10/19/2022 ; 12/14/2022 ; 12/13/2023 ; 02/16/2024 ; 02/20/2025 ; 2/20/2026

1 . Indications

Drug Name: Sodium Phenylbutyrate
Urea cycle disorders Indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). **Neonatal-onset deficiency** Indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). **Late-onset disease (partial enzymatic deficiency, presenting after the first month of life)** Indicated in patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy.

2 . Criteria

Product Name:Brand Buphenyl, generic sodium phenylbutyrate, Olpruva, Pheburane [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of urea cycle disorders (UCDs)

AND

2 - Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Buphenyl, generic sodium phenylbutyrate, Olpruva, Pheburane [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to sodium phenylbutyrate therapy

AND

2 - Patient is actively on dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Sodium phenylbutyrate (Buphenyl) is indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). It is indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy. Sodium phenylbutyrate must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits may be in place

4 . References

1. Buphenyl [package insert], Lake Forest, IL: Horizon Therapeutics, Inc.; March 2023.
2. Pheburane [package insert]. Bryn Mawr, PA: Medunik USA, Inc.; August 2023.
3. Olpruva™ [package insert]. Newton, MA: Acer Therapeutics, Inc.; October 2025.

5 . Revision History

Date	Notes
2/19/2026	Annual review with no changes to coverage criteria. Updated references.

Bylvay

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-355210
Guideline Name	Bylvay
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	10/1/2025
P&T Approval Date:	6/15/2022
P&T Revision Date:	08/19/2022 ; 12/14/2022 ; 08/18/2023 ; 10/18/2023 ; 08/16/2024 ; 8/22/2025

1 . Indications

Drug Name: Bylvay (odevixibat)
Progressive Familial Intrahepatic Cholestasis (PFIC) Indicated for the treatment of pruritus in patients aged 3 months or older with progressive familial intrahepatic cholestasis (PFIC). **Alagille syndrome (ALGS)** Indicated for the treatment of pruritis in patients 12 months of age and older with Alagille syndrome (ALGS).

2 . Criteria

Product Name:Bylvay [a]

Diagnosis	Progressive Familial Intrahepatic Cholestasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Confirmed molecular diagnosis of progressive familial intrahepatic cholestasis (PFIC)

AND

2 - Patient does not have an ABCB11 variant resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3)

AND

3 - Patient is experiencing moderate to severe pruritus associated with PFIC

AND

4 - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory

AND

5 - Patient has had an inadequate response to at least two other conventional treatments for the symptomatic relief of pruritus (e.g., uroseoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, and sertraline)

AND

6 - Prescribed by a gastroenterologist or hepatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Bylvay [a]	
Diagnosis	Progressive Familial Intrahepatic Cholestasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to Bylvay therapy (e.g., reduced serum bile acids, improved pruritus and less sleep disturbance) **AND** **2** - Prescribed by a gastroenterologist or hepatologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Bylvay [a]	
Diagnosis	Alagille Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
Approval Criteria **1** - Diagnosis of Alagille syndrome (ALGS)	

AND

2 - Confirmation of diagnosis by presence of the JAG1 or Notch2 gene mutation

AND

3 - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory.

AND

4 - Patient is experiencing moderate to severe pruritis associated with ALGS

AND

5 - Patient has had an inadequate response to at least two other conventional treatments for the symptomatic relief of pruritus (e.g., uroseoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, and sertraline).

AND

6 - Prescribed by a gastroenterologist or hepatologist.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Bylvay [a]	
Diagnosis	Alagille Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria **1** - Documentation of positive clinical response to Bylvay therapy (e.g., reduced serum bile acids, improved pruritis) **AND** **2** - Prescribed by a gastroenterologist or hepatologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

Background:

Bylvay® (odevixibat) is an ileal bile acid transporter inhibitor indicated for the treatment of pruritis in patients aged 3 months or older with progressive familial intrahepatic cholestasis (PFIC). Bylvay is also indicated for the treatment of pruritis in patients 12 months of age and older with Alagille syndrome (ALGS).

PFIC is a heterogeneous group of liver disorders of autosomal recessive inheritance, characterized by an early onset of cholestasis (usually during infancy) with pruritus and malabsorption, which rapidly progresses and ends up as liver failure. Pruritus is the most obvious and the most unbearable symptom in cholestasis. It has been proposed that it is

induced by the stimulation of nonmyelinated subepidermal free nerve ends because of increased serum bile acids.

ALGS is a rare genetic disorder caused by a mutation in the JAG1 or Notch2 genes which are involved in embryonic development in utero. In ALGS patients, multiple organ systems may be affected by the mutation. In the liver, the mutation causes the bile ducts to abnormally narrow, malform and reduce in number, leading to bile acid accumulation, cholestasis, and ultimately progressive liver disease. The cholestatic pruritus experienced by patients with ALGS is among the most severe in any chronic liver disease and is present in most affected children by the third year of life.

Conventional treatments for pruritis associated with PFIC or Alagille syndrome include uroseoxycholic acid (UCDA), antihistamines (e,g., diphenhydramine), bile acid sequestrants (e.g., cholestyramine), rifampin, naltrexone and sertraline.

Limitation of Use:

Bylvay may not be effective in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).

4 . References

1. Bylvay [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; March 2025.
2. Thompson RJ, Arnell H, Artan R, et al. Odevixibat treatment in progressive familial intrahepatic cholestasis: a randomised, placebo-controlled, phase 3 trial. Lancet Gastroenterol Hepatol. 2022;7(9):830-842.
3. Ovchinsky N, Aumar M, Baker A, et al. Efficacy and safety of odevixibat in patients with Alagille syndrome (ASSERT): a phase 3, double-blind, randomised, placebo-controlled trial. Lancet Gastroenterol Hepatol. 2024;9(7):632-645.
4. Chowdhury JR, Chowdhury NR. Inherited disorders associated with conjugated hyperbilirubinemia in adults. In: Post TW, ed. UpToDate. UpToDate, 2025. Accessed June 23, 2025. Inherited disorders associated with conjugated hyperbilirubinemia in adults - UpToDate
5. Kohut TJ, Loomes KM. Alaglle syndrome. In: Post TW, ed. UpToDate. UpToDate, 2025. Accessed June 23, 2025. Alagille syndrome - UpToDate

5 . Revision History

Date	Notes
8/1/2025	Annual review with no changes to criteria. Updated references.

Cablivi

Prior Authorization Guideline

Guideline ID	GL-232246
Guideline Name	Cablivi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	6/1/2025
P&T Approval Date:	7/17/2024
P&T Revision Date:	4/16/2025

1 . Indications

Drug Name: Cablivi (caplacizumab-yhdp)
Acquired thrombotic thrombocytopenic purpura (aTTP) Indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

2 . Criteria

Product Name:Cablivi [a]	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)

AND

2 - Cablivi was initiated as a bolus intravenous injection administered by a healthcare provider in combination with plasma exchange therapy.

AND

3 - Cablivi will be used in combination with immunosuppressive therapy (e.g., corticosteroids)

AND

4 - Total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cablivi [a]	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 months for a new episode of aTTP
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Request is for a new (different) episode requiring the re-initiation of plasma exchange for the treatment of aTTP. (Documentation of date of prior episode and documentation date of new episode required)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Cablivi (caplacizumab-yhdp) is a von Willebrand factor (vWF)-directed antibody fragment indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Cablivi [package insert]. Cambridge, MA: Genzyme Corporation; April 2024.

5 . Revision History

Date	Notes
4/4/2025	Annual review with no change to clinical criteria. Updated reference.

Cabometyx

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-375638
Guideline Name	Cabometyx
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	03/17/2021 ; 11/19/2021 ; 08/19/2022 ; 11/18/2022 ; 08/18/2023 ; 11/17/2023 ; 10/01/2024 ; 11/22/2024 ; 9/25/2025

1 . Indications

Drug Name: Cabometyx (cabozantinib)
Renal cell carcinoma (RCC) Indicated for the treatment of patients with advanced renal cell carcinoma. Cabometyx is also indicated for the treatment of patients with advanced renal cell carcinoma as a first-line treatment in combination with Opdivo (nivolumab). [1] **Hepatocellular carcinoma (HCC)** Indicated for the treatment of patients with hepatocellular carcinoma who have been previously treated with Nexavar (sorafenib). **Differentiated Thyroid Cancer** Indicated for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible. **Neuroendocrine Tumors** Indicated for the treatment of adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-

differentiated pancreatic neuroendocrine tumors (pNET). Indicated for the treatment of adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated extra-pancreatic neuroendocrine tumors (epNET).

2 . Criteria

Product Name:Cabometyx [a]	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of ONE of the following: • Advanced renal cell carcinoma (RCC) • Relapsed renal cell carcinoma (RCC) • Hereditary leiomyomatosis and RCC (HLRCC)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient does not show evidence of progressive disease while on Cabometyx therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Positive for RET gene rearrangements

AND

3 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

4 - Used as subsequent therapy following progression on ONE of the following^:

- Gavreto (pralsetinib)
- Retevmo (selpercatinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines

Product Name:Cabometyx [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Cabometyx therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hepatocellular carcinoma **AND** **2** - Used as subsequent-line systemic therapy	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cabometyx therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Dedifferentiated chondrosarcoma
- Ewing Sarcoma
- High-Grade undifferentiated pleomorphic sarcoma (UPS)
- Mesenchymal chondrosarcoma
- Osteosarcoma
- Primary round cell tumor of the bone (e.g., CIC::DUX4, BCOR::CCNB3)

AND

2 - Disease is ONE of the following:

- Relapsed/refractory
- Metastatic

AND

3 - Used as second line therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cabometyx therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of GIST

AND

2 - Patient has ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Recurrent/metastatic disease

AND

3 - Disease has progressed on ALL of the following^:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)
- Stivarga (regorafenib)
- Standard dose Qinlock (ripretinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines

Product Name:Cabometyx [a]	
Diagnosis	Gastrointestinal Stromal Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Cabometyx therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of endometrial carcinoma **AND** **2** - Used as second-line or subsequent treatment	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient does not show evidence of progressive disease while on Cabometyx therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC)

AND

2 - Disease is locally advanced or metastatic

AND

3 - Disease has progressed following prior VEGFR-targeted therapy

AND

4 - Disease is radioactive iodine-refractory or ineligible

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]

Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cabometyx therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of ONE of the following soft tissue sarcoma subtypes:

- Extremity/body wall
- Head/neck
- Pleomorphic Rhabdomyosarcoma (RMS)
- Retroperitoneal/intraabdominal

AND

1.2 Disease is advanced/metastatic

AND

1.3 Used as subsequent line of therapy

OR

2 - Diagnosis of ONE of the following soft tissue sarcoma subtypes:

- Alveolar soft part sarcoma (ASPS)
- Epithelioid hemangioendothelioma
- Extraskeletal myxoid chondrosarcoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cabometyx therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following neuroendocrine tumors:

- Well-differentiated pancreatic neuroendocrine tumor (pNET)
- Well-differentiated extra-pancreatic neuroendocrine tumor (epNET)

AND

2 - Disease is ONE of the following:

- Locally advanced
- Metastatic
- Unresectable

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cabometyx therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Cabometyx will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cabometyx [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cabometyx therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Cabometyx® (cabozantinib) is a kinase inhibitor indicated for the treatment of patients with advanced renal cell carcinoma (RCC); patients with advanced RCC as a first-line treatment in combination with Opdivo (nivolumab); patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar (sorafenib tosylate); adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible; adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors (pNET); and adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated extra-pancreatic neuroendocrine tumors (epNET). The National Cancer Comprehensive Network (NCCN) recommends Cabometyx for the treatment of non-small cell lung cancer (NSCLC) with RET gene rearrangement and HCC as a single agent for progressive disease. Cabometyx is also recommended in NCCN guidelines for bone cancer, gastrointestinal stromal tumors (GIST), kidney cancer, soft tissue sarcoma and endometrial carcinoma. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Cabometyx [package insert]. South San Francisco, CA: Exelixis, Inc.; March 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 31, 2025.

5 . Revision History

Date	Notes

8/30/2025	Annual review. Added new section for neuroendocrine and adrenal tu mors based on updated FDA label and NCCN guidelines. Updated cr iteria for kidney cancer, non-small cell lung cancer, hepatocellular car cinoma, bone cancer, and soft tissue sarcoma based on NCCN upda tes. Updated background and references.

Calquence

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-207301
Guideline Name	Calquence
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	05/20/2022 ; 05/25/2023 ; 05/17/2024 ; 3/19/2025

1 . Indications

Drug Name: Calquence (acalabrutinib)
Mantle cell lymphoma Indicated in combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous hematopoietic stem cell transplantation (HSCT) **Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma** Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

2 . Criteria

Product Name:Calquence [a]	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - ONE of the following:

2.1 ALL of the following:

- Patient has not received prior therapy (e.g., bortezomib, rituximab) for MCL
- Patient is ineligible for autologous hematopoietic stem cell transplantation (HSCT)
- Used in combination with bendamustine and rituximab

OR

2.2 Patient has received at least one prior therapy for MCL (e.g., bortezomib, rituximab)^

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines.

Product Name:Calquence [a]	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Calquence therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Calquence [a]	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Calquence [a]	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Calquence therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Calquence [a]	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Nodal Marginal Zone Lymphoma
- Extranodal Marginal Zone Lymphoma (EMZL) of the stomach
- Splenic Marginal Zone Lymphoma
- Extranodal Marginal Zone Lymphoma of Nongastric Sites (Non-cutaneous)

AND

2 - Disease is recurrent, relapsed, refractory, or progressive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines.

Product Name:Calquence [a]	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Calquence therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Calquence [a]	
Diagnosis	Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma

AND

1.2 ONE of the following:

- Patient did not respond to primary therapy
- Disease is relapsed or progressive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Calquence [a]	
Diagnosis	Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Calquence therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Calquence [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Calquence will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Calquence [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Calquence therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background

Calquence® (acalabrutinib) is a kinase inhibitor indicated:

- In combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous hematopoietic stem cell transplantation (HSCT).
- For the treatment of adult patients with MCL who have received at least one prior therapy.
- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

The National Comprehensive Cancer Network (NCCN) recommends the use of Calquence for the treatment of B-cell lymphomas, including splenic and nodal marginal zone lymphoma, extranodal marginal zone lymphoma (EMZL) of the stomach, extranodal marginal zone lymphoma of nongastric sites (noncutaneous), and Waldenström macroglobulinemia/lymphoplasmacytic lymphoma.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Calquence [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP. January 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 12, 2025.

5 . Revision History

Date	Notes
3/4/2025	Updated criteria to reflect FDA indication for patients with previously untreated MCL who are ineligible for HSCT. Updated background an d references.

Camzyos

Prior Authorization Guideline

Guideline ID	GL-552193
Guideline Name	Camzyos
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	7/20/2022
P&T Revision Date:	11/18/2022 ; 08/18/2023 ; 08/16/2024 ; 08/22/2025 ; 2/20/2026

1 . Indications

Drug Name: Camzyos (mavacamten)
Obstructive hypertrophic cardiomyopathy (HCM) Indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

2 . Criteria

Product Name:Camzyos [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of obstructive hypertrophic cardiomyopathy (HCM)

AND

2 - Heart failure is classified as ONE of the following:

- New York Heart Association (NYHA) class II heart failure
- New York Heart Association (NYHA) class III heart failure

AND

3 - BOTH of the following were measured prior to Camzyos therapy:

- Patient had a left ventricular ejection fraction of greater than or equal to 55%
- Patient had a Valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation

AND

4 - History of inadequate response, intolerance, failure, or contraindication to ONE of the following at a maximally tolerated dose:

- Non-vasodilating beta blocker (e.g., atenolol, bisoprolol, metoprolol, nadolol, propranolol)
- Nondihydropyridine calcium channel blocker (i.e., diltiazem, verapamil)

AND

5 - Not used in combination with another cardiac myosin inhibitor [i.e., Myqorzo (aficamten)]

AND

6 - Prescribed by or in consultation with a cardiologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Camzyos [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in NYHA class, no worsening in NYHA class)

AND

2 - Patient has a left ventricular ejection fraction of greater than or equal to 50%

AND

3 - Not used in combination with another cardiac myosin inhibitor [i.e., Myqorzo (aficamten)]

AND

4 - Prescribed by or in consultation with a cardiologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Camzyos (mavacamten) is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Camzyos [package insert]. Brisbane, CA: Bristol Myers Squibb; April 2024.
2. Wasfy JH, Walton SM, Beinfeld M, Nhan E, Sarker J, Whittington MD, Pearson SD, Rind DM. Mavacamten for Hypertrophic Cardiomyopathy: Effectiveness and Value; Final Evidence Report and Meeting Summary. Institute for Clinical and Economic Review, November 16, 2021. https://icer.org/hypertrophic-cardiomyopathy-2021/.
3. Ommen SR, Ho CY, Asif IM, et al. 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR Guideline for the Management of Hypertrophic Cardiomyopathy: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines [published correction appears in Circulation. 2024 Aug 20;150(8):e198. doi: 10.1161/CIR.0000000000001277.]. Circulation. 2024;149(23):e1239-e1311. doi:10.1161/CIR.0000000000001250

5 . Revision History

Date	Notes
3/16/2026	Updated criteria for a left ventricular ejection fraction and LVOT to cla rify these measurements are prior to Camzyos therapy without chang e to clinical intent. Added not used in combination criteria.

Caprelsa

Prior Authorization Guideline

Guideline ID	GL-405336
Guideline Name	Caprelsa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	09/18/2019 ; 02/19/2021 ; 10/20/2021 ; 10/19/2022 ; 10/18/2023 ; 10/16/2024 ; 10/15/2025

1 . Indications

Drug Name: Caprelsa (vandetanib)
Medullary thyroid cancer Indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. **Off Label Uses: Follicular, Hurthle cell, Papillary carcinoma** The National Cancer Comprehensive Network (NCCN) recommends the use of Caprelsa for the treatment of follicular, oncocytic, and papillary carcinomas.

2 . Criteria

Product Name:Caprelsa [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following criteria:

1.1 Diagnosis of medullary thyroid cancer (MTC)

AND

1.2 ONE of the following

- Unresectable locoregional disease that is symptomatic or progressing
- Asymptomatic recurrent or persistent distant metastatic disease if unresectable and progressing
- Recurrent or persistent distant metastases if symptomatic disease or progression

OR

2 - ALL of the following:

2.1 ONE of the following diagnoses:

- Follicular Carcinoma
- Papillary Carcinoma

AND

2.2 ONE of the following:

- Unresectable locoregional recurrent
- Persistent disease
- Distant metastatic disease

AND

2.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

2.4 Disease is refractory to radioactive iodine treatment

OR

3 - ALL of the following:

3.1 Diagnosis of Oncocytic Carcinoma

AND

3.2 ONE of the following:

- Unresectable locoregional recurrent
- Persistent disease
- Distant metastatic disease

AND

3.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Caprelsa [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Caprelsa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Caprelsa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Caprelsa will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Caprelsa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Caprelsa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Caprelsa (vandetanib) is a kinase inhibitor indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. The National Cancer Comprehensive Network (NCCN) recommends the use of Caprelsa for the treatment of medullary, follicular, oncocytic, and papillary carcinomas. Caprelsa may be used in patients with indolent, asymptomatic or slowly progressing disease after careful consideration of the treatment related risks. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Caprelsa [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2025.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed September 3, 2025.

5 . Revision History

Date	Notes
9/29/2025	Annual review. Updated criteria for oncocytic, papillary, and follicular carcinoma per NCCN. Updated references.

Carbaglu

Prior Authorization Guideline

Guideline ID	GL-149903
Guideline Name	Carbaglu
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	9/1/2024
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 07/21/2021 ; 07/20/2022 ; 07/14/2023 ; 7/17/2024

1 . Indications

Drug Name: Carbaglu (carglumic acid)
Chronic Hyperammonemia Indicated for maintenance therapy in pediatric and adult patients for the treatment of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency. **Acute Hyperammonemia** Indicated as an adjunctive therapy to standard of care in pediatric and adult patients for the treatment of acute hyperammonemia due to NAGS deficiency, and adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).

2 . Criteria

Product Name:Brand Carbaglu, carglumic (generic Carbaglu) [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hyperammonemia due to ONE of the following: • N-acetylglutamate synthase (NAGS) deficiency • Propionic acidemia (PA) • Methylmalonic acidemia (MMA)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Carbaglu, carglumic (generic Carbaglu) [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Carbaglu therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Carbaglu (carglumic acid) is a Carbamoyl Phosphate Synthetase 1 (CPS 1) activator indicated in pediatric and adult patients as maintenance therapy for the treatment of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency, adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to NAGS deficiency, and adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Carbaglu® [package insert]. Lebanon, NJ: Recordati Rare Diseases Inc.; January 2024.

5 . Revision History

Date	Notes
7/16/2024	Annual review with no changes to coverage criteria. Updated reference.

CGRP Antagonist

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-493412
Guideline Name	CGRP Antagonist
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	10/1/2024
P&T Revision Date:	02/20/2025 ; 1/21/2026

1 . Indications

Drug Name: Aimovig (erenumab), Emgality 120mg (galcanezumab)
Preventive treatment of migraine Indicated for the preventive treatment of migraine in adults.
Drug Name: Emgality 100mg (galcanezumab)
Treatment of episodic cluster headache Indicated for the treatment of episodic cluster headache in adults.
Drug Name: Ajovy (fremanezumab)
Preventive treatment of migraine Indicated for the preventive treatment of migraine in adults. **Episodic migraine** Indicated for the preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age and who weigh 45 kg or more.

2 . Criteria

Product Name:Aimovig, Emgality 120mg [a]	
Diagnosis	Migraines
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition

AND

2 - ONE of the following:

2.1 4 to 7 migraine days per month and at least ONE of the following:

- Less than 15 headache days per month
- Provider attests this is the member's predominant headache diagnosis (i.e., primary driver of headaches is not a different, non-migrainous condition)

OR

2.2 Greater than or equal to 8 migraine days per month

AND

3 - Failure (after a trial of at least two months), contraindication or intolerance to TWO of the following prophylactic therapies (document name and date tried):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- Divalproex sodium (Depakote/Depakote ER)

- OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines [e.g. Ajovy, Nurtec ODT, Qulipta, Vyepti (eptinezumab-jjmr)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ajovy [a]	
Diagnosis	Migraines
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition

AND

2 - ONE of the following:

2.1 4 to 7 migraine days per month and at least ONE of the following:

- Less than 15 headache days per month
- Provider attests this is the member's predominant headache diagnosis (i.e., primary driver of headaches is not a different, non-migrainous condition)

OR

2.2 Greater than or equal to 8 migraine days per month

AND

3 - Failure (after a trial of at least two months), contraindication or intolerance to TWO of the following prophylactic therapies from the list below (document name and date tried):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- Divalproex sodium (Depakote/Depakote ER)
- OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - ONE of the following:

4.1 Failure (after a trial of at least three months), contraindication or intolerance to BOTH of the following (document date tried):

- Aimovig
- Emgality 120mg

OR

4.2 Provider attests that use of Aimovig and Emgality are not an option due to age less than 18.

AND

5 - Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Aimovig, Emgality, Nurtec ODT, Qulipta, Vyepti)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Aimovig, Ajovy, Emgality 120mg [a]	
Diagnosis	Migraines
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Nurtec ODT, Qulipta, Vyepti)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Emgality 100mg	
Diagnosis	Episodic Cluster Headache
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic cluster headache

AND

2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.

AND

3 - Medication will not be used in combination with another CGRP antagonist or inhibitor (e.g., Aimovig, Ajovy, Nurtec ODT, Qulipta, Ubrelvy, Vyepti)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Emgality 100mg	
Diagnosis	Episodic Cluster Headache
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Medication will not be used in combination with another CGRP antagonist or inhibitor (e.g., Aimovig, Ajovy, Nurtec ODT, Qulipta, Ubrelvy, Vyepti)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Aimovig, Ajovy and Emgality 120 mg are calcitonin gene-related peptide receptor (CGRP) antagonists indicated for the preventive treatment of migraine in adults. The 100 mg strength of Emgality is indicated for the treatment of episodic cluster headache in adults. In addition, Ajovyy is indicated for the preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age and who weigh 45 kg or more. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Aimovig [package insert]. Thousand Oaks, CA: Amgen Inc; March 2025.
2. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; August 2025.
3. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; May 2025.
4. International Headache Society (IHS); Headache Classification Committee. The International Classification of Headache Disorders, 3rd edition. Cephalalgia 2018; 38:1-211.
5. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. AHS Consensus Statement. Headache. 2024; 64:333-41.
6. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26.
7. Oskoui, M., Pringsheim, T., Billinghurst, L., et. al. Practice guideline update summary: Pharmacologic treatment for pediatric migraine prevention: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2019; 93(11): 500–509

5 . Revision History

Date	Notes
1/10/2026	Updated background section with pediatric information for Ajovy. Add ed bypass for pediatric patients. Updated statement for Emgality 100 mg of on concomitant use of CGRPs. Updated references.

Cholbam

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-259203
Guideline Name	Cholbam
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	03/17/2021 ; 03/16/2022 ; 05/20/2022 ; 05/25/2023 ; 08/18/2023 ; 05/17/2024 ; 5/16/2025

1 . Indications

Drug Name: Cholbam (cholic acid)
Bile acid synthesis disorders (BASDs) Indicated for treatment of bile acid synthesis disorders due to single enzyme defects (SEDs). Limitation of use: The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due to SEDs have not been established. **Peroxisomal disorders (PDs) including Zellweger spectrum disorders** Indicated as an adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption. Limitation of use: The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due PDs including Zellweger spectrum disorders have not been established.

2 . Criteria

Product Name:Cholbam [a]	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - BOTH of the following:

- Diagnosis of a bile acid synthesis disorder
- Bile acid synthesis disorder is due to single enzyme defects (SEDs)

OR

2 - ALL of the following:

- Diagnosis of a peroxisomal disorder including Zellweger spectrum disorders
- Patient exhibits manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption
- Cholbam is being used as adjunctive treatment

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cholbam [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Cholbam therapy as evidenced by BOTH of the following: • Improvement in liver function (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT]) • Absence of complete biliary obstruction	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background

Cholbam (cholic acid) is a bile acid indicated for the treatment of bile acid synthesis disorders due to single enzyme defects (SEDs) and as an adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption.

Cholbam should be discontinued if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis.

Limitation of use:
The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs including Zellweger spectrum disorders have not been established.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program.
- Supply limitations may be in place

4 . References

1. Cholbam [package insert]. Foster City, CA: Mirum Pharmaceuticals, Inc.; June 2024

5 . Revision History

Date	Notes
5/14/2025	Annual review with no change to coverage criteria. Updated referenc e.

Cibinqo

Prior Authorization Guideline

Guideline ID	GL-405337
Guideline Name	Cibinqo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	4/20/2022
P&T Revision Date:	07/20/2022 ; 10/19/2022 ; 03/15/2023 ; 09/20/2023 ; 03/20/2024 ; 04/16/2025 ; 10/15/2025

1 . Indications

Drug Name: Cibinqo (abrocitinib)
Atopic Dermatitis Indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

2 . Criteria

Product Name:Cibinqo [a]

Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderate-to-severe chronic atopic dermatitis

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 History of failure, contraindication, or intolerance to BOTH of the following therapeutic classes of topical therapies (document drug, date of trial, and/or contraindication to medication)

- Medium, high, or very-high potency topical corticosteroids [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]
- Topical calcineurin inhibitor [e.g., tacrolimus (generic Protopic)]

AND

2.1.2 ONE of the following^:

2.1.2.1 BOTH of the following:

- Submission of medical records (e.g., chart notes, laboratory values) documenting a 3 month trial of a systemic drug product for the treatment of atopic dermatitis [examples include, but are not limited to, Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), etc.] (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration)
- Physician attests that the patient was not adequately controlled with the documented systemic drug product

OR

2.1.2.2 Physician attests that systemic treatment with ALL of the following, FDA-approved chronic atopic dermatitis therapies is inadvisable (Document drug and contraindication rationale)^

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)
- Ebglyss (lebrikizumab-lbkz)
- Nemluvio (nemolizumab-ilto)

OR

2.1.2.3 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria) [5]

AND

2.1.3 History of failure, contraindication, or intolerance to Rinvoq (upadacitinib) (document date and duration of trial).

OR

2.2 BOTH of the following:

2.2.1 Patient is currently on Cibinqo therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

AND

2.2.2 Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer dermatology patient access program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cibinqo*

AND

3 - Patient is NOT receiving Cibinqo in combination with any of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto)]
- Janus kinase inhibitor [e.g., Olumiant (baricitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer dermatology patient access program shall be required to meet initial authorization criteria as if patient were new to therapy. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Cibinqo [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Cibinqo therapy

AND

2 - Patient is not receiving Cibinqo in combination with any of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto)]
- Janus kinase inhibitor [e.g., Olumiant (baricitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

3 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Cibinqo is a Janus kinase (JAK) inhibitor indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Limitation of Use: Cibinqo is not recommended in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants. Table 1: Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1

	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Cibinqo [package insert]. New York, NY: Pfizer Inc.; December 2023.
2. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014; 70(1):338-51.
3. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
4. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.
5. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Arlington, VA: American Psychiatric Publishing. 2013.

5 . Revision History

Date	Notes
9/29/2025	Added step through Rinvoq.

Cimzia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-447198
Guideline Name	Cimzia
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 05/21/2021 ; 05/20/2022 ; 09/21/2022 ; 05/25/2023 ; 06/17/2024 ; 10/16/2024 ; 11/22/2024 ; 12/18/2024 ; 01/15/2025 ; 11/21/2025

1 . Indications

Drug Name: Cimzia (certolizumab)
Crohn's disease (CD) Indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. **Rheumatoid Arthritis (RA)** Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis. **Active Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis. **Active Ankylosing Spondylitis (SpA)** Indicated for the treatment of adults with active ankylosing spondylitis.

Plaque Psoriasis (PS) Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Non-Radiographic Axial Spondyloarthritis (nr-axSpA) Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.

Polyarticular juvenile idiopathic arthritis (pJIA) Indicated for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.

2 . Criteria

Product Name:Cimzia [a]	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - ONE of the following^:

2.1 History of failure to ONE of the following conventional therapies at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of Crohn's disease as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), ustekinumab, Tremfya (guselkumab), Skyrizi (risankizumab)].

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to TWO of the following preferred products (document drug, date, and duration of trial):

- One of the preferred adalimumab products [b]
- Skyrizi (risankizumab)
- Rinvoq (upadacitinib)
- One of the preferred ustekinumab products [c]

OR

3.2 BOTH of the following:

- Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the UCB sponsored CIMplicity® program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cimzia*

AND

4 - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with a gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. [c] For a list of preferred ustekinumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the UCB sponsored CIMplicity® program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. ^ Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Cimzia [a]	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cimzia therapy **AND** **2** - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cimzia [a]	
Diagnosis	Rheumatoid Arthritis (RA)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - ONE of the following:

2.1 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to TWO of the following preferred products (document drug, date, and duration of trial):

- Actemra (tocilizumab)
- One of the preferred adalimumab products [b]
- Simponi (golimumab)
- Olumiant (baricitinib)
- Rinvoq (upadacitinib)
- Xeljanz/Xeljanz XR (tofacitinib)

OR

3.2 BOTH of the following:

- Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the UCB sponsored CIMplicity® program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cimzia*

AND

4 - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the UCB sponsored CIMplicity® program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Cimzia [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cimzia [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - ONE of the following:

2.1 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab]

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to TWO of the following preferred products (document drug, date, and duration of trial):

- One of the preferred adalimumab products [b]
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Skyrizi (risankizumab)
- Taltz (ixekizumab)
- One of the preferred ustekinumab products [c]
- Xeljanz/Xeljanz XR (tofacitinib)

OR

3.2 BOTH of the following:

- Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the UCB sponsored CIMplicity® program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cimzia*

AND

4 - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab),

Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication. **AND** **5** - Prescribed by or in consultation with ONE of the following: • Rheumatologist • Dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. [c] For a list of preferred ustekinumab products please reference drug coverage tools. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the UCB sponsored CIMplicity® program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Cimzia [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is not receiving Cimzia in combination with another systemic targeted

immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cimzia [a]	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - ONE of the following:

2.1 History of failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Simponi (golimumab), Taltz (ixekizumab), Xeljanz/Xeljanz XR (tofacitinib), Rinvoq (upadacitinib)].

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to TWO of the following preferred products (document drug, date, and duration of trial):

- One of the preferred adalimumab products [b]
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Taltz (ixekizumab)
- Xeljanz/Xeljanz XR (tofacitinib)

OR

3.2 BOTH of the following:

- Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the UCB sponsored CIMplicity® program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cimzia*

AND

4 - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Simponi (golimumab), Taltz (ixekizumab), Xeljanz/Xeljanz XR (tofacitinib), Rinvoq (upadacitinib)].for treatment of the same indication.

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply. [b] For a list of preferred adalimumab products please reference drug

	coverage tools. * Patients requesting initial authorization who were established on ther apy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the UCB sponsored CIMplicity® program SHALL BE REQUIRED to meet initial authorizati on criteria as if patient were new to therapy.

Product Name:Cimzia [a]	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cimzia therapy **AND** **2** - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Simponi (golimumab), Taltz (ixekizumab), Xeljanz/Xeljanz XR (tofacitinib), Rinvoq (upadacitinib)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Cimzia [a]	
Diagnosis	Plaque Psoriasis (PS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

2.1.2 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Coal tar

AND

2.1.3 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab].

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to TWO of the following preferred products (document drug, date, and duration of trial):

- One of the preferred adalimumab products [b]
- Skyrizi (risankizumab)
- Taltz (ixekizumab)
- One of the preferred ustekinumab products [c]

OR

3.2 BOTH of the following:

- Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the UCB sponsored CIMplicity® program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cimzia*

AND

4 - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply. [b] For a list of preferred adalimumab products please reference drug

	coverage tools. [c] For a list of preferred ustekinumab products please reference drug coverage tools. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the UCB sponsored CIMplicity® program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Cimzia [a]	
Diagnosis	Plaque Psoriasis (PS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cimzia therapy **AND** **2** - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cimzia [a]	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis active polyarticular juvenile idiopathic arthritis

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to TWO of the following preferred products (document drug, date, and duration of trial):

- Actemra (tocilizumab)
- One of the preferred adalimumab products [b]
- Rinvoq (upadacitinib)
- Xeljanz/Xeljanz XR (tofacitinib)

OR

2.2 BOTH of the following:

- Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the UCB sponsored CIMplicity® program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cimzia*

AND

3 - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the UCB sponsored CIMplicity® program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Cimzia [a]	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cimzia therapy **AND** **2** - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Rinvoq (upadacitinib)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cimzia [a]	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-radiographic axial spondyloarthritis

AND

2 - ONE of the following:

2.1 History of failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Rinvoq (upadacitinib), Taltz (ixekizumab)].

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to BOTH of the following preferred products (document drug, date, and duration of trial):

- Rinvoq (upadacitinib)
- Taltz (ixekizumab)

OR

3.2 BOTH of the following:

- Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the UCB sponsored CIMplicity®

program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cimzia* **AND** **4** - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Rinvoq (upadacitinib), Taltz (ixekizumab)] for treatment of the same indication. **AND** **5** - Prescribed by or in consultation with a rheumatologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the UCB sponsored CIMplicity® program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Cimzia [a]	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cimzia therapy **AND** **2** - Patient is not receiving Cimzia in combination with another systemic targeted	

immunomodulator [e.g., Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Rinvoq (upadacitinib), Taltz (ixekizumab)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information

Background:

Cimzia (certolizumab) is a tumor necrosis factor (TNF) blocker indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. Cimzia is also indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA), treatment of adult patients with active psoriatic arthritis (PsA), treatment of adults with active ankylosing spondylitis (SpA), treatment of adults with moderate to severe plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA), with objective signs of inflammation, and for treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

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5 . Revision History

Date	Notes
11/10/2025	Updated examples with no change to clinical intent. Updated referen ces.

Cinryze

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-555207
Guideline Name	Cinryze
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/18/2023
P&T Revision Date:	03/20/2024 ; 03/19/2025 ; 3/18/2026

1 . Indications

Drug Name: Cinryze (C1 esterase inhibitor, human)
Hereditary angioedema (HAE) Cinryze is a plasma-derived C1 esterase inhibitor (human) indicated for routine prophylaxis against angioedema attacks in adults, adolescents, and pediatric patients (6 years of age and older) with hereditary angioedema (HAE).

2 . Criteria

Product Name:Cinryze [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - ALL of the following:

- Prescribed for the prophylaxis of HAE attacks
- Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Andembry, Dawnzera, Haegarda, Orladeyo, Takhzyro)
- Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Cinryze

AND

3 - Submission of medical records documenting a history of failure, contraindication, or intolerance to Haegarda (C1 esterase inhibitor, human)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cinryze [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Cinryze therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Ekterly, Firazyr, icatibant, Ruconest) as determined by claims information, while on Cinryze therapy

AND

3 - BOTH of the following:

- Prescribed for the prophylaxis of HAE attacks
- Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Andembry, Dawnzera, Haegarda, Orladeyo, Takhzyro)

AND **4** - Prescribed by ONE of the following: • Immunologist • Allergist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Cinryze is a plasma-derived C1 esterase inhibitor (human) indicated for routine prophylaxis against angioedema attacks in adults, adolescents, and pediatric patients (6 years of age and older) with hereditary angioedema (HAE). **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Cinryze [package insert]. Lexington, MA: ViroPharma Biologics LLC; November 2024.
2. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2023.

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5 . Revision History

Date	Notes
3/18/2026	Annual review. Updated list of examples of prophylactic and acute H AE therapies. Updated references.

Clomid, Milophene

Prior Authorization Guideline

Guideline ID	GL-436463
Guideline Name	Clomid, Milophene
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	
P&T Revision Date:	11/21/2025

1 . Indications

Drug Name: Clomid, Milophene (clomiphene citrate)
Ovulatory dysfunction Indicated for the treatment of ovulatory dysfunction in women desiring pregnancy. Impediments to achieving pregnancy must be excluded or adequately treated before beginning clomiphene therapy. Those patients most likely to achieve success with clomiphene therapy include patients with polycystic ovary syndrome, amenorrhea-galactorrhea syndrome, psychogenic amenorrhea, certain cases of secondary amenorrhea of undetermined etiology, and post-oral contraceptive amenorrhea.

2 . Criteria

Product Name:Brand Clomid, generic clomiphene, generic milophene [a]

Diagnosis	Ovulation Induction
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ovulatory dysfunction

AND

2 - ONE of the following exists:

- Anovulation
- Oligo-ovulation
- Amenorrhea

AND

3 - Other specific causative factors (e.g., thyroid disease, hyperprolactinemia) have been excluded or treated

AND

4 - Infertility is not due to primary ovarian failure

AND

5 - For induction of ovulation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Clomid, generic clomiphene, generic milophene [a]	
Diagnosis	Controlled Ovarian Stimulation**

Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND

2 - ONE of the following exists:

- Unexplained infertility
- Endometriosis
- Male factor infertility
- Diminished ovarian reserve
- Unilateral tubal factor infertility

AND

3 - For the development of one or more follicles (controlled ovarian stimulation)

AND

4 - Will be used in conjunction with intrauterine insemination (IUI)

Notes	**Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Clomid, generic clomiphene, generic milophene [a]	
Diagnosis	Clomiphene Challenge Test**
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - To be used to conduct a clomiphene challenge test

Notes	**Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Clomid, generic clomiphene, generic milophene [a]	
Diagnosis	Male Factor Infertility/Oligospermia [off-label]**
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Mild, moderate, or severe male factor infertility
- Oligospermia

AND

2 - At least ONE of the following exists on at least 2 separate semen analyses obtained at least 4 weeks apart:

- Sperm concentration is < 16 million/mL
- Progressive motility < 30%
- Sperm morphology < 4%
- Semen volume < 1.4 mL

AND

3 - Patient condition has not improved despite an adequate trial (two to three months) of

positive lifestyle changes (e.g., weight loss, healthy diet, smoking cessation, reduction of alcohol intake)	
Notes	**Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

This program is designed to provide coverage for these medications to be used in conjunction with Assisted Reproductive Technologies (ART).

Clomiphene citrate is a nonsteroidal fertility agent used to induce ovulation in infrequently ovulating or anovulatory women, including patients with polycystic ovary syndrome (PCOS). It is also used for controlled ovarian stimulation in ovulatory women. The drug is effective at producing ovulation in patients with an intact hypothalamic-pituitary-ovarian axis and with ovaries that are capable of functioning normally. Clomiphene therapy is not effective in patients with primary pituitary or ovarian failure. Dosage should generally not exceed 100 mg daily for 5 days. If ovulation has not occurred after 3 courses of therapy, the patient should be reevaluated. If pregnancy does not occur within a total of 6 cycles, clomiphene should be discontinued as prolonged administration is not recommended.

Clomiphene citrate is indicated for the treatment of ovulatory dysfunction in women desiring pregnancy. Impediments to achieving pregnancy must be excluded or adequately treated before beginning clomiphene therapy. Those patients most likely to achieve success with clomiphene therapy include patients with polycystic ovary syndrome, amenorrhea-galactorrhea syndrome, psychogenic amenorrhea, certain cases of secondary amenorrhea of undetermined etiology, and post-oral contraceptive amenorrhea.

Clomiphene may be used to evaluate a woman’s ovulation and egg quality in what is referred to as the Clomiphene Challenge Test. When given early in a woman’s menstrual

cycle for 5 days, clomiphene elevates a woman's follicle-stimulating hormone (FSH) level. On the next day, an FSH blood level that has dropped back to normal is a sign of a normal ovarian reserve and ovulation. An elevated FSH is a sign of low ovarian reserve. Women who have a diminished ovarian reserve can use donor eggs, which greatly improves their chances of giving birth to a healthy child.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

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5. ASRM. Evidence-based treatments for couples with unexplained infertility: a guideline. Fertil Steril 2020; 113:305-22.
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7. World Health Organization. WHO Laboratory Manual for the 46th ed. Geneva: World Health Organization; 2021
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5 . Revision History

Date	Notes
10/30/2025	Annual review. Added New York to ovulation induction operation note for 2026 implementation. Updated cut-offs for semen analysis based off of updated guidance from WHO. Updated references. Added Milo phene to policy.

CNS Stimulants



Prior Authorization Guideline

Guideline ID	GL-412187
Guideline Name	CNS Stimulants
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/15/2020
P&T Revision Date:	02/19/2021 ; 10/06/2021 ; 10/20/2021 ; 10/20/2021 ; 05/20/2022 ; 12/14/2022 ; 02/16/2024 ; 10/01/2024 ; 08/22/2025

1 . Indications

Drug Name: CNS stimulants
Attention Deficit Hyperactivity Disorder (ADHD) FDA approved indication for Attention Deficit Hyperactivity Disorder (ADHD) **Attention Deficit Disorder (ADD)** FDA approved indication for Attention Deficit Disorder (ADD) **Narcolepsy** FDA approved indication for narcolepsy **Off Label Uses: Idiopathic hypersomnolence** There is evidence for off label use for idiopathic hypersomnolence. **Fatigue associated with multiple sclerosis** There is evidence for off label use for fatigue associated with multiple sclerosis. **Mental fatigue secondary to traumatic brain injury** There is evidence for off label use for

mental fatigue secondary to traumatic brain injury. **Depression** There is evidence for off label use for depression. **Weight Loss (Not Covered Benefit)** The potential use of these agents for weight loss is not a covered benefit.
Drug Name: Vyvanse (lisdexamfetamine)
Moderate to Severe Binge Eating Disorder (BED) Indicated for Moderate to Severe Binge Eating Disorder (BED). **Attention Deficit Hyperactivity Disorder (ADHD)** Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.

2 . Criteria

Product Name:CNS Stimulants (Includes both brand and generic versions of the listed products unless otherwise noted: Products containing amphetamine, dexmethylphenidate, dextroamphetamine, methamphetamine, methylphenidate, serdexmethylphenidate or any combinations of the mentioned products) [a]	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is less than 18 years of age

OR

2 - BOTH of the following:

2.1 The patient is greater than or equal to 18 years of age

AND

2.2 The patient has ONE of the following diagnoses:

- Attention-deficit hyperactivity disorder (ADHD) or attention-deficit disorder (ADD)
- Depression
- Narcolepsy
- Other hypersomnia of central origin
- Autism Spectrum Disorder
- Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
- Fatigue associated with medical illness in patients in palliative or end of life care
- Fatigue associated with multiple sclerosis

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Vyvanse, generic lisdexamfetamine [a]	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is less than 18 years of age

OR

2 - BOTH of the following:

2.1 The patient is greater than or equal to 18 years of age

AND

2.2 ONE of the following:

2.2.1 BOTH of the following:

2.2.1.1 The patient has ONE of the following diagnoses:

- Attention-deficit hyperactivity disorder (ADHD) or attention-deficit disorder (ADD)
- Depression
- Narcolepsy
- Other hypersomnia of central origin
- Autism Spectrum Disorder
- Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
- Fatigue associated with medical illness in patients in palliative or end of life care
- Fatigue associated with multiple sclerosis

AND

2.2.1.2 ONE of the following:

2.2.1.2.1 History of failure, contraindication or intolerance to ONE of the following:

- amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- dexmethylphenidate ER capsule (generic Focalin XR)

OR

2.2.1.2.2 History of, or potential for, a substance abuse disorder

OR

2.2.2 Diagnosis of Binge Eating Disorder (BED)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background:

This program will allow coverage for diagnoses supported by FDA labeling and clinical evidence. The CNS stimulants have a variety of FDA approved labeled indications, such as Attention Deficit Hyperactivity Disorder (ADHD), Attention Deficit Disorder (ADD), and narcolepsy. There is evidence for off label use for the stimulants in idiopathic hypersomnolence, fatigue associated with multiple sclerosis, mental fatigue secondary to traumatic brain injury, and depression. The potential use of these agents for weight loss is not a covered benefit. Because of the high abuse potential for this class of medications, their use should be closely monitored in certain age groups. In addition, if the member is less than 18 years of age, the prescription will automatically process without a coverage review.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may also be in place

4 . References

1. Adderall [package insert]. Parsippany, NJ: Teva Pharmaceuticals; October 2023.
2. Adderall XR [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc; October 2023.
3. Focalin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
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10. Ritalin LA [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; October 2023.
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13. Concerta [package insert]. Titusville, NJ. Janssen Pharmaceuticals. October 2023.
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24. QuilliChew ER extended-release chewable tablets [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc.; October 2023.
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26. Adzenys XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics; October 2023.
27. Quillivant XR [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc; October 2023.
28. Cotempla XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics Brands, LLC; June 2021.
29. Mydayis [package insert]. Lexington, MA: Takeda Pharmaceuticals America; October 2023.
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33. Adhansia XR extended-release capsules [package insert]. Wilson, NC: Purdue Pharmaceuticals; June 2021.
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5 . Revision History

Date	Notes
10/5/2025	Added GPI for AG of Adzenys

COC Oncology Hepatitis C Administrative

Prior Authorization Guideline

Guideline ID	GL-133876
Guideline Name	COC Oncology Hepatitis C Administrative
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	1/20/2022
P&T Revision Date:	

1 . Criteria

Product Name:Hepatitis C Medications*	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria **1** - Member is new to plan (within first 120 days of eligibility with the plan)	

AND

2 - Diagnosis of hepatitis C**

AND

3 - Previous use of the requested medication within the past 120 days

AND

4 - The patient requires continuation of therapy to complete the course of treatment

Notes	*Applicable drugs will have a Clinical Program of Continuity of Care. **This policy applies to requests for hepatitis C only. Requests for dia gnoses other than hepatitis C should not reviewed using this policy. Policy is to be applied if drug specific criteria are not met.

Product Name:Drugs and Biological Used in An Anti-Cancer Chemotherapeutic Regimen*	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Member is new to plan (within first 120 days of eligibility with the plan)

AND

2 - Meets Off-Label Administrative guideline criteria

AND

3 - Previous use of the requested medication within the past 120 days

AND **4** - The patient requires continuation of therapy to complete the course of treatment	
Notes	*Applicable drugs will have a Clinical Program of Continuity of Care. Policy is to be applied if drug specific criteria are not met.

2 . Background

Benefit/Coverage/Program Information
Background: This program is to be administered to members who are new to plan (within the past 120 days) and who have started an oncology or hepatitis C regimen prior to starting with the plan to allow continuation of therapy. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

3 . Revision History

Date	Notes
9/27/2023	New guideline.

Cometriq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-285259
Guideline Name	Cometriq
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 06/16/2021 ; 09/15/2021 ; 06/15/2022 ; 06/21/2023 ; 08/18/2023 ; 06/17/2024 ; 6/18/2025

1 . Indications

Drug Name: Cometriq (cabozantinib)
Medullary thyroid cancer (MTC) Indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC).

2 . Criteria

Product Name:Cometriq [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of medullary carcinoma

OR

1.2 ALL of the following:

1.2.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Oncocytic cell carcinoma
- Papillary carcinoma

AND

1.2.2 Disease is progressive after treatment with ONE of the following^:

- Lenvima (lenvatinib)
- sorafenib (generic Nexavar)

AND

1.2.3 Disease is at least ONE of the following:

- Symptomatic iodine-refractory
- Unresectable locoregional recurrent or persistent disease
- Distant metastatic disease

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

	^Tried/failed alternative(s) are supported by FDA labeling and/or treatment guidelines.

Product Name:Cometriq [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Cometriq therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cometriq [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC) **AND** **2** - Positive for RET gene rearrangements	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cometriq [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Cometriq therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cometriq [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Cometriq will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cometriq [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cometriq therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Cometriq (cabozantinib) is a kinase inhibitor indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC).

In addition, the National Cancer Comprehensive Network (NCCN) recommends Cometriq for the treatment of medullary, follicular, oncocytic, and papillary thyroid carcinomas. NCCN also recommends Cometriq for the treatment of non-small cell lung cancer (NSCLC) with RET gene rearrangement.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

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2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/login/?ReturnURL=/professionals/drug_compendium/content. Accessed May 5, 2025.

5 . Revision History

Date	Notes
6/3/2025	Annual review. Updated references.

Compounded Drugs Administrative

Prior Authorization Guideline

Guideline ID	GL-424269
Guideline Name	Compounded Drugs Administrative
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	10/20/2021
P&T Revision Date:	10/20/2021 ; 10/15/2025

1 . Criteria

Product Name:Compound Drugs	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria **1** - The compound route of administration is NOT an intravenous injectable	

AND

2 - One of the following:

2.1 Each active ingredient in the compound is/are FDA-approved for the requested indication

OR

2.2 If requested for an off-label indication, the Off-Label guideline approval criteria have been met for the requested indication

AND

3 - If a drug included in the compound requires prior authorization and/or step therapy, all drug specific clinical criteria must also be met

AND

4 - If the drug component is no longer available commercially it must not have been withdrawn for safety reasons

AND

5 - One of the following:

5.1 A unique vehicle is required

OR

5.2 A unique dosage form is required for a commercially available product due to patient's age, weight, or inability to take a solid dosage form

OR

5.3 A unique formulation is required for a commercially available product due to an allergy or intolerance to an inactive ingredient in the commercially available product

OR

5.4 There is a shortage of the commercially available product per the FDA Drug Shortage database or the ASHP Current Drug Shortages tracking log

AND

6 - Coverage for compounds and bulk powders will NOT be approved for any of the following:

6.1 For topical compound preparations (e.g., creams, ointments, lotions, or gels to be applied to the skin for transdermal, transcutaneous, or any other topical route), if the requested compound contains any FDA approved ingredient that is not FDA approved for TOPICAL use

OR

6.2 Requested compound contains topical fluticasone. Topical fluticasone will NOT be approved unless:

6.2.1 Topical fluticasone is intended to treat a dermatologic condition. Scar treatments are considered cosmetic and will not be covered

AND

6.2.2 Patient has a contraindication to all commercially available topically fluticasone formulations

OR

6.3 Requested compound is for cosmetic use or contains any ingredients when used for cosmetic purposes (see Appendix for examples)

OR

6.4 Requested compound does NOT contain any ingredients which are on the FDA's Do Not Compound List (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=216.24)

AND

7 - The use is not excluded as documented in the limitations and exclusions section of the certificate of coverage (see technician note in Background for the Exclusions and Limitations Grid URL)

AND

8 - One of the following:

8.1 If the request has one or more ACA/HCR ingredients, ACA/HCR criteria within the ACA/HCR Administrative guideline are met for ALL ingredients*

OR

8.2 The request does not contain any ACA/HCR ingredients^

Notes	Only ingredients that are available on formulary in one of the formulary tiers, or has a non-formulary status are approvable and should be included in the effectuation. If an approved compound contains an excluded drug such as OTC products, excipients, inactive ingredient that is a BULK chemical, injectable drugs covered under the medical benefit, etc. these ingredients should not be included in the effectuation. If the compound request includes an active ingredient that is a BULK chemical, the request should be denied as benefit exclusion. Injectable products (such as IV antibiotics, infusions, etc.) may be covered under the medical benefit and are excluded from the pharmacy benefit. These should be denied as benefit exclusion. *If compound and ACA/HCR criteria are met, approve the compound at $0 cost share. If only compound criteria are met and not ACA/HCR criteria, deny the request for not meeting ACA/HCR and approve the compound at regular cost share. ^If all compound criteria are met, approve the compound at regular cost share.

2 . Background

Benefit/Coverage/Program Information

Background:

Compounded drugs that exceed $50 in cost or contain an ingredient that is commercially available but is never supported by the standard references to be compounded will reject at point of sale as product service not covered. These compounds may be approved if below criteria are met.

Appendix:

Example topical compound preparations (e.g., creams, ointments, lotions or gels to be applied to the skin for transdermal, transcutaneous or any other topical route) that contain any FDA approved ingredient that are not FDA approved for TOPICAL use, including but NOT LIMITED TO the following:

(1) Ketamine
(2) Gabapentin
(3) Flurbiprofen (topical ophthalmic use not included)
(4) Ketoprofen
(5) Morphine
(6) Nabumetone
(7) Oxycodone
(8) Cyclobenzaprine
(9) Baclofen
(10) Tramadol
(11) Hydrocodone
(12) Meloxicam
(13) Amitriptyline
(14) Pentoxifylline
(15) Orphenadrine
(16) Piroxicam
(17) Levocetirizine
(18) Amantadine
(19) Oxytocin
(20) Sumatriptan
(21) Chorionic gonadotropin (human)
(22) Clomipramine
(23) Dexamethasone
(24) Hydromorphone
(25) Methadone
(26) Papaverine

(27) Mefenamic acid
(28) Promethazine
(29) Succimer DMSA
(30) Tizanidine
(31) Apomorphine
(32) Carbamazepine
(33) Ketorolac
(34) Dimercaptopropane-sulfonate
(35) Dimercaptosuccinic acid
(36) Duloxetine
(37) Fluoxetine
(38) Bromfenac (topical ophthalmic use not included)
(39) Nepafenac (topical ophthalmic use not included)

Example compounds that contain ingredients for cosmetic purposes:
(1) Hydroquinone
(2) Acetyl hexapeptide-8
(3) Tocopheryl Acid Succinate
(4) PracaSil TM-Plus
(5) Chrysaderm Day Cream
(6) Chrysaderm Night Cream
(7) PCCA Spira-Wash
(8) Lipopen Ultra
(9) Versapro
(10) Fluticasone
(11) Mometasone
(12) Halobetasol
(13) Betamethasone
(14) Clobetasol
(15) Triamcinolone
(16) Minoxidil
(17) Tretinoin
(18) Dexamethasone
(19) Spironolactone
(20) Cycloserine
(21) Tamoxifen
(22) Sermorelin
(23) Mederma Cream
(24) PCCA Cosmetic HRT Base
(25) Sanare Scar Therapy Cream
(26) Scarcin Cream
(27) Apothederm
(28) Stera Cream

(29) Copasil
(30) Collagenase
(31) Arbutin Alpha
(32) Nourisil
(33) Freedom Cepapro
(34) Freedom Silomac Andydrous
(35) Retinaldehyde
(36) Apothederm

Example ingredients on the FDA's Do Not Compound List:
(1) 3,3′,4′,5-tetrachlorosalicylanilide
(2) Adenosine phosphate
(3) Adrenal cortex
(4) Alatrofloxacin mesylate
(5) Aminopyrine
(6) Astemizole
(7) Azaribine
(8) Benoxaprofen
(9) Bithionol
(10) Camphorated oil
(11) Carbetapentane citrate
(12) Casein, iodinated
(13) Cerivastatin sodium
(14) Chlormadinone acetate
(15) Chloroform
(16) Cisapride
(17) Defenfluramine hydrochloride
(18) Diamthazole dihydrochloride
(19) Dibromsalan
(20) Dihydrostreptomycin sulfate
(21) Dipyrone
(22) Encainide hydrochloride
(23) Etretinate
(24) Fenfluramine hydrochloride
(25) Flosequinan
(26) Glycerol, iodinated
(27) Grepafloxacin
(28) Mepazine
(29) Metabromsalan
(30) Methapyrilene
(31) Methopholine
(32) Methoxyflurane
(33) Mibefradil dihydrochloride

(34) Nomifensine maleate
(35) Novobiocin sodium
(36) Oxyphenisatin acetate
(37) Oxyphenisatin
(38) Pemoline
(39) Pergolide mesylate
(40) Phenacetin
(41) Phenformin hydrochloride
(42) Phenylpropanolamine
(43) Pipamazine
(44) Potassium arsenite
(45) Propoxyphene
(46) Rapacuronium bromide
(47) Rofecoxib
(48) Sibutramine hydrochloride
(49) Sparteine sulfate
(50) Sulfadimethoxine
(51) Sweet spirits of nitre
(52) Tegaserod maleate
(53) Temafloxacin hydrochloride
(54) Terfenadine
(55) Ticrynafen
(56) Tribromsalan
(57) Trichloroethane
(58) Troglitazone
(59) Trovafloxacin mesylate:
(60) Urethane
(61) Valdecoxib
(62) Zomepirac sodium

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

Technician Note: Link of Exclusions and Limitations Grid:
https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x01200027C80175A8369D44AC45A99A99328B80&View=%7B4B6D25AD%2D6A95%2D496D%2D9937%2D65CECD43AFE7%7D&viewid=c2ad0afa%2D814c%2D499e

%2Dbf25%2D3411fac9171f&id=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FUHCGP%20Exchange

3 . References

1. Food and Drug Administration (2014, July 02). Additions and Modifications to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety and Effectiveness. Retrieved from http://federalregister.gov/a/2014-15371. Accessed October 1, 2025.
2. FDA Drug Shortages. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA. Available at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm. Accessed October 1, 2025.
3. Current Drug Shortages. Available at: https://www.ashp.org/Drug-Shortages/Current-Shortages. Accessed October 1, 2025.
4. CFR - code of federal Regulations Title 21. accessdata.fda.gov. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=216.24. Published November 10, 2020. Accessed October 1, 2025.

4 . Revision History

Date	Notes
10/21/2025	Annual review. Updated references.

Continuous Glucose System (PA, QL)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-374425
Guideline Name	Continuous Glucose System (PA, QL)
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	10/1/2024
P&T Revision Date:	11/22/2024 ; 02/20/2025 ; 03/19/2025 ; 9/25/2025

1 . Indications

Drug Name: Continuous Glucose System
Diabetes Indicated for use by patients with diabetes who require glucose monitoring beyond what can be achieved with a standard blood glucose monitor.

2 . Criteria

Product Name:Continuous Glucose System [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diabetes

AND

2 - ALL of the following:

- Patient is motivated and knowledgeable about use of continuous glucose monitoring
- Patient is adherent to diabetic treatment plan
- Patient participates in ongoing education and support

AND

3 - ONE of the following:

3.1 Patient is on an intensive insulin regimen (3 or more insulin injections per day or uses continuous subcutaneous insulin infusion pump)

OR

3.2 ONE of the following:

- Patient has a history of a level 3 hypoglycemic event [glucose <54mg/dL (3.0mmol/L)] characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia
- Patient has a history of more than one level 2 hypoglycemia events [(glucose <54mg/dL (3.0mmol/L)] that persist despite multiple attempts to adjust medication(s) or modify diabetes treatment plan

AND

4 - Patient regularly monitors blood glucose 4 or more times per day

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Continuous Glucose System [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Continuous Glucose System monitors (receivers) or transmitters [a]	
Approval Length	7 Day(s)
Guideline Type	Quantity Limit
Approval Criteria **1** - Quantity requests for monitors (receivers) or transmitters exceeding the limited amount will be approved if the current monitor/receiver or transmitter is out of warranty and no longer functionally operating.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Continuous Glucose System sensors [a]	
Approval Length	12 months
Guideline Type	Quantity Limit
Approval Criteria	

1 - Quantity requests for system sensors exceeding the limited amount will be approved if the member requires additional sensors due to increased frequency of change (e.g. adhesive no longer functional due to physical activity).	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background Continuous glucose systems may be used by patients with diabetes who require glucose monitoring beyond what can be achieved with a standard blood glucose monitor. **Additional Clinical Rules** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. American Diabetes Association. (2024). 7. Diabetes technology: Standards of care in diabetes—2024. Diabetes Care, 47(Supplement_1), S126–S144. https://doi.org/10.2337/dc24-S007
2. Lane AS, Mlynarczyk MA, de Veciana M, et al. Real-time continuous glucose monitoring in gestational diabetes: a randomized controlled trial. Am J Perinatol. 2019 Jul;36(9):891-897.
3. LeRoith D, Biessels GJ, Braithwaite SS, et al. Treatment of diabetes in older adults: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2019 May 1;104(5):1520-1574.

5 . Revision History

Date	Notes
9/16/2025	Added definitions to hypoglycemia criteria.

Corlanor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-402271
Guideline Name	Corlanor
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/18/2020
P&T Revision Date:	02/19/2021 ; 11/19/2021 ; 08/19/2022 ; 10/19/2022 ; 08/18/2023 ; 09/18/2024 ; 9/25/2025

1 . Indications

Drug Name: Corlanor (ivabradine)
Heart failure in adult patients Indicated to reduce the risk of hospitalization for worsening of heart failure in adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction less than or equal to 35%, who are in sinus rhythm with resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use. **Heart failure in pediatric patients** Indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate.

2 . Criteria

Product Name:Brand Corlanor, generic ivabradine [a]	
Diagnosis	Symptomatic Chronic Heart Failure
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Worsening heart failure in a diagnosis of stable, symptomatic chronic [e.g. New York Heart Association (NYHA) class II, III or IV] heart failure

AND

1.2 Patient has a left ventricular ejection fraction (EF) less than or equal to 35%

AND

1.3 The patient is in sinus rhythm

AND

1.4 Patient has a resting heart rate greater than or equal to 70 beats per minute

AND

1.5 ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with a maximum tolerated beta blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
- Patient has a contraindication or intolerance to beta-blocker therapy

AND

1.6 ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with Jardiance, Farxiga, or Inpefa (includes combination products containing empagliflozin and dapagliflozin)
- Patient has a contraindication or intolerance to SGLT2 inhibitor therapy

AND

1.7 ONE of the following:

1.7.1 Patient is on a stabilized dose and receiving concomitant therapy with one of the following:

- angiotensin-converting enzyme (ACE) inhibitor (e.g. captopril, enalapril)
- angiotensin II receptor blocker (ARB) (e.g. candesartan, valsartan)
- angiotensin receptor-neprilysin inhibitor (ARNI) (e.g. Entresto)

OR

1.7.2 Patient has a contraindication or intolerance to ACE inhibitors, ARBs, and ARNIs

AND

1.8 ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated aldosterone antagonist (e.g. eplerenone, spironolactone)
- Patient has a contraindication or intolerance to aldosterone antagonist therapy

AND

1.9 Prescribed by or in consultation with a cardiologist

OR

2 - ALL of the following:

- Diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy (DCM)
- Patient is in sinus rhythm
- Patient has an elevated heart rate
- Prescribed by or in consultation with a cardiologist

OR

3 - ALL of the following:

3.1 Diagnosis of inappropriate sinus tachycardia (IST)

AND

3.2 Patient is in sinus rhythm

AND

3.3 ONE of the following:

- Patient has tried and failed or had an inadequate response to a beta blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
- Patient has a contraindication or intolerance to beta-blocker therapy

AND

3.4 Prescribed by or in consultation with a cardiologist

OR

4 - Patient is currently established on Corlanor therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Corlanor, generic ivabradine [a]	
Diagnosis	Symptomatic Chronic Heart Failure
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Corlanor therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Corlanor (ivabradine) is a hyperpolarization-activated cycle nucleotide-gated channel blocker indicated to reduce the risk of hospitalization for worsening of heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use. It is also indicated to treat stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate. Also, although not an FDA-approved indication, Corlanor has also shown to have efficacy in treating inappropriate sinus tachycardia (IST). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply Limits may be in place.

4 . References

1. Corlanor [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2021.
2. Heidenreich, P. A., Bozkurt, B., Aguilar, D., et al. 2022 ACC/AHA/HFSA guideline for the management of heart failure. Journal of Cardiac Failure, 2022 28(5), e1-e167.
3. Sheldon, R.S., Grubb, B.P., et al. 2015 Heart Rhythm Society Expert Consensus Statement on the Diagnosis and Treatment of Postural Tachycardia Syndrome, Inappropriate Sinus Tachycardia, and Vasovagal Syncope. Heart Rhythm, 2015, 12(6), e41-e63.

5 . Revision History

Date	Notes
10/1/2025	Annual review. Added Inpefa as option for SGLT2 requirement.

Cotellic

Prior Authorization Guideline

Guideline ID	GL-436495
Guideline Name	Cotellic
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	11/17/2023
P&T Revision Date:	02/19/2021 ; 11/19/2021 ; 11/18/2022 ; 11/17/2023 ; 11/22/2024 ; 11/21/2025

1 . Indications

Drug Name: Cotellic (cobimetinib)
Melanoma Indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with Zelboraf (vemurafenib) and as a single agent for the treatment of patients with histiocytic neoplasms. [1] **NCCN recommendations** Indicated in combination with Zelboraf (vemurafenib) as treatment for Central Nervous System (CNS) Cancers.

2 . Criteria

Product Name:Cotellic [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - ONE of the following:

2.1 Patient has unacceptable toxicities to Tafinlar (dabrafenib)/Mekinist (trametinib) on the basis of agent side-effect profile

OR

2.2 Disease is ONE of the following:

- Relapsed > 3 months after treatment discontinuation
- Unresectable
- Metastatic

AND

3 - Disease is positive for ONE of the following mutations:

- BRAF V600E
- BRAF V600K

AND

4 - Used in combination with Zelboraf (vemurafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cotellic [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cotellic therapy

AND

2 - Used in combination with Zelboraf (vemurafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cotellic [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Circumscribed glioma

- Glioblastoma

AND

2 - Disease is BRAF V600E positive

AND

3 - Used in combination with Zelboraf (vemurafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cotellic [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cotellic therapy

AND

2 - Used in combination with Zelboraf (vemurafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cotellic [a]	
Diagnosis	Histiocytic Neoplasms

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following histiocytic neoplasms:

- Langerhans cell histiocytosis
- Erdheim-Chester disease
- Rosai-Dorfman Disease

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cotellic [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cotellic therapy.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cotellic [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Cotellic will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cotellic [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cotellic therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Cotellic (cobimetinib) is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in

combination with Zelboraf (vemurafenib) and as a single agent for the treatment of patients with histiocytic neoplasms. [1]

The National Cancer Comprehensive Network (NCCN) also recommends the use of Cotellic in combination with Zelboraf® (vemurafenib) as treatment for Central Nervous System (CNS) Cancers.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Cotellic [package insert]. Genentech USA, Inc.: South San Francisco, CA; May 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org. Accessed September 29, 2025.

5 . Revision History

Date	Notes
11/3/2025	Updated coverage criteria for central nervous system cancers and hi stiocytic neoplasms based on NCCN recommendations.

Cough and Cold



Prior Authorization Guideline

Guideline ID	GL-270219
Guideline Name	Cough and Cold
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	12/16/2020
P&T Revision Date:	02/19/2021 ; 08/20/2021 ; 09/15/2021 ; 03/15/2023 ; 03/20/2024 ; 5/16/2025

1 . Criteria

Product Name:Opioid Containing Cough and Cold Products for Patients Younger than 18 Years* [a]	
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Prescriber attests they are aware of FDA labeled contraindications regarding use of opioid	

containing cough and cold products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use). **AND** **2** - Patient does not have a comorbid condition that may impact respiratory depression (e.g., asthma or other chronic lung disease, sleep apnea, body mass index greater than 30) **AND** **3** - Patient has tried and failed at least one non-opioid containing cough and cold remedy

Notes	*Includes both brand and generic versions of the listed products unless otherwise noted: Products containing codeine or hydrocodone in combinations with one or more of the following: homatropine, chlorpheniramine, guaifenesin, pyrilamine, brompheniramine, phenylephrine, triprolidine, dexchlorpheniramine, promethazine, pseudoephedrine. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Opioid Containing Cough and Cold Products*	
Approval Length	Authorization will be issued for up to 30 days. The authorization should be entered for the quantity requested.
Guideline Type	Quantity Limit

Approval Criteria

1 - Requests exceeding the quantity limit will be approved based on BOTH of the following:

1.1 Doses exceeding the quantity limit will be approved up to the requested amount if the prescriber attests that a larger quantity is medically necessary

AND

1.2 The requested dose is within FDA maximum dose per day, where an FDA maximum dose per day exists	
Notes	*Includes both brand and generic versions of the listed products unles s otherwise noted: Products containing codeine or hydrocodone in combinations with one or more of the following: homatropine, chlorpheniramine, guaifenesin, pyrilamine, brompheniramine, phenylephrine, triprolidine, dexchlorph eniramine, promethazine, pseudoephedrine.

2 . Background

Benefit/Coverage/Program Information
Background Opioid (codeine or hydrocodone) containing cough and cold products are FDA labeled for use in adults 18 years of age and older. Use of prescription opioid cough and cold medicines containing codeine or hydrocodone should be limited in children younger than 18 years old due to serious risks associated with use. Coverage for patients age 18 or greater will process automatically. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

3 . References

1. Approach to Chronic Cough in Children. UpToDate. October 2024. Accessed March 25, 2025.
2. FDA Drug Safety Communication (2018a). FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older. US Food and Drug Administration website. https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-requires-labeling-changes-prescription-opioid-cough-and-cold. Published January 11, 2018. Accessed March 25, 2025.

4 . Revision History

Date	Notes
5/19/2025	Annual review, updated references.

Crenessity

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523262
Guideline Name	Crenessity
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	3/19/2025
P&T Revision Date:	05/16/2025 ; 2/20/2026

1 . Indications

Drug Name: Crenessity (crinecerfont)
Classic congenital adrenal hyperplasia Indicated as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH).

2 . Criteria

Product Name:Crenessity oral capsule and oral suspension [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of classic congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency

AND

2 - Diagnosis confirmed by ONE of the following:

- Pretreatment serum 17-hydroxyprogesterone (17-OHP) level > 3,000 ng/dL
- Cosyntropin stimulation 17OHP level > 10,000 ng/dL
- Genetic variant in CYP21A2 gene

AND

3 - Patient is 4 years of age or older

AND

4 - Chronic treatment with a supraphysiologic glucocorticoid (GC) regimen (e.g., dexamethasone, hydrocortisone, methylprednisolone, prednisone, prednisolone) defined as ONE of the following:

4.1 BOTH of the following:

- Patient is 4 to 17 years old
- Daily glucocorticoid dose > 12 mg/m2 in hydrocortisone dose equivalents

OR

4.2 BOTH of the following:

- Patient is ≥ 18 years old
- Daily glucocorticoid dose > 13 mg/m2/day in hydrocortisone dose equivalents

AND

5 - Prescribed by an endocrinologist

AND

6 - If the request is for Crenessity oral suspension, ONE of the following:

6.1 Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to ONE of the following:

- Age
- oral-motor difficulties
- dysphagia

OR

6.2 Patient utilizes a feeding tube for medication administration

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Crenessity oral capsule and oral suspension [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Crenessity therapy (e.g., reduction in total glucocorticoid daily dose, decreased androstenedione levels)

AND

2 - Patient will continue to receive concomitant glucocorticoid replacement (e.g., dexamethasone, hydrocortisone, methylprednisolone, prednisone, prednisolone)

AND

3 - Prescribed by an endocrinologist

AND

4 - If the request is for Crenessity oral suspension, ONE of the following:

4.1 Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to ONE of the following:

- Age
- oral-motor difficulties
- dysphagia

OR

4.2 Patient utilizes a feeding tube for medication administration

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Crenessity (crinecerfont) is a corticotropin-releasing factor type 1 receptor antagonist indicated as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH).

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Crenessity [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.; December 2024.
2. Sarafoglou K, Kim MS, Lodish M, et al. Phase 3 Trial of Crinecerfont in Pediatric Congenital Adrenal Hyperplasia. N Engl J Med. 2024;391(6):493-503.
3. Auchus RJ, Hamidi O, Pivonello R, et al. Phase 3 Trial of Crinecerfont in Adult Congenital Adrenal Hyperplasia. N Engl J Med. 2024;391(6):504-514.
4. New MI, Lorenzen F, Lerner AJ, et al. Genotyping steroid 21-hydroxylase deficiency: hormonal reference data. J Clin Endocrinol Metab. 1983;57(2):320-326.
5. Speiser PW, Arlt W, Auchus RJ, et al. Congenital Adrenal Hyperplasia Due to Steroid 21-Hydroxylase Deficiency: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2019 Jan 1;104(1):39-40. J Clin Endocrinol Metab. 2018;103(11):4043-4088.

5 . Revision History

Date	Notes
2/20/2026	Added new strength crenessity tab

Ctexli

Prior Authorization Guideline

Guideline ID	GL-428197
Guideline Name	Ctexli
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	10/25/2025
P&T Approval Date:	7/24/2025
P&T Revision Date:	

1 . Indications

Drug Name: Ctexli (chenodiol)
Cerebrotendinous xanthomatosis Indicated for treatment of cerebrotendinous xanthomatosis (CTX) in adults.

2 . Criteria

Product Name:Ctexli [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of cerebrotendinous xanthomatosis (cholestanol storage disease)

AND

2 - Disease is confirmed by the presence of pathogenic variant(s) in the CYP27A1 gene

AND

3 - Prescribed by or in consultation with ONE of the following:

- Endocrinologist
- Geneticist
- Neurologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ctexli [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Ctexli therapy

AND

2 - Prescribed by or in consultation with ONE of the following: • Endocrinologist • Geneticist • Neurologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Ctexli (chenodiol) is a bile acid indicated for treatment of cerebrotendinous xanthomatosis (CTX) in adults. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Ctexli [package insert]. Foster City, CA: Mirum Pharmaceuticals, Inc.; July 2024.
2. Stelten BML, Dotti MT, Verrips A, Elibol B, Falik-Zaccai TC, Hanman K, Mignarri A, Sithole B, Steiner RD, Verma S, Yahalom G, Zubarioglu T, Mochel F, Federico A. Expert opinion on diagnosing, treating and managing patients with cerebrotendinous xanthomatosis (CTX): a modified Delphi study. Orphanet J Rare Dis. 2021;16(1):353. doi:10.1186/s13023-021-01980-5.
3. DeBarber A, Kisanuki Y, Nobrega P, Himes R, Jayadev S, Bernat J, Prakash V, Gibson J, Larson A, Sgobbi P, Murphy E, Fedor B, Wong Po Foo C, Dutta R, Imperiale M, Garner W, Vig P, Perez S, Ramdhani R, Saute J, Duell PB. Evaluation of Chenodeoxycholic Acid

Treatment in Adult Patients with Cerebrotendinous Xanthomatosis: A Randomized, Placebo-Controlled Phase 3 Study [abstract].

5 . Revision History

Date	Notes
10/24/2025	Updated GPI

Cuvrior

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164985
Guideline Name	Cuvrior
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	1/1/2023
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Cuvrior (trientine tetrahydrochloride)
Wilson's Disease Indicated for the treatment of adult patients with Wilson's disease who are de-coppered and tolerant to penicillamine.

2 . Criteria

Product Name:Cuvrior [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Wilson's disease

AND

2 - Patient is de-coppered [i.e., serum non-ceruloplasmin copper (NCC) level greater than or equal to 25 and less than or equal to 150 mcg/L]

AND

3 - Patient is tolerant to penicillamine

AND

4 - Prescriber provides a reason or special circumstance why the patient cannot use penicillamine

AND

5 - Patient will not use penicillamine in conjunction with Cuvrior

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cuvrior [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria **1** - Documentation of positive clinical response to Cuvrior therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Cuvrior (trientine tetrahydrochloride) is a copper chelator indicated for the treatment of adult patients with Wilson's disease who are de-coppered and tolerant to penicillamine. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits may be in place

4 . References

1. Cuvrior [package insert]. Chicago, IL: Orphalan; April 2022.

5 . Revision History

Date	Notes

2/11/2025	Annual review. Updated authorization durations to 12 months. Added SML.

Cystaran

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436496
Guideline Name	Cystaran
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	11/18/2022 ; 11/21/2025

1 . Indications

Drug Name: Cystaran (cysteamine 0.44% ophthalmic solution)
Cystinosis Indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.

2 . Criteria

Product Name:Cystaran [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystinosis **AND** **2** - Treatment of corneal cystine crystal accumulation	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cystaran [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cystaran therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Cystaran [package insert]. Rockville MD: Leadiant Biosciences, Inc.; April 2025.

5 . Revision History

Date	Notes
11/3/2025	Annual review. Updated reference. Added state mandate language.

Daraprim

Prior Authorization Guideline

Guideline ID	GL-259210
Guideline Name	Daraprim
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	11/13/2020
P&T Revision Date:	05/21/2021 ; 09/15/2021 ; 05/20/2022 ; 05/25/2023 ; 05/17/2024 ; 10/01/2024 ; 03/19/2025 ; 5/16/2025

1 . Indications

Drug Name: Daraprim (pyrimethamine)
Toxoplasmosis Indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.

2 . Criteria

Product Name:Brand Daraprim, generic pyrimethamine [a]	
Approval Length	12 months*
Guideline Type	Prior Authorization

Approval Criteria

1 - Daraprim will be approved based on submission of medical record (e.g., chart notes) documenting ONE of the following criteria:

1.1 Treatment of severe acquired toxoplasmosis, including toxoplasmic encephalitis

OR

1.2 Treatment of congenital toxoplasmosis

OR

1.3 Secondary prophylaxis of toxoplasmic encephalitis

OR

1.4 ALL of the following:

1.4.1 Primary Pneumocystis pneumonia (PCP) prophylaxis in HIV-infected patients or as secondary prophylaxis in HIV-infected patients who have been treated for an acute episode of Pneumocystis pneumonia

AND

1.4.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)^

AND

1.4.3 ONE of the following:

- Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX)^ using a desensitization protocol and is still unable to tolerate

- Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX)^ in the past (e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)

OR

1.5 ALL of the following:

1.5.1 Primary prophylaxis of toxoplasmic encephalitis

AND

1.5.2 Toxoplasma IgG positive

AND

1.5.3 CD4 count is less than or equal to 100 cells/mm3 if initiating prophylaxis or CD4 count is less than 100-200 cells/mm3 if reinstituting prophylaxis

AND

1.5.4 Will be used in combination with dapsone or atovaquone

AND

1.5.5 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)^

AND

1.5.6 ONE of the following:

- Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX)^ using a desensitization protocol and is still unable to tolerate

• Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX)^ in the past (e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)	
Notes	* Consider discontinuation of primary prophylaxis if CD4 count is greater than 200 cells/mm3 for greater than 3 months after institution of combination antiretroviral therapy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by clinical guidelines.

3 . Background

Benefit/Coverage/Program Information

Background:

Daraprim (pyrimethamine) is indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.

The use of pyrimethamine for the treatment or prophylaxis of malaria is no longer recommended in the CDC Guidelines for the Treatment of Malaria in the United States. For the treatment of malaria, contact the CDC Malaria Hotline: (770) 488-7788 or (855) 856-4713 toll-free Monday-Friday 9 am to 5 pm EST - (770) 488-7100 after hours, weekends and federal holidays.

Limitations of Use:
Outpatient medication access to Daraprim is available exclusively through the Daraprim Direct program in partnership with Optime Care, Inc.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Daraprim [Package Insert]. Jersey City, NJ: Tilde Sciences LLC: October 2023.
2. Centers for Disease Control and Prevention. Treatment of Uncomplicated Malaria. Clinical guidance: Malaria diagnosis and treatment in the U.S. Accessed January 31, 2025: Treatment of Uncomplicated Malaria | Malaria | CDC
3. Centers for Disease Control and Prevention. CDC Yellow Book: Health Information for International Travel 2020. New York: Oxford University Press; 2024. Accessed April 10, 2025: https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/malaria
4. Daraprim Accessing Daraprim. Accessed April 10, 2025: Welcome to DARAPRIM® Direct - For Healthcare Providers | DARAPRIM® (pyrimethamine) 25mg tablets
5. Department of Health and Human Services. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. Accessed April 10,2025: What's New: Adult and Adolescent OIs HIV Clinical Guidelines | NIH
6. Department of Health and Human Services. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Accessed April 10, 2025: Toxoplasmosis | Pediatric Opportunistic Infection | ClinicalInfo (hiv.gov)

5 . Revision History

Date	Notes
5/14/2025	Annual review without change to coverage criteria. Updated referenc es.

Dawnzera

Prior Authorization Guideline

Guideline ID	GL-493413
Guideline Name	Dawnzera
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	1/21/2026
P&T Revision Date:	

1 . Indications

Drug Name: Dawnzera (donidalorsen)
Hereditary angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years of age and older.

2 . Criteria

Product Name:Dawnzera [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - BOTH of the following:

- For prophylaxis against HAE attacks
- Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo)

AND

3 - Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Dawnzera.

AND

4 - Submission of medical records documenting a history of failure, contraindication, or intolerance to Haegarda (C1 esterase inhibitor, human)

AND

5 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Dawnzera [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Dawnzera therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, icatibant, Firazyr, Ruconest) as determined by claims information, while on Dawnzera therapy.

AND

3 - BOTH of the following:

- For prophylaxis against HAE attacks

• Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo) **AND** **4** - Prescribed by ONE of the following: • Immunologist • Allergist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Dawnzera is a prekallikrein directed antisense oligonucleotide indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years of age and older. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Dawnzera [package insert]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; September 2025.
2. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2025.

3. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2021 revision and update. Allergy. 2022;77(7):1961-1990. doi:10.1111/all.15214

5 . Revision History

Date	Notes
1/10/2026	New program.

Daybue

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-500256
Guideline Name	Daybue
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/15/2026
P&T Approval Date:	5/25/2023
P&T Revision Date:	04/17/2024 ; 05/16/2025

1 . Indications

Drug Name: Daybue, Daybue Stix (trofinetide)
Rett syndrome (RTT) Indicated for the treatment of Rett syndrome (RTT) in adults and pediatric patients aged 2 years and older.

2 . Criteria

Product Name:Daybue, Daybue Stix [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Rett Syndrome (RTT) confirmed by ONE of the following:

1.1 ALL of the following clinical signs and symptoms:

- A pattern of development, regression, then recovery or stabilization
- Partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose
- Partial or complete loss of spoken language
- Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing
- Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait

OR

1.2 Confirmed genetic mutation in the MECP2 gene

AND

2 - Prescribed by, or in consultation with, ONE of the following:

- Geneticist
- Pediatrician who specializes in childhood neurological or developmental disorders
- Neurologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Daybue, Daybue Stix [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Daybue therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Daybue is a synthetic analog of the amino-terminal tripeptide of insulin-like growth factor-1 (IGF-1) indicated for the treatment of Rett syndrome (RTT) in adults and pediatric patients aged 2 years and older. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits may be in place.

4 . References

1. Daybue [package insert]. San Diego, CA: Acadia Pharmaceuticals, Inc.; September 2024.

5 . Revision History

Date	Notes
1/21/2026	Added Daybue Stix

Diabetic Meters and Test Strips - PA, NF, QL

Prior Authorization Guideline

Guideline ID	GL-412252
Guideline Name	Diabetic Meters and Test Strips - PA, NF, QL
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	1/20/2021
P&T Revision Date:	09/15/2021 ; 9/17/2025

Note:

NOTE: Continuous Glucose Monitoring (CGM) and components (reader, sensor) should be reviewed using the Continuous Glucose Monitor guideline.

1 . Criteria

Product Name:Test Strips and Glucose Meters (preferred and non-preferred)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization, Non-Formulary
Approval Criteria	

1 - One of the following reasons that a preferred Test Strip/Glucometer (Accu-Chek Guide or Contour strip/meter) cannot be used:

- The member has a vision problem/blindness that requires the use of a special glucometer/test strip
- The member is currently on an insulin pump or an insulin delivery device (e.g., OmniPod) that requires a specific glucometer/test strip
- There is a medically necessary justification (e.g., an impairment of manual dexterity) requiring use of a special monitoring system and/or test strip

Notes	NOTE: a) Before approving/denying a product, please check for a previous approval on file for the member for a non-preferred product. If an approval is on file, an automatic approval is appropriate. b) If a non-preferred test strip/meter is approved for a member, future requests for non-preferred test strip/meter products should also be approved. NOTE: Continuous Glucose Monitoring (CGM) and components (reader, sensor) should be reviewed using the Continuous Glucose Monitor guideline.

Product Name:Test Strips (preferred and non-preferred)	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Quantities exceeding the plan's limit of 100 test strips per 30 days are approved for one of the following:

- The patient is insulin dependent or pregnant and the physician confirms the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions)
- The patient is experiencing or is prone to hypoglycemia or hyperglycemia and requires additional testing to achieve glycemic control
- The patient’s physician is adjusting medications and the patient requires additional blood glucose testing during this time
- The patient’s physician is adjusting MNT (medical nutrition therapy) and the patient requires additional blood glucose testing during this time
- The patient requires additional testing due to fluctuations in blood glucose due to physical activity/exercise
- Other circumstances where prescribing physician confirms that the patient requires a greater quantity because of more frequent blood glucose testing (clinical review required by UnitedHealthcare reviewing pharmacist and/or medical director)

Notes	NOTE: Effectuate approvals with quantity limit that corresponds to the approved MDD (max daily dose) for test strips to the requested quant ity.

2 . Background

Benefit/Coverage/Program Information
Background: This program is to be administered for diabetic meters and test strips with a prior authorization or quantity limit requirement. It is also to be administered for members requesting an exception for non-preferred diabetic meters and test strips. Preferred test strips and meters are Accu-Chek Guide and Contour. All other brands are non-preferred. All preferred and non-preferred test strips have a quantity limit of 100 strips per 30 days. In addition, all preferred and non-preferred meters have a quantity limit of one per 365 days. NOTE: Continuous Glucose Monitoring (CGM) and components (reader, sensor) should be reviewed using the Continuous Glucose Monitor guideline.

3 . Revision History

Date	Notes
10/8/2025	Updated preferred products for 2026.

Dojolvi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-267189
Guideline Name	Dojolvi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	12/16/2020
P&T Revision Date:	02/19/2021 ; 05/20/2022 ; 5/16/2025

1 . Indications

Drug Name: Dojolvi (triheptanoin)
Long-chain fatty acid oxidation disorders (LC-FAOD) Dojolvi (triheptanoin) is a medium-chain triglyceride indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).

2 . Criteria

Product Name:Dojolvi [a]	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records confirming the diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD) with at least TWO of the following diagnostic criteria:

- Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma
- Low enzyme activity in cultured fibroblasts
- Genetic testing demonstrating one or more pathogenic mutations in a gene associated with long-chain fatty acid oxidation disorders (e.g., CPT2, ACADVL, HADHA, or HADHB)

AND

2 - Patient is not receiving Dojolvi in combination with any other medium-chain triglyceride (MCT) products

AND

3 - Prescribed by a board certified medical geneticist experienced in the treatment of long-chain fatty acid oxidation disorders (LC-FAOD)

AND

4 - Target recommended daily dosage does not exceed 35% of the patient's total prescribed daily caloric intake (DCI)

AND

5 - Patient is receiving disease related dietary management

AND

6 - If not diagnosed by newborn screening, patient has a history of clinical manifestations of long-chain fatty acid oxidation disorders LC-FAOD (e.g., rhabdomyolysis)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Dojolvi [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Dojolvi therapy (e.g., increased cardiac efficiency, decreased left ventricular wall mass, decreased incidence of rhabdomyolysis, etc.)

AND

2 - Patient is not receiving Dojolvi in combination with any other medium-chain triglyceride (MCT) products

AND

3 - Prescribed by a board certified medical geneticist experienced in the treatment of long-chain fatty acid oxidation disorders (LC-FAOD)

AND

4 - Target recommended daily dosage does not exceed 35% of the patient's total prescribed daily caloric intake (DCI)

AND

5 - Patient is receiving disease related dietary management	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background Dojolvi (triheptanoin) is a medium-chain triglyceride indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD). **Additional Clinical Rules:** • Supply limits may be in place • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Dojolvi [package insert]. Novato, CA: Ultragenyx Pharmaceutical, Inc.; October 2023.
2. Merritt JL 2nd, Norris M, Kanungo S. Fatty acid oxidation disorders. Ann Transl Med. 2018;6(24):473. doi:10.21037/atm.2018.10.57
3. Knottnerus SJG, Bleeker JC, Wüst RCI, et al. Disorders of mitochondrial long-chain fatty acid oxidation and the carnitine shuttle. Rev Endocr Metab Disord. 2018;19(1):93-106. doi:10.1007/s11154-018-9448-1

5 . Revision History

Date	Notes

5/14/2025	Annual review. Revised listing of genes associated with long-chain fa tty acid disorders. Revised initial authorization to 12 months. Update d references. Added state mandate note.

Doptelet

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-540187
Guideline Name	Doptelet
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	3/18/2026
P&T Revision Date:	

1 . Indications

Drug Name: Doptelet (avatrombopag tablet)
Thrombocytopenia Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure, thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. **Immune Thrombocytopenia** Indicated for the treatment of thrombocytopenia in pediatric patients 6 years and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.
Drug Name: Doptelet Sprinkle (avatrombopag oral granules)
Immune Thrombocytopenia Indicated for pediatric patients aged 1 year to less than 6 years with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

2 . Criteria

Product Name:Doptelet or Doptelet Sprinkle [a]	
Diagnosis	Immune Thrombocytopenia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic immune thrombocytopenia (ITP)

AND

2 - ONE of the following:

2.1 Patient has had a prior splenectomy

OR

2.2 History of failure/inadequate response, contraindication, or intolerance to ONE of the following (document drug, date, and duration of trial):

- Corticosteroids (e.g., prednisone, methylprednisolone)
- Immunoglobulins

AND

3 - History of failure/inadequate response, contraindication, or intolerance, to eltrombopag (e.g. Alvaiz, generic Promacta) (document date and duration of trial)

AND **4** - Platelet count remains less than 30,000/mcL despite previous treatment **AND** **5** - Prescribed by or in consultation with a hematologist/oncologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Doptelet or Doptelet Sprinkle [a]	
Diagnosis	Immune Thrombocytopenia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Doptelet or Doptelet Sprinkle therapy (e.g. an increase in platelet count to a level sufficient to avoid clinically important bleeding)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Doptelet [a]	
Diagnosis	Thrombocytopenia
Approval Length	1 month(s)
Guideline Type	Non Formulary

Approval Criteria **1** - Diagnosis of thrombocytopenia **AND** **2** - Patient has chronic liver disease **AND** **3** - Patient is scheduled to undergo a procedure	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Doptelet is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure, thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment, and thrombocytopenia in pediatric patients 6 years and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. Doptelet Sprinkle is indicated for pediatric patients aged 1 year to less than 6 years with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Doptelet [Package Insert]. Morrisville, North Carolina: AkaRx, Inc.; July 2025.
2. Neunert C,et. al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv. 2019 Dec 10;3(23):3829-3866.

5 . Revision History

Date	Notes
3/4/2026	New program.

Dry Eye Disease

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-374426
Guideline Name	Dry Eye Disease
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/18/2023
P&T Revision Date:	03/20/2024 ; 07/17/2024 ; 10/01/2024 ; 07/24/2025 ; 9/25/2025

1 . Indications

Drug Name: Cequa (cyclosporine 0.09% ophthalmic solution), Restasis (cyclosporine 0.05% ophthalmic emulsion), Restasis Multidose (cyclosporine 0.05% ophthalmic emulsion)
Keratoconjunctivitis sicca Indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.
Drug Name: Miebo (perfluorohexyloctane ophthalmic solution), Tryptyr (acoltremon ophthalmic solution), Tyrvaya (varenicline nasal spray), Vevye (cyclosporine 0.1%) , Xiidra (lifitegrast 5% ophthalmic solution)
Dry eye disease Indicated for the treatment of the signs and symptoms of dry eye disease.

2 . Criteria

Product Name:Cequa, Miebo, Restasis Multidose, Brand Restasis, Tryptyr, Tyrvaya, Vevye, Xiidra [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Moderate to severe keratoconjunctivitis sicca
- Moderate to severe dry eye disease

AND

2 - Not prescribed to manage dry eyes peri-operative elective eye surgery (e.g., LASIK)

AND

3 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist
- Rheumatologist

AND

4 - Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Miebo, Restasis single dose-vials, Tyrvaya, Xiidra)

AND

5 - The patient has a history of failure, contraindication, or intolerance to a trial of cyclosporine 0.05% ophthalmic emulsion (generic Restasis or generic Restasis Multidose)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Cequa, Miebo, Restasis Multidose, Brand Restasis, Tryptyr, Tyrvaya, Vevye, Xiidra [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has demonstrated clinically significant improvement with therapy

AND

2 - Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Miebo, Restasis single dose-vials, Tyrvaya, Xiidra)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:cyclosporine 0.05% ophthalmic emulsion (generic Restasis) [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Moderate to severe keratoconjunctivitis sicca
- Moderate to severe dry eye disease

AND

2 - Not prescribed to manage dry eyes peri-operative elective eye surgery (e.g., LASIK)

AND

3 - Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Cequa, Miebo, Restasis, Vevye, Xiidra)

AND

4 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist
- Rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:cyclosporine 0.05% ophthalmic emulsion (generic Restasis) [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has demonstrated clinically significant improvement with therapy

AND **2** - Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Cequa, Miebo, Restasis, Vevye Xiidra)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Cequa™ (cyclosporine 0.09% ophthalmic solution), Restasis® (cyclosporine 0.05% ophthalmic emulsion) and Restasis Multidose (cyclosporine 0.05% ophthalmic emulsion) are indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Miebo (perfluorohexyloctane ophthalmic solution), Tryptyr (acoltremon ophthalmic solution), Tyrvaya (varenicline nasal spray), Vevye (cyclosporine 0.1%) and Xiidra™ (lifitegrast 5% ophthalmic solution) are indicated for the treatment of the signs and symptoms of dry eye disease. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Cequa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; December 2022.
2. Restasis [package insert]. North Chicago, IL: AbbVie Inc.; September 2024
3. Restasis MultiDose [package insert]. North Chicago, IL: AbbVie Inc.; September 2024
4. Tyrvaya [package insert]. Princeton NJ: Oyster Point Pharma, Inc; February 2024.
5. Xiidra [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc;: December 2023.
6. Miebo [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc; June 2023.
7. American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern 2023.
8. Vevye [package insert]. Nashville, TN: Harrow Eye, LLC; November 2023
9. Tryptyr [package insert]. Fort Worth, TX: Alcon Laboratories, Inc.; May 2025.

5 . Revision History

Date	Notes
9/3/2025	Added Tryptyr to policy. Removed requirement for OTC artificial tear product use.

Duopa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-355215
Guideline Name	Duopa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	10/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/21/2022 ; 08/18/2023 ; 8/22/2025

1 . Indications

Drug Name: Duopa (carbidopa/levodopa)
Advanced Parkinson's disease Indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease.

2 . Criteria

Product Name:Duopa [a]	
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced Parkinson's Disease

AND

2 - Patient experiences a wearing "off" phenomenon that cannot be managed by increasing the dose of oral levodopa

AND

3 - Has undergone or has planned placement of a procedurally-placed tube

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Duopa [a]	
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Duopa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Duopa (carbidopa/levodopa) enteral suspension is indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease. Duopa should be administered continuously via an infusion pump over 16 hours through a procedurally-placed tube. Duopa may be administered through a naso-jejunal (NJ) tube for a short period of time until a gastrostomy tube can be placed.[1,2,3] **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Duopa [package insert]. North Chicago, IL: AbbVie, Inc.; May 2025.
2. International Parkinson and Movement Disorder Society Evidence-Based Medicine Review: Update on Treatments for the Motor Symptoms of Parkinson's Disease. Movement Disorders. 2018.

5 . Revision History

Date	Notes
8/1/2025	Annual review. Updated references.

Dupixent

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-356193
Guideline Name	Dupixent
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	10/1/2025
P&T Approval Date:	1/20/2021
P&T Revision Date:	06/16/2021 ; 08/20/2021 ; 10/20/2021 ; 12/15/2021 ; 01/19/2022 ; 02/18/2022 ; 04/20/2022 ; 07/20/2022 ; 11/18/2022 ; 03/15/2023 ; 07/19/2023 ; 08/18/2023 ; 03/20/2024 ; 11/22/2024 ; 03/19/2025 ; 06/18/2025 ; 8/22/2025

1 . Indications

Drug Name: Dupixent (dupilumab)
Atopic Dermatitis Indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids. **Asthma** Indicated as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma **Chronic Rhinosinusitis with Nasal Polyps** Indicated as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

Eosinophilic Esophagitis Indicated for treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).

Prurigo nodularis (PN) Indicated for the treatment of adult patients with prurigo nodularis (PN).

Chronic Obstructive Pulmonary Disorder (COPD) Indicated for add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

Chronic Spontaneous Urticaria Indicated for the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.

Bullous Pemphigoid Indicated for the treatment of adult patients with bullous pemphigoid.

2 . Criteria

Product Name:Dupixent [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe chronic atopic dermatitis

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to BOTH of the following therapeutic classes of topical therapies (document drug, date of trial, and/or contraindication to medication)^:

- Medium, high, or very-high potency topical corticosteroids [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]
- Topical calcineurin inhibitor [e.g., tacrolimus (generic Protopic)]

OR

2.2 BOTH of the following:

- Patient is currently on Dupixent therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has not received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Sanofi and Regeneron Pharmaceuticals sponsored Dupixent MyWay program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Dupixent*

AND

3 - Patient is not receiving Dupixent in combination with EITHER of the following for treatment of the same indication:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Nemluvio (nemolizumab-ilto)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the

	prescriber's office or any form of assistance from the Sanofi and Regeneron Pharmaceuticals sponsored Dupixent MyWay program shall be required to meet initial authorization criteria as if patient were new to therapy. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Dupixent [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy

AND

2 - Patient is not receiving Dupixent in combination with EITHER of the following for treatment of the same indication:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Nemluvio (nemolizumab-ilto)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Dupixent [a]	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe asthma

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:

- Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
- Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
- Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
- Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
- Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

2.1.2 Dupixent will be used in combination with ONE of the following:

2.1.2.1 ONE maximally dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., fluticasone propionate/salmeterol, Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

2.1.2.2 Combination therapy including BOTH of the following:

- ONE maximally dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]
- ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or salmeterol (Serevent); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

2.1.3 ONE of the following:

- Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting that asthma is an eosinophilic phenotype as defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level greater than or equal to 150 cells/uL (microliter)
- Patient is currently dependent on oral corticosteroids for the treatment of asthma

OR

2.2 BOTH of the following:

- Patient is currently on Dupixent therapy
- Patient has not received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Sanofi and Regeneron Pharmaceuticals sponsored Dupixent MyWay program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Dupixent*

AND

3 - Patient is not receiving Dupixent in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]

- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Sanofi and Regeneron Pharmaceuticals sponsored Dupixent MyWay program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Dupixent [a]	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Dupixent is being used in combination with an ICS-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

3 - Patient is not receiving Dupixent in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Dupixent [a]	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyposis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) defined by ALL of the following:

1.1.1 TWO OR MORE of the following symptoms for longer than 12 weeks duration:

- Nasal mucopurulent discharge
- Nasal obstruction, blockage, or congestion
- Facial pain, pressure, and/or fullness
- Reduction or loss of sense of smell

AND

1.1.2 ONE of the following findings using nasal endoscopy and/or sinus computed tomography (CT):

- Purulent mucus or edema in the middle meatus or ethmoid regions
- Polyps in the nasal cavity or the middle meatus
- Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

AND

1.1.3 ONE of the following:

- Presence of bilateral nasal polyposis
- Patient has previously required surgical removal of bilateral nasal polyps

AND

1.1.4 ONE of the following:

1.1.4.1 Patient has required prior sinus surgery

OR

1.1.4.2 Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for CRSwNP in the previous 2 years

OR

1.1.4.3 Patient has been unable to obtain symptom relief after trial of TWO of the following classes of agents:

- Nasal saline irrigations
- Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)
- Antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)

OR

1.2 ALL of the following:

- Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)
- Patient is currently on Dupixent therapy
- Patient has not received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Sanofi and Regeneron Pharmaceuticals sponsored Dupixent MyWay program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Dupixent*

AND

2 - Patient will receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

3 - Patient is NOT receiving Dupixent in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Sanofi and Regeneron Pharmaceuticals sponsored Dupixent MyWay program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Dupixent [a]	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyposis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy

AND

2 - Patient will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

3 - Patient is NOT receiving Dupixent in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by or in consultation with ONE of the following

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Dupixent [a]	
Diagnosis	Eosinophilic Esophagitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of eosinophilic esophagitis

AND

2 - Patient is experiencing symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, chest pain that is often centrally located and may not respond to antacids, gastroesophageal reflux disease-like symptoms/refractory heartburn, upper abdominal pain)

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting eosinophil-predominant inflammation on esophageal biopsy, consisting of a peak value of greater than or equal to 15 intraepithelial eosinophils per high power field (HPF) (or 60 eosinophils per mm^2)

AND

4 - Secondary causes of esophageal eosinophilia have been ruled out

AND

5 - Mucosal eosinophilia is isolated to the esophagus and symptoms have persisted after an 8-week trial of at least ONE of the following:

- Proton pump inhibitors (e.g., pantoprazole, omeprazole)
- Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone)

AND

6 - Patient is not receiving Dupixent in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

7 - Prescribed by ONE of the following:

- Allergist
- Gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Dupixent [a]	
Diagnosis	Eosinophilic Esophagitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy as evidenced by improvement of at least ONE of the following from baseline:

- Symptoms (e.g., dysphagia, chest pain, heartburn)
- Histologic measures (e.g., esophageal intraepithelial eosinophil count)
- Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures)

AND

2 - Patient is not receiving Dupixent in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

3 - Prescribed by or in consultation with a gastroenterologist or allergist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Dupixent [a]	
Diagnosis	Prurigo Nodularis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prurigo nodularis

AND

2 - Patient has greater than or equal to 20 nodular lesions

AND

3 - History of failure, contraindication, or intolerance to at least ONE previous prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin)

AND

4 - Patient is not receiving Dupixent in combination with EITHER of the following for treatment of the same indication:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm, Nemluvio (nemolizumab-ilto)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

AND

5 - Prescribed by ONE of the following:

- Dermatologist
- Allergist

• Immunologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Dupixent [a]	
Diagnosis	Prurigo Nodularis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy

AND

2 - Patient is not receiving Dupixent in combination with EITHER of the following for treatment of the same indication:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Nemluvio (nemolizumab-ilto)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

AND

3 - Prescribed by ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Dupixent [a]	
Diagnosis	Chronic Obstructive Pulmonary Disorder (COPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of COPD

AND

2 - Submission of medical records (e.g., chart notes) documenting ALL of the following:

- Post-bronchodilator forced expiratory volume (FEV1) / forced vital capacity (FVC) ratio less than 0.7
- Post-bronchodilator FEV1 % predicted greater than or equal to 30% and less than or equal to 70%
- Patient has an eosinophilic phenotype defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level greater than or equal to 300 cells/µL

AND

3 - Uncontrolled or inadequately controlled COPD demonstrated by BOTH of the following:

3.1 ONE of the following:

- Two or more COPD exacerbations in the previous year requiring treatment with systemic corticosteroids and/or antibiotics
- One or more COPD exacerbation(s) that resulted in hospitalization or observation for over 24 hours in an emergency department or urgent care facility in the past year

AND

3.2 COPD exacerbation(s) occurred while receiving maintenance therapy with ONE of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

AND

4 - Symptoms of chronic productive cough for at least 3 months in the past year

AND

5 - Dupixent will be used as add-on maintenance therapy with ONE of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

AND

6 - Patient is not receiving Dupixent in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

7 - Prescribed by ONE of the following:

- Allergist

• Immunologist • Pulmonologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Dupixent [a]	
Diagnosis	Chronic Obstructive Pulmonary Disorder (COPD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to Dupixent therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of COPD exacerbations
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of COPD-related symptoms (e.g., dyspnea, wheezing, cough, sputum volume, decrease in sputum purulence)
- Reduction in oral corticosteroid requirements

AND

2 - Dupixent is being used as add-on maintenance therapy with ONE of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a long-acting muscarinic antagonist (LAMA) and long-acting beta agonist (LABA) (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

AND

3 - Patient is not receiving Dupixent in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Dupixent [a]	
Diagnosis	Chronic Spontaneous Urticaria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic spontaneous urticaria

AND

2 - ONE of the following:

2.1 Patient remains symptomatic despite at least a 2-week trial of, or history of

contraindication or intolerance to, TWO H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]^

OR

2.2 Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to BOTH of the following taken in combination^:

2.2.1 A second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

AND

2.2.2 ONE of the following:

- A different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]
- A first generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]
- An H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]
- A leukotriene modifier [e.g., Singulair (montelukast)]

AND

3 - Patient is not receiving Dupixent in combination with Xolair (omalizumab) for treatment of the same indication

AND

4 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Dermatologist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may ap

	ply. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Dupixent [a]	
Diagnosis	Chronic Spontaneous Urticaria
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy (e.g., reduction in exacerbations, itch severity, hives)

AND

2 - Patient is not receiving Dupixent in combination with Xolair (omalizumab) for treatment of the same indication

AND

3 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Dermatologist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Dupixent [a]	
Diagnosis	Bullous Pemphigoid
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bullous pemphigoid

AND

2 - Prescribed by ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Dupixent [a]	
Diagnosis	Bullous Pemphigoid
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy

AND

2 - Prescribed by ONE of the following:

- Dermatologist

• Allergist • Immunologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Clinical Practice Guidelines

Table 1: Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1

	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Table 2: Low, medium and high daily doses of inhaled corticosteroids

Adults and adolescents (12 years of age and older)

Drug	Daily dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (CFC)	200-500	>500-1000	>1000

Beclometasone dipropionate (HFA)	100-200	>200-400	>400
Budesonide DPI	200-400	>400-800	>800
Ciclesonide (HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	n.a	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (HFA)	100-250	>250-500	>500
Mometasone furoate	110-220	>220-440	>440
Triamcinolone acetonide	400-1000	>1000-2000	>2000

Benefit/Coverage/Program Information

Background:

Dupixent® (dupilumab) is an interleukin-4 receptor alpha antagonist indicated for treatment of patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids. Dupixent is also indicated as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma, as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP), for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE), and for adult patients with prurigo nodularis (PN), as add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype, for the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment, and for the treatment of adult patients with bullous pemphigoid.

Limitation of Use:

Dupixent is not for the relief of acute bronchospasm or status asthmaticus and is not indicated for other forms of urticaria.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place.

4 . References

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5 . Revision History

Date	Notes
8/1/2025	Added criteria for the new indication for bullous pemphigoid. Updated background and reference.

Duvyzat

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436497
Guideline Name	Duvyzat
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	7/17/2024
P&T Revision Date:	07/16/2025 ; 11/21/2025

1 . Indications

Drug Name: Duvyzat (givinostat) oral suspension
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.

2 . Criteria

Product Name:Duvyzat [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Diagnosis confirmed by the presence of a mutation in the DMD gene

AND

3 - Patient is 6 years of age or older

AND

4 - Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

5 - Patient has been or will be established on a stable corticosteroid regimen

AND

6 - Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the treatment of DMD

AND

7 - ONE of the following:

7.1 Patient has not received gene therapy [e.g., Elevidys (delandistrogene moxeparvovec-rokl)] for the treatment of DMD

OR

7.2 BOTH of the following:

- Patient has previously received gene therapy [e.g., Elevidys (delandistrogene moxparvovec-rokl)] for the treatment of DMD
- Submission of medical records (e.g., chart notes, laboratory values) documenting a clinically meaningful functional decline resulting from loss of muscle strength/motor ability (e.g., loss of a motor milestone) since receiving gene replacement therapy [e.g., Elevidys (delandistrogene moxparvovec-rokl)]

AND

8 - Patient will not receive Duvyzat in combination with exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Duvyzat [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Physician attestation that patient would benefit from continued administration.

AND

2 - Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory

WITHOUT needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) **AND** **3** - Patient continues to receive concomitant corticosteroid regimen **AND** **4** - Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the treatment of DMD **AND** **5** - Patient will not receive Duvyzat in combination with exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Duvyzat (givinostat) is a histone deacetylase inhibitor indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place

4 . References

1. Duvyzat [package insert]. Concord, MA: ITF Therapeutics, LLC; November 2024.
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5 . Revision History

Date	Notes
11/3/2025	Added criterion for initial authorization addressing previous treatment with gene therapy for DMD. Removed criterion from reauthorization addressing previous treatment with gene therapy for DMD.

Ebglyss

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-555208
Guideline Name	Ebglyss
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	3/19/2025
P&T Revision Date:	10/15/2025 ; 3/18/2026

1 . Indications

Drug Name: Ebglyss (lebrikizumab-lbkz)
Moderate-to-severe chronic atopic dermatitis Indicated for the treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

2 . Criteria

Product Name:Ebglyss [a]	
Diagnosis	Atopic Dermatitis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderate-to-severe chronic atopic dermatitis

AND

2 - ONE of the following:

2.1 History of inadequate response, contraindication or intolerance to BOTH of the following therapeutic classes of topical therapies (document drug, date of trial, and/or contraindication to medication)^:

- One medium, high or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]

OR

2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of atopic dermatitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Opzelura (ruxolitinib), Rinvoq (upadacitinib)].

AND

3 - ONE of the following:

- History of failure, contraindication, or intolerance to Dupixent (dupilumab) (document date and duration of trial)
- Patient is currently on Ebglyss therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

AND

4 - Patient is NOT receiving Ebglyss in combination with either of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupxient (dupilumab)]
- Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]

AND

5 - Prescribed by, or in consultation with, ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Ebglyss [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Ebglyss therapy

AND

2 - Patient is NOT receiving Ebglyss in combination with either of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupxient (dupilumab)]
- Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Clinical Practice Guidelines

Table 1: Relative potencies of topical corticosteroids [3]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05

	tridifloronide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Table 2: Low, medium and high daily doses of inhaled corticosteroids [6]

Adults and adolescents (12 years of age and older)			
Drug	Daily dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (CFC)	200-500	>500-1000	>1000
Beclometasone dipropionate (HFA)	100-200	>200-400	>400
Budesonide DPI	200-400	>400-800	>800
Ciclesonide (HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	N/A	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (HFA)	100-250	>250-500	>500
Mometasone furoate	110-220	>220-440	>440
Triamcinolone acetonide	400-1000	>1000-2000	>2000

Benefit/Coverage/Program Information
Background: Ebglyss (lebrikizumab-lbkz) is an interleukin-13 antagonist indicated for the treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Ebglyss can be used with or without topical corticosteroids. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limitations may be in place

4 . References

1. Ebglyss [package insert]. Indianapolis, IN: Eli Lilly and Company; October 2025.
2. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014; 70(1):338-51.
3. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
4. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.

5 . Revision History

Date	Notes
3/18/2026	Annual review with no changes to clinical criteria. Updated reference s.

Egrifta

Prior Authorization Guideline

Guideline ID	GL-405339
Guideline Name	Egrifta
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	02/17/2023 ; 02/20/2025 ; 10/15/2025

1 . Indications

Drug Name: Egrifta (tesamorelin)
Reduction of excess abdominal fat in HIV-infected patients with lipodystrophy Indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

2 . Criteria

Product Name:Egrifta [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of HIV-associated lipodystrophy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Egrifta [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response (e.g., improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance) while on Egrifta SV therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Additional Clinical Programs: • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

Background

Egrifta (tesamorelin) is a growth hormone releasing factor (GHRF) analog indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Limitations of Use:

- Long-term cardiovascular safety of Egrifta has not been established.
- Not indicated for weight loss management.
- There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta SV.

4 . References

1. Egrifta SV [prescribing information]. Montreal, Quebec, Canada. Theratechnologies, Inc. February 2024.
2. Egrifta WR [prescribing information]. Montreal, Quebec, Canada: Theratechnologies, Inc.; March 2025.

5 . Revision History

Date	Notes
9/29/2025	Added Egrifta WR to program. Updated references.

Ekterly

Prior Authorization Guideline

Guideline ID	GL-436499
Guideline Name	Ekterly
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/22/2025
P&T Revision Date:	11/21/2025

1 . Indications

Drug Name: Ekterly (sebetralstat)
Hereditary angioedema (HAE) Indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older.

2 . Criteria

Product Name:Ekterly [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - BOTH of the following:

- Prescribed for the acute treatment of HAE attacks
- Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr, icatibant, Kalbitor, Ruconest, Sajazir)

AND

3 - ONE of the following:

3.1 Patient is less than 18 years of age

OR

3.2 BOTH of the following:

- Patient is 18 years of age or older
- Submission of medical records documenting a history of failure, contraindication, or intolerance to icatibant (generic Firazyr)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ekterly [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Ekterly therapy

AND

2 - BOTH of the following:

- Prescribed for the acute treatment of HAE attacks

• Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr, icatibant, Kalbitor, Ruconest, Sajazir) **AND** **3** - Prescribed by ONE of the following: • Immunologist • Allergist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Ekterly® (sebetralstat) is a plasma kallikrein inhibitor indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Ekterly [package insert]. Cambridge, MA: KalVista Pharmaceuticals, Inc; July 2025.
2. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018 Jan 10.
3. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2025.

4. Busse, P., Christiansen, S., Riedl, M., et. al. “US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema.” The Journal of Allergy and Clinical Immunology. 2020 September 05.
5. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2021 revision and update. Allergy. 2022;77(7):1961-1990. doi:10.1111/all.15214

5 . Revision History

Date	Notes
11/3/2025	Added criteria requiring trial, failure, or contraindication to other HAE products based on age.

Emflaza, Jaythari, Kymbee, Pyquvi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-500235
Guideline Name	Emflaza, Jaythari, Kymbee, Pyquvi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	11/21/2025
P&T Revision Date:	1/21/2026

1 . Indications

Drug Name: Emflaza (deflazacort)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.
Drug Name: Jaythari (deflazacort), Kymbee (deflazacort), Pyquvi (deflazacort)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older

2 . Criteria

Product Name:Brand Emflaza, generic deflazacort, generic jaythari, generic Kymbee, generic pyquvi [a]	
Diagnosis	Duchenne Muscular Dystrophy
Guideline Type	Prior Authorization
Approval Criteria **1** - Published clinical evidence shows Emflaza, Jaythari, Kymbee, and Pyquvi is likely to produce equivalent therapeutic results as other available corticosteroids (e.g., prednisone); therefore, these products are NOT MEDICALLY NECESSARY for treatment of Duchenne muscular dystrophy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background Emflaza (deflazacort) is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older. [1] Jaythari (deflazacort), Kymbee (deflazacort), and Pyquvi (deflazacort) are indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older. [2-4] The UnitedHealthcare Pharmacy and Therapeutics Committee has determined that deflazacort is Therapeutically Equivalent to prednisone in the treatment of DMD. While adverse effect profiles may differ among glucocorticoids, deflazacort does not offer a clear advantage over other glucocorticoids for DMD with respect to efficacy and overall safety. [5-8] **Additional Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Emflaza [package insert]. Warren, NJ: PTC Therapeutics Inc.; May 2024.
2. Jaythari [package insert]. Pennington, NJ: Zydus Pharmaceuticals, Inc.; October 2024.
3. Kymbee [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC.; July 2025.
4. Pyquvi [package insert]. Piscataway, NJ: Aucta Pharmaceuticals, Inc.; February 2025.
5. Griggs RC, Miller JP, Greenberg CR, et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. Neurology. 2016;87(20):2123-2131.
6. Guglieri M, Bushby K, McDermott MP, et al. Effect of Different Corticosteroid Dosing Regimens on Clinical Outcomes in Boys With Duchenne Muscular Dystrophy: A Randomized Clinical Trial. JAMA. 2022;327(15):1456-1468.
7. Biggar WD, Skalsky A, McDonald CM. Comparing Deflazacort and Prednisone in Duchenne Muscular Dystrophy. J Neuromuscul Dis. 2022;9(4):463-476.
8. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. Lancet Neurol. 2018;17(3):251-267.

5 . Revision History

Date	Notes
1/20/2026	Added Kymbee to policy.

Empaveli

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436544
Guideline Name	Empaveli
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	
P&T Revision Date:	

1 . Indications

Drug Name: Empaveli (pegcetacoplan)
Proxysmal nocturnal hemoglobinuria (PNH) Indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). **C3 glomerulopathy or primary immune-complex membranoproliferative glomerulonephritis** Indicated for the treatment of adult and pediatric patients aged 12 years and older with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria.

2 . Criteria

Product Name:Empaveli [a]	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by BOTH of the following:

- Flow cytometry analysis confirming presence of PNH clones
- Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - ONE of the following:

- Patient will not be prescribed Empaveli in combination with another complement inhibitor used for the treatment of PNH (e.g., Bkemv, Epysqli, Fabhalta, PiaSky, Soliris, Ultomiris)
- Patient is currently receiving another complement inhibitor (e.g., Bkemv, Epysqli, Fabhalta, PiaSky, Soliris, Ultomiris) which will be discontinued and Empaveli will be initiated in accordance with the United States Food and Drug Administration approved labeling

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Empaveli [a]	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Empaveli therapy (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc.)

AND

2 - Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of PNH (e.g., Bkemv, Epysqli, Fabhalta, PiaSky, Soliris, Ultomiris)

AND

3 - Prescribed by, or in consultation with, one of the following:

- Hematologist
- Oncologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Empaveli [a]	
Diagnosis	C3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of immune complex/monoclonal immunoglobulin-mediated Membranoproliferative glomerulonephritis (IC-MPGN)

AND

1.1.2 Confirmation of diagnosis is based on immunofluorescence microscopy on kidney biopsy

AND

1.1.3 ALL of the following secondary causes of IC-MPGN have been ruled out:

- Infections (e.g., Hepatitis B and hepatitis C virus, chronic bacterial infections, parasitic infections)
- Autoimmune diseases [e.g., systemic lupus erythematosus (SLE), Sjogren's syndrome, rheumatoid arthritis, systemic sclerosis]
- Monoclonal gammopathy

AND

1.1.4 Patient has not had a kidney transplant

OR

1.2 ALL of the following:

1.2.1 Diagnosis of complement 3 glomerulopathy (C3G)

AND

1.2.2 Confirmation of diagnosis is based on immunofluorescence microscopy on kidney biopsy

AND

1.2.3 ONE of the following:

- Serum complement 3 (C3) protein < 77 mg/dL (alternatively, less than 0.85 x lower limit of the central laboratory normal range)
- Other complement abnormalities are present [e.g., soluble membrane attack complex (sC5b-9), serum factor H, serum factor B, factor I, membrane cofactor protein (MCP, CD46), C3/C4/C5 nephritic factor (NeF)] which are suggestive of a C3 glomerulopathy

AND

1.2.4 Presence of monoclonal gammopathy of undetermined significance (MGUS) has been excluded by measurement of serum free light chains or other investigative means based on standards of care

AND

2 - Glomerulonephritis has persisted ≥ 3 months in duration

AND

3 - Disease is considered to be moderate to severe based on proteinuria ≥ 1.5 g/day and/or abnormal kidney function

AND

4 - Used to reduce proteinuria

AND

5 - History of failure, contraindication or intolerance to a glucocorticoid (e.g., methylprednisolone, prednisone)

AND

6 - ONE of the following:

6.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

6.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs

AND

7 - Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of C3G or IC-MPGN (e.g., Bkemv, Epysqli, Fabhalta, PiaSky, Soliris, Ultomiris)

AND

8 - Prescribed by or in consultation with a nephrologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Empaveli [a]

Diagnosis	C3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Empaveli therapy demonstrated by a reduction in proteinuria

AND

2 - Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of C3G or IC-MPGN (e.g., Bkemv, Epysqli, Fabhalta, PiaSky, Soliris, Ultomiris)

AND

3 - Prescribed by or in consultation with a nephrologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Empaveli (pegcetacoplan) is a complement inhibitor indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH) and for the treatment of adult and pediatric patients aged 12 years and older with C3 glomerulopathy (C3G) or primary

immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.

4 . References

1. Empaveli [package insert], Waltham, MA: Apellis Pharmaceuticals, Inc.; September 2023.
2. Parker C, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood. 2005 Dec 1; 106(12): 3699–3709.
3. Devalet B, Mullier F, Chatelain B, et al. Pathophysiology, diagnosis, and treatment of paroxysmal nocturnal hemoglobinuria: a review. Eur J Haematol. 2015 Sep;95(3):190-8.
4. Sutherland DR, Keeney M, Illingworth A. Practical guidelines for the high-sensitivity detection and monitoring of paroxysmal nocturnal hemoglobinuria clones by flow cytometry. Cytometry B Clin Cytom. 2012 Jul;82(4):195-208.
5. Röth A, Maciejewski J, Nishimura JI, et al. Screening and diagnostic clinical algorithm for paroxysmal nocturnal hemoglobinuria: Expert consensus. Eur J Haematol. 2018 Jul;101(1):3-11.
6. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021;100(4S):S1-S276. doi:10.1016/j.kint.2021.05.021
7. Fervenza, FC. Membranoproliferative glomerulonephritis: classification, clinical features, and diagnosis. In: UpToDate, Lam A (Ed), UpToDate, Waltham, MA, 2025.
8. Kopel, T. C3 glomerulopathies: Dense deposit disease and C3 glomerulonephritis. In: UpToDate, Lam, A (Ed), UpToDate, Waltham, MA, 2025.

5 . Revision History

Date	Notes
11/5/2025	Updated GPI

Emsam

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399274
Guideline Name	Emsam
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	9/25/2025
P&T Revision Date:	

1 . Indications

Drug Name: Emsam (selegiline)
Major Depressive Disorder (MDD) Indicated for the treatment of major depressive disorder (MDD).

2 . Criteria

Product Name:Emsam [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of major depressive disorder (MDD), according to the current DSM (i.e., DSM-5-TR) criteria

AND

2 - ONE of the following:

2.1 History of failure after at least 4 weeks of therapy, contraindication, or intolerance to at least THREE of any formulation of the following (document drug and date of trials):

- Bupropion
- Citalopram
- Desvenlafaxine
- Duloxetine
- Escitalopram
- Fetzima
- Fluoxetine
- Marplan
- Mirtazapine
- Paroxetine
- Phenelzine
- Sertraline
- Tranylcypromine
- Venlafaxine
- Vilazodone

OR

2.2 The requested medication was initiated during a recent inpatient mental health hospitalization, and the member is stabilized on the requested medication

OR

2.3 Member is new to the plan and currently stabilized on the requested medication (as evidenced by coverage effective date of less than or equal to 120 days)

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Emsam [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy.	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Emsam (selegiline transdermal system) is a monoamine oxidase inhibitor (MAOI) indicated for the treatment of major depressive disorder (MDD). **Additional Clinical Rules:** • Supply limits may be in place. • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Emsam [package insert]. Morgantown, WV. Somerset Pharmaceuticals, Inc.; May 2020.

5 . Revision History

Date	Notes
9/19/2025	New program

Enbumyst, Furoscix, Lasix ONYU

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-516227
Guideline Name	Enbumyst, Furoscix, Lasix ONYU
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	3/15/2023
P&T Revision Date:	03/20/2024 ; 10/16/2024 ; 05/16/2025 ; 2/20/2026

1 . Indications

Drug Name: Furoscix (furosemide injection)
Edema Indicated for the treatment of edema in pediatric patients weighing 43 kg and above and in adult patients with chronic heart failure or chronic kidney disease, including the nephrotic syndrome.
Drug Name: Enbumyst (bumetanide nasal spray)
Edema Indicated for the treatment of edema associated with congestive heart failure, hepatic and renal disease, including the nephrotic syndrome in adults.
Drug Name: Lasix ONYU (furosemide injection)
Edema Indicated for the treatment of edema in adult patients with chronic heart failure.

2 . Criteria

Product Name:Enbumyst, Furoscix, Lasix ONYU [a]	
Approval Length	1 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Edema associated with ONE of the following:

- Congestive heart failure
- Renal disease, including nephrotic syndrome
- Hepatic disease

AND

2 - Submission of medical records confirming that the patient is established on background loop diuretic therapy (e.g., bumetanide, furosemide, torsemide) for the treatment of edema

AND

3 - BOTH of the following:

- Patient does not require ongoing emergency care or hospitalization
- Patient is currently a candidate for parenteral or nasal diuresis outside of the hospital

AND

4 - Prescribed by or in consultation with ONE of the following:

- Cardiologist
- Nephrologist
- Hepatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Enbumyst (bumetanide nasal spray), Furoscix (furosemide injection) and Lasix ONYU (furosemide injection) are loop diuretics. Enbumyst is indicated for the treatment of edema associated with congestive heart failure, hepatic and renal disease, including the nephrotic syndrome in adults. Furoscix (furosemide injection) is indicated for the treatment of edema in pediatric patients weighing 43 kg and above and in adult patients with chronic heart failure or chronic kidney disease, including the nephrotic syndrome. Lasix ONYU (furosemide injection) is indicated for the treatment of edema in adult patients with chronic heart failure. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Furoscix [package insert]. Burlington, MA: scPharmaceuticals, Inc.; March 2025.
2. Heidenreich PA, Bozkurt, B, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145(18):e895-e1032.
3. Enbumyst [package insert]. Henderson, NV: Corstasis USA LLC; November 2025.
4. Lasix ONYU [package insert]. Burlington, MA: SQ Innovation, Inc.; October 2025.

5 . Revision History

Date	Notes
2/10/2026	Added Enbumyst and Lasix ONYU to criteria.

Entresto

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436509
Guideline Name	Entresto
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 04/21/2021 ; 08/19/2022 ; 10/19/2022 ; 11/17/2023 ; 08/16/2024 ; 11/21/2025

1 . Indications

Drug Name: Entresto (valsartan-sacubitril)
Heart Failure Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal. It is also indicated for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

2 . Criteria

Product Name:Brand Entresto, generic sacubitril/valsartan [a]	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - As continuation of therapy initiated during an inpatient stay

OR

2 - ALL of the following:

- Diagnosis of pediatric heart failure with systemic left ventricular systolic dysfunction which is symptomatic
- Prescribed by or in consultation with a cardiologist
- If the request is for Entresto Sprinkles, the prescriber has given a clinical reason or special circumstance why the patient is unable to use regular Entresto tablets

OR

3 - ALL of the following:

3.1 Diagnosis of heart failure (with or without hypertension)

AND

3.2 ONE of the following:

3.2.1 Ejection fraction is less than or equal to 40 percent

OR

3.2.2 BOTH of the following:

- Ejection fraction greater than 40 percent
- Patient has structural heart disease (i.e. left atrial enlargement (LAE) or left ventricular hypertrophy (LVH)

AND

3.3 Heart failure is classified as ONE of the following:

- New York Heart Association Class II
- New York Heart Association Class III
- New York Heart Association Class IV

AND

3.4 Patient does not have a history of angioedema

AND

3.5 Patient will discontinue any use of concomitant ACE Inhibitor or ARB before initiating treatment with Entresto. ACE inhibitors must be discontinued at least 36 hours prior to initiation of Entresto

AND

3.6 Patient is not concomitantly on aliskiren therapy

AND

3.7 Entresto is prescribed by, or in consultation with, a cardiologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Entresto, generic sacubitril/valsartan [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The Entresto dose has been titrated to a dose of 97 mg/103 mg twice daily or the maximum labeled dose for pediatric patients, or to a maximum dose as tolerated by the patient

AND

2 - Documentation of positive clinical response to therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may be in place.

Background:

Entresto (valsartan-sacubitril) is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal. It is also indicated for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

4 . References

1. Entresto [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.
2. McMurray JJ, Desai AS, Gong J. Dual angiotensin receptor and neprilysin inhibition as an alternative to angiotensin-converting enzyme inhibition in patients with chronic systolic heart failure: rationale for and design of the prospective comparison of ARNI with ACEI to determine impact on global mortality and morbidity in heart failure trial (PARADIGM-HF). European Journal of Heart Failure 2013; 15: 1062-1073.
3. McMurray JJ, Packer M, Desai AS, et al. Angio-tensin-neprilysin inhibition versus enalapril in heart failure. N Engl J Med 2014;371:993-1004.
4. Heidenreich PA, Bozkurt, B, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiolgy/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145(18):e895-e1032.

5 . Revision History

Date	Notes
11/3/2025	Updated indications

Entyvio Pen

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-405341
Guideline Name	Entyvio Pen
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	10/15/2025
P&T Revision Date:	

Note:

*This program applies to the subcutaneous (SC) formulations of vedolizumab

1 . Indications

Drug Name: Entyvio® (vedolizumab)
Ulcerative colitis (UC) Indicated in adults for the treatment of moderately to severely active ulcerative colitis (UC) in adults. **Crohn's disease (CD)** Indicated in adults for the treatment of moderately to severely active Crohn's disease (CD) in adults.

2 . Criteria

Product Name:Entyvio [a]	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	All requests for authorization will be denied.
Guideline Type	Non Formulary
Approval Criteria **1** - Subcutaneous Entyvio provides similar efficacy as intravenous administration of Entyvio; therefore, subcutaneous Entyvio is not medically necessary for treatment of ulcerative colitis since its use is mainly for convenience as compared to intravenous administration of Entyvio.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Entyvio [a]	
Diagnosis	Crohn’s Disease (CD)
Approval Length	All requests for authorization will be denied.
Guideline Type	Non Formulary
Approval Criteria **1** - Subcutaneous Entyvio provides similar efficacy as intravenous administration of Entyvio; therefore, subcutaneous Entyvio is not medically necessary for treatment of Crohn’s Disease since its use is mainly for convenience as compared to intravenous administration of Entyvio.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Entyvio (vedolizumab) for subcutaneous use is an integrin receptor antagonist indicated in adults for the treatment of moderately to severely active ulcerative colitis (UC) and moderately to severely active Crohn's disease (CD) in adults. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits may be in place

4 . References

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; April 2024.

5 . Revision History

Date	Notes
9/29/2025	New program.

Eohilia

Prior Authorization Guideline

Guideline ID	GL-248189
Guideline Name	Eohilia
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	5/17/2024
P&T Revision Date:	5/16/2025

1 . Indications

Drug Name: Eohilia (budesonide oral suspension)
Eosinophilic esophagitis (EoE) Indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE).

2 . Criteria

Product Name:Eohilia [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of eosinophilic esophagitis (EoE)

AND

2 - Patient is experiencing symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, chest pain that is often centrally located and may not respond to antacids, gastroesophageal reflux disease-like symptoms/refractory heartburn, upper abdominal pain)

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting eosinophil-predominant inflammation on esophageal biopsy, consisting of a peak value of ≥15 intraepithelial eosinophils per high power field (HPF)

AND

4 - Secondary causes of esophageal eosinophilia have been ruled out

AND

5 - History of suboptimal response, contraindication or intolerance to an 8-week trial of BOTH of the following (document name and date tried):

- Proton pump inhibitor (e.g., pantoprazole, omeprazole)
- Inhalational corticosteroid administered orally [e.g., budesonide nebulized solution (Pulmicort respules), Fluticasone HFA (Flovent HFA authorized generic)]

AND

6 - Prescribed by or in consultation with ONE of the following:

- Allergist/Immunologist

• Gastroenterologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Eohilia [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to Eohilia therapy as evidenced by a reduction in intraepithelial eosinophils per high power field (HPF)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3 . References

1. Eohilia [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc; May 2024.
2. Hirano, I, Chan, ES, Rank MA, et. al. AGA Institute and the Joint Task Force on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esophagitis. Gastroenterology. 2020; 158: 1776-86.
3. Delton, ES, Gonsalves, N, Hirano, I, et al. ACG Clinical Guideline: Evidenced Based Approach to the Diagnosis and Management of Esophageal Eosinophilia and Eosinophilic Esophagitis (EoE). Am J Gastroenterol. 2013; 108: 679-92.

4 . Revision History

Date	Notes

4/29/2025	Annual review. Updated failure language to suboptimal response. Up dated authorization duration and added reauthorization criteria

Erleada



Prior Authorization Guideline

Guideline ID	GL-436510
Guideline Name	Erleada
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 11/19/2021 ; 08/19/2022 ; 11/18/2022 ; 11/18/2022 ; 11/17/2023 ; 11/22/2024 ; 11/21/2025

1 . Indications

Drug Name: Erleada (apalutamide)
Prostate cancer Indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer. It is also indicated for the treatment of metastatic castration-sensitive prostate cancer.

2 . Criteria

Product Name:Erleada [a]	
Diagnosis	Prostate Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - One of the following:

2.1 Both of the following:

- Disease is castration-resistant or recurrent
- Disease is non-metastatic

OR

2.2 Both of the following:

- Disease is castration-sensitive or naive
- Disease is metastatic

AND

3 - One of the following:

3.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

3.2 Patient has had bilateral orchiectomy

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Erleada [a]	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Erleada therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Erleada [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Erleada will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Erleada [a]	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Erleada therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Erleada (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer. It is also indicated for the treatment of metastatic castration-sensitive prostate cancer. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently while taking Erleada or should have had bilateral orchiectomy. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Erleada [package insert]. Horsham, PA: Janssen Products LP. August 2024.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at NCCN Drugs and Biologics Compendium. Accessed September 26, 2025.

5 . Revision History

Date	Notes
11/3/2025	Annual review with no change to coverage criteria. Updated referenc es.

Evrysdi

Prior Authorization Guideline

Guideline ID	GL-232223
Guideline Name	Evrysdi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	6/1/2025
P&T Approval Date:	7/20/2022
P&T Revision Date:	08/19/2022 ; 08/18/2023 ; 07/17/2024 ; 12/18/2024 ; 4/16/2025

1 . Indications

Drug Name: Evrysdi (risdiplam)
Spinal muscular atrophy (SMA) Indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

2 . Criteria

Product Name:Evrysdi [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in ONE of the following:

- Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)
- Compound heterozygous mutation of SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

3 - Patient is not dependent on either of the following:

- Invasive ventilation
- Use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

4 - Patient is not receiving concomitant chronic survival motor neuron (SMN) modifying therapy [e.g., Spinraza (nusinersen)]

AND

5 - ONE of the following:

5.1 Patient has not previously received gene replacement therapy for the treatment of SMA [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

OR

5.2 BOTH of the following:

5.2.1 Patient has previously received gene replacement therapy [e.g., Zolgensma (onasemnogene abeparvovec-xioi)] for the treatment of SMA

AND

5.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting a clinically meaningful functional decline (e.g., loss of motor milestone) since receiving gene replacement therapy [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

AND

6 - Submission of medical records (e.g., chart notes, laboratory values) documenting the baseline assessment of at least ONE of the following exams (based on patient age and motor ability) to establish baseline motor ability (baseline motor function analysis could include assessments evaluated prior to receipt of previous chronic SMN modifying therapy if transitioning therapy)*:

- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Hammersmith Infant Neurological Exam Part 2 (HINE-2)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Revised Upper Limb Module (RULM) Test
- Motor Function Measure 32 (MFM-32) Scale

AND

7 - Prescribed by or in consultation with a neurologist with expertise in the treatment of SMA

Notes	* Baseline assessments for patients less than 2 months of age requesting Evrysdi are not necessary in order to not delay access to initial therapy in recently diagnosed infants. Initial assessments shortly post-therapy can serve as baseline with respect to efficacy reauthorization assessment. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Evrysdi [a]

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) with the most recent results documenting a positive clinical response to Evrysdi compared to pretreatment baseline status (inclusive of baseline assessments prior to receipt of previous chronic SMN modifying therapy) as demonstrated by at least one of the following exams:

1.1 CHOP INTEND: ONE of the following:

- Improvement or maintenance of previous improvement of at least a 4 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.2 HINE-2: ONE of the following:

- Improvement or maintenance of previous improvement of at least 2 point (or maximal score) increase in ability to kick
- Improvement or maintenance of previous improvement of at least 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp
- The patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
- Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so

OR

1.3 HFMSE: ONE of the following

- Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline

- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.4 RULM: ONE of the following:

- Improvement or maintenance of previous improvement of at least a 2 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.5 MFM-32: ONE of the following:

- Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

AND

2 - Patient is not dependent on either of the following:

- Invasive ventilation
- Use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

3 - Patient is not receiving concomitant chronic survival motor neuron (SMN) modifying therapy [e.g., Spinraza (nusinersen)]

AND

4 - Prescribed by or in consultation with a neurologist with expertise in the treatment of SMA

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Evrysdi is a survival of motor neuron 2 (SMN2) splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Evrysdi [package insert]. South San Francisco, CA: Genentech, Inc; September 2024.
2. Mercuri E, Darras BT, Chiriboga CA, et al. Nusinersen versus Sham Control in Later-Onset Spinal Muscular Atrophy. N Engl J Med. 2018 Feb 15;378(7):625-635.
3. Finkel RS, Mercuri E, Darras BT, et al. Nusinersen versus Sham Control in Infantile-Onset Spinal Muscular Atrophy. N Engl J Med. 2017 Nov 2;377(18):1723-1732.
4. Markowitz JA, Singh P, Darras BT. Spinal Muscular Atrophy: A Clinical and Research Update. Pediatric Neurology 46 (2012) 1-12.
5. Mendell JR, Al-Zaidy S, Shell R, et al. Single-dose gene-replacement therapy for spinal muscular atrophy. N Engl J Med. 2017;377:1713-22
6. Chiriboga C, Mercuri E, Fischer D, et al. JEWELFISH: Risdiplam (RG7916) increased survival of motor neuron (SMN) protein levels in non-naïve patients with spinal muscular atrophy (SMA). Presented at the 6th International Congress of Myology in Bordeux, France; March 25-28, 2019. Poster.
7. Chiriboga C, Bruno C, Duong T, et al. JEWELFISH: Safety and pharmacodynamic data in non-naïve patients with spinal muscular atrophy receiving treatment with risdiplam. Presented at the 2020 Virtual SMA Research & Clinical Care Meeting. June 12, 2020.
8. Day JW, Annoussamy M, Baranello G, et al. SUNFISH Part 1: 24-month safety and exploratory outcomes of risdiplam (RG7916) treatment in patients with Type 2 or 3 spinal muscular atrophy (SMA). Presented at the 2020 Virtual SMA Research & Clinical Care Meeting. June 12, 2020.

9. Servais L, Baranello G, Masson R, et al. FIREFISH Part 2: Efficacy and safety of risdiplam (RG7916) in infants with Type 1 spinal muscular atrophy (SMA). Presented at the 2020 Virtual SMA Research & Clinical Care Meeting. June 12, 2020.
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5 . Revision History

Date	Notes
4/1/2025	Revised criteria for patients that have documented decline from pretr eatment baseline status following administration of gene replacement therapy.

Fabhalta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-248190
Guideline Name	Fabhalta
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	2/16/2024
P&T Revision Date:	04/17/2024 ; 10/16/2024 ; 5/16/2025

1 . Indications

Drug Name: Fabhalta (iptacopan)
Paroxysmal Nocturnal Hemoglobinuria Indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH) **Primary immunoglobulin A nephropathy (IgAN)** Indicated for the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

2 . Criteria

Product Name:Fabhalta [a]

Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by BOTH of the following [2,3,4,5]:

- Flow cytometry analysis confirming presence of PNH clones
- Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - ONE of the following:

2.1 Patient will not be prescribed Fabhalta in combination with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, PiaSky, eculizumab, Ultomiris)

OR

2.2 Patient is currently receiving another complement inhibitor (e.g., Empaveli, PiaSky, eculizumab, Ultomiris) which will be discontinued and Fabhalta will be initiated in accordance with the United States Food and Drug Administration approved labeling

AND

3 - Prescribed by, or in consultation with one of the following:

- Hematologist
- Oncologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Fabhalta [a]	
Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Fabhalta therapy (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc.)

AND

2 - Patient is not receiving Fabhalta in combination with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, PiaSky, eculizumab, Ultomiris)

AND

3 - Prescribed by, or in consultation with one of the following:

- Hematologist
- Oncologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Fabhalta [a]	
Diagnosis	Primary immunoglobulin A nephropathy (IgAN)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]

AND

3 - Used to reduce proteinuria

AND

4 - Estimated glomerular filtration rate (eGFR) is greater than or equal to 30 mL/min/1.73 m2

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

5.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs

AND

6 - ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin)]
- Patient has an allergy, contraindication, or intolerance to SGLT2 inhibitors

AND

7 - History of failure, contraindication or intolerance to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone)

AND

8 - Prescribed by or in consultation with a nephrologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Fabhalta [a]	
Diagnosis	Primary immunoglobulin A nephropathy (IgAN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Fabhalta therapy demonstrated by a reduction in proteinuria

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Fabhalta [a]	
Diagnosis	Complement 3 glomerulopathy (C3G)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of complement 3 glomerulopathy (C3G) confirmed by ALL of the following:

1.1 Documentation of a kidney biopsy demonstrating characteristic findings of C3G

AND

1.2 Glomerulonephritis has persisted ≥ 3 months in duration

AND

1.3 ONE of the following:

- Serum complement 3 (C3) protein < 77 mg/dL (alternatively, less than 0.85 x lower limit of the central laboratory normal range)
- Other complement abnormalities are present [e.g., soluble membrane attack complex (sC5b-9), serum factor H, serum factor B, factor I, membrane cofactor protein (MCP, CD46), C3/C4/C5 nephritic factor (NeF)] which are suggestive of a C3 glomerulopathy

AND

1.4 Presence of monoclonal gammopathy of undetermined significance (MGUS) has been excluded by measurement of serum free light chains or other investigative means based on standards of care

AND

2 - Disease is considered to be moderate to severe based on proteinuria ≥ 1.5 g/day and/or abnormal kidney function

AND

3 - Used to reduce proteinuria

AND

4 - History of failure, contraindication or intolerance to a glucocorticoid (e.g., methylprednisolone, prednisone)

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

5.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs

AND

6 - Patient has not undergone a solid-organ or cell transplant, including kidney transplant

AND **7** - Prescribed by or in consultation with a nephrologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Fabhalta [a]	
Diagnosis	Complement 3 glomerulopathy (C3G)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to Fabhalta therapy demonstrated by a reduction in proteinuria	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Fabhalta (iptacopan) is a complement factor B inhibitor, indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH) the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g; and for the treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria. [1]

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place

4 . References

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5 . Revision History

Date	Notes
4/29/2025	Added new indication and criteria for C3 glomerulopathy (C3G). Repl aced Soliris with eculizumab in list of examples of complement inhibit ors. Updated background and references.

Fasenra

Prior Authorization Guideline

Guideline ID	GL-424217
Guideline Name	Fasenra
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	7/21/2021
P&T Revision Date:	11/19/2021 ; 12/15/2021 ; 02/18/2022 ; 02/17/2023 ; 07/19/2023 ; 07/17/2024 ; 07/16/2025 ; 10/15/2025

Note:

This program applies to the prefilled autoinjector formulation.

1 . Indications

Drug Name: Fasenra (benralizumab) prefilled auto-injector
Severe Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. **Eosinophilic granulomatosis with polyangiitis (EGPA)** Indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

2 . Criteria

Product Name:Fasenra (benralizumab) [a]	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - ALL of the following:

1.1 Patient has been established on therapy with Fasenra under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

AND

1.2 Documentation of positive clinical response to Fasenra therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

1.3 Fasenra is being used in combination with an inhaled corticosteroin (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

1.4 Patient is not receiving Fasenra in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

1.5 Prescribed by ONE of the following:

- Pulmonologist
- Allergist
- Immunologist

OR

2 - ALL of the following:

2.1 Diagnosis of severe asthma

AND

2.2 Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:

- Poor symptom control ((e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
- Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
- Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
- Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
- Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

2.3 Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level ≥ 150 cells/µL

AND

2.4 Fasenra will be used in combination with ONE of the following:

2.4.1 ONE maximally dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

2.4.2 Combination therapy including BOTH of the following:

- ONE maximally dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]
- ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

2.5 History of failure, contraindication, or intolerance to BOTH of the following products (document date and duration of trial):

- Dupixent (dupilumab)
- Xolair (omalizumab)

AND

2.5 Patient is not receiving Fasenra in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

2.7 Prescribed by ONE of the following:

- Pulmonologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Fasenra (benralizumab) [a]	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Fasenra therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Fasenra is being used in combination with an ICS-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol),

Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

3 - Patient is not receiving Fasenra in combination with ANY of the following for treatment of the same indication::

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Fasenra (benralizumab) [a]	
Diagnosis	Eosinophilic granulomatosis with polyangiitis (EGPA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - ALL of the following:

1.1 Patient has been established on therapy with Fasenra under an active UnitedHealthcare medical benefit prior authorization for the treatment of EGPA

AND

1.2 Documentation of positive clinical response to Fasenra therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency and/or severity of relapses
- Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant

- Disease remission
- Reduction in severity or frequency of EGPA-related symptoms

AND

1.3 Patient is not receiving Fasenra in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

1.4 Prescribed by ONE of the following:

- Pulmonologist
- Rheumatologist
- Allergist
- Immunologist

OR

2 - ALL of the following:

2.1 Diagnosis of relapsing or refractory EGPA as defined by ALL of the following:

2.1.1 Diagnosis of EGPA

AND

2.1.2 Past medical history or presence of asthma

AND

2.1.3 Presence of at least TWO of the following characteristics typical of EGPA:

- Histopathological evidence of: Eosinophilic vasculitis, Perivascular eosinophilic infiltration, Eosinophil-rich granulomatous inflammation
- Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
- Pulmonary infiltrates, non-fixed
- Sino-nasal abnormality
- Cardiomyopathy (established by echocardiography or MRI)
- Glomerulonephritis (hematuria, red cell casts, proteinuria)
- Alveolar hemorrhage
- Palpable purpura
- Anti-neutrophil cytoplasmic antibody (ANCA) positive

AND

2.2 History of relapsing or refractory disease defined as ONE of the following:

- Relapsing disease as defined as a past history (within the past 2 years) of at least one EGPA relapse (requiring additional or dose escalation of corticosteroids or immunosuppressant, or hospitalization)
- Refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens

AND

2.3 Patient is currently taking standard therapy [i.e., systemic glucocorticoids (e.g., prednisone, methylprednisolone) with or without immunosuppressive therapy (e.g., cyclophosphamide, rituximab)]

AND

2.4 Patient is not receiving Fasenra in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

2.5 Prescribed by ONE of the following:

- Pulmonologist
- Rheumatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Fasenra (benralizumab) [a]	
Diagnosis	Eosinophilic granulomatosis with polyangiitis (EGPA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Fasenra therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency and/or severity of relapses
- Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant
- Disease remission
- Reduction in severity or frequency of EGPA-related symptoms

AND

2 - Patient is not receiving Fasenra in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Fasenra (benralizumab) is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody indicated for the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype; and for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). Fasenra is not used for treatment of other eosinophilic conditions or for relief of acute bronchospasm or status asthmaticus. [1] **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place. • The prefilled syringe is typically covered under the medical benefit. Please refer to the United Healthcare Medical Benefit Drug Policy: “Respiratory Interleukins (Cinqair®, Fasenra®, and Nucala®)”.

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5 . Revision History

Date	Notes
10/17/2025	Added step through both Dupixent and Xolair for Severe Asthma.

Fentanyl Transmucosal

Prior Authorization Guideline

Guideline ID	GL-399218
Guideline Name	Fentanyl Transmucosal
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 02/18/2022 ; 04/19/2023 ; 04/17/2024 ; 05/16/2025 ; 9/25/2025

1 . Indications

Drug Name: Fentanyl citrate lozenge, Fentora (fentanyl buccal tablet), fentanyl buccal tablet (authorized generic of Fentora)
Breakthrough cancer pain Indicated for the management of breakthrough cancer pain in patients who are already receiving and have developed tolerance to around-the-clock opioid therapy for their underlying persistent cancer pain.

2 . Criteria

Product Name:Fentanyl citrate lozenge, Brand Fentora, fentanyl buccal tablet (AG of Fentora) [a]

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records demonstrating ALL of the following:

1.1 Use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented in the medical record).

AND

1.2 Patient must have at least a ONE week history of ONE of the following medications to demonstrate tolerance to opioids:

- Morphine sulfate at a dose of greater than or equal to 60 mg/day
- Fentanyl transdermal patch at a dose of greater than or equal to 25 mcg/hr
- Oral oxycodone at a dose of greater than or equal to 30 mg/day
- Oral hydromorphone at a dose of greater than or equal to 8 mg/day
- Oral oxymorphone at a dose of greater than or equal to 25 mg/day
- Oral hydrocodone at a dose of greater than or equal to 60 mg/day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

1.3 The patient is currently taking a long-acting opioid around the clock for cancer pain.

AND

1.4 ONE of the following:

- The patient is not concurrently receiving an alternative transmucosal fentanyl product.
- The patient is currently receiving an alternative transmucosal fentanyl product AND the prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication. Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied.

OR **2** - The patient is currently taking fentanyl citrate lozenge, Fentora, or fentanyl buccal tablet (AG of Fentora) and does not meet the prior authorization criteria requirements based on the FDA-approved indication for breakthrough cancer pain (a one-time fill may be approved for transition to an alternative treatment).	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Fentanyl citrate lozenge, Fentora, and fentanyl buccal tablet (authorized generic of Fentora) are rapid-acting opioid analgesics indicated for the management of breakthrough cancer pain in patients who are already receiving and have developed tolerance to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine daily, at least 25 mcg/hour of transdermal fentanyl, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg of oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer. Patients must remain on around-the-clock opioids while taking a rapid-acting fentanyl product. Fentanyl citrate lozenge, Fentora, and fentanyl buccal tablet (generic Fentora) must not be used in opioid non-tolerant patients because life-threatening hypoventilation could occur at any dose in patients not on a chronic regimen of opiates.

Additional Clinical Programs:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Fentanyl citrate [package insert]. Parsippany, NJ: Teva; January 2024.
2. Fentanyl buccal [package insert]. Raleigh, NC: Mayne Pharma; January 2024.
3. Fentora [package insert]. Parsippany, NJ: Cephalon; December 2023.

5 . Revision History

Date	Notes
9/17/2025	Removed Actiq brand as it is no longer on the market. Updated back ground and references.

Filspari

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-540191
Guideline Name	Filspari
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	4/19/2023
P&T Revision Date:	10/16/2024 ; 06/18/2025 ; 07/16/2025 ; 3/18/2026

1 . Indications

Drug Name: Filspari (sparsentan)
immunoglobulin A nephropathy (IgAN) Indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression

2 . Criteria

Product Name:Filspari [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

AND

2 - Patient is at risk of disease progression

AND

3 - Used to slow kidney function decline

AND

4 - Used to reduce proteinuria

AND

5 - Estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m2

AND

6 - BOTH of the following:

6.1 Patient is on a maximized stable dose with ONE of the following prior to initiating therapy:

- maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

AND

6.2 Use of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE inhibitors, ARBs), endothelin receptor antagonists [(ERAs) e.g., Letairis, Opsumit, Tracleer)], and Tekturna will be discontinued prior to initiating treatment **AND** **7** - History of failure (after a 30-day trial), contraindication or intolerance to a glucocorticoid (e.g., budesonide, methylprednisolone, prednisone) **AND** **8** - Prescribed by or in consultation with a nephrologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Filspari [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response demonstrated by a reduction in proteinuria	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background

Filspari (sparsentan) is indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program.
- Supply limitations may be in place

4 . References

1. Filspari [package insert]. San Diego, CA: Traverse Therapeutics, Inc; August 2025.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. (2025). KDIGO 2025 clinical practice guideline for the management of IgA nephropathy (IgAN) and IgA vasculitis (IgAV). KDIGO. https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2025-IgAN-IgAV-Guideline.pdf

5 . Revision History

Date	Notes
3/4/2026	Added budesonide as a corticosteroid example. Removed step through SGLT2. Updated references.

Filsuvez

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-237189
Guideline Name	Filsuvez
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	6/1/2025
P&T Approval Date:	4/17/2024
P&T Revision Date:	4/16/2025

1 . Indications

Drug Name: Filsuvez (birch triterpenes)
Epidermolysis bullosa Indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older.

2 . Criteria

Product Name:Filsuvez [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Patient is at least 6 months of age and older

AND

2 - ONE of the following diagnoses:

- Dystrophic epidermolysis bullosa (DEB)
- Junctional epidermolysis bullosa (JEB)

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) confirming a genetic mutation associated with DEB or JEB (i.e., COL7A1, LAMA3, LAMB3, LAMC2, COL17A1, ITGA6, ITGB4, ITGA3)

AND

4 - Patient has at least one partial thickness wound that meets ALL of the following criteria:

- 10-50 cm2 in size
- Present for at least 3 weeks
- Adequate granulation tissue
- Excellent vascularization
- No evidence of active wound infection
- No evidence or history of basal or squamous cell carcinomas (SCC)

AND

5 - Prescribed by, or in consultation with, a dermatologist with expertise in the treatment of epidermolysis bullosa (EB)

AND

6 - Patient is NOT receiving Filsuvez in combination with Vyjuvek (beremagene geperpavec-svdt) on the same wound(s)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Filsuvez [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Filsuvez therapy (e.g., complete wound closure, reduction in wound size, decrease in procedural pain, less frequent dressing changes, decreased total body wound burden)

AND

2 - Wound(s) being treated meet all of the following criteria:

- Adequate granulation tissue
- Excellent vascularization
- No evidence of active wound infection
- No evidence or history of basal or squamous cell carcinomas (SCC)

AND

3 - Filsuvez is prescribed by, or in consultation with, a dermatologist with expertise in the treatment of epidermolysis bullosa (EB)

AND

4 - Patient is NOT receiving Filsuvez in combination with Vyjuvek (beremagene geperpavec-svdt) on the same wound(s)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Filsuvez (birch triterpenes) topical gel is indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limitations may be in place.

4 . References

1. Filsuvez [package insert]. Boston, MA: Chiesi Global Rare Diseases; May 2024.
2. Kern JS, Sprecher E, Fernandez MF, et al. Efficacy and safety of Oleogel-S10 (birch triterpenes) for epidermolysis bullosa: results from the phase III randomized double-blind phase of the EASE study. Br J Dermatol. 2023;188(1):12-21.
3. Varki R, Sadowski S, Pfendner E, Uitto J. Epidermolysis bullosa. I. Molecular genetics of the junctional and hemidesmosomal variants. J Med Genet. 2006;43(8):641-652.

5 . Revision History

Date	Notes
4/7/2025	Annual review with no changes to criteria. Updated references.

Firazyr, Sajazir

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523263
Guideline Name	Firazyr, Sajazir
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/19/2022
P&T Revision Date:	04/19/2023 ; 02/16/2024 ; 04/17/2024 ; 04/16/2025 ; 2/20/2026

1 . Indications

Drug Name: Firazyr (icatibant)
Hereditary angioedema (HAE) Indicated for the treatment of acute attacks of HAE in adults 18 years of age and older.
Drug Name: Sajazir (icatibant)
Hereditary angioedema (HAE) Indicated for the treatment of acute attacks of HAE in adults 18 years of age and older.

2 . Criteria

Product Name:Brand Firazyr, generic icatibant, Brand Sajazir [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - BOTH of the following:

2.1 Prescribed for the acute treatment of HAE attacks

AND

2.2 Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Ekterly, Kalbitor, or Ruconest)

AND

3 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Firazyr, generic icatibant, Brand Sajazir [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - BOTH of the following:

2.1 Prescribed for the acute treatment of HAE attacks

AND

2.2 Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Ekterly, Kalbitor, or Ruconest)

AND

3 - Prescribed by ONE of the following: • Immunologist • Allergist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Firazyr (icatibant) is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older. Sajazir (icatibant) injection is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of HAE in adults 18 years of age and older. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Firazyr [package insert]. Lexington, MA: Shire Orphan Therapies, LLC; June 2025.
2. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2025.
3. Busse, P., Christiansen, S., Riedl., M., et. al. “US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema.” The Journal of Allergy and Clinical Immunology. 2020 September 05.

4. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2021 revision and update. Allergy. 2022;77(7):1961-1990. doi:10.1111/all.15214
5. Sajazir [package insert]. Cambridge, CB3 0FA, United Kingdom: Cycle Pharmaceuticals Ltd; February 2024.

5 . Revision History

Date	Notes
2/20/2026	Updated examples of acute treatments for HAE attacks. No changes to coverage criteria. Updated references.

Forzinity

Prior Authorization Guideline

Guideline ID	GL-493414
Guideline Name	Forzinity
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	1/21/2026
P&T Revision Date:	

1 . Indications

Drug Name: Forzinity (elamipretide)
Barth syndrome Indicated to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30 kg.

2 . Criteria

Product Name:Forzinity [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Barth syndrome

AND

2 - Diagnosis has been confirmed by the presence of a pathogenic variant in the TAFAZZIN gene identified by molecular genetic testing

AND

3 - Patient weight is greater than or equal to 30 kg

AND

4 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Geneticist
- Metabolic specialist
- Neurologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Forzinity [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria **1** - Documentation of positive clinical response to Forzinity therapy (e.g., improvement or stabilization in 6-minute walk test, improvement or stabilization in knee extensor muscle strength) **AND** **2** - Prescribed by or in consultation with one of the following: • Cardiologist • Geneticist • Metabolic specialist • Neurologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Forzinity™ (elamipretide) is a mitochondrial cardiolipin binder indicated to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30 kg. This indication is approved under accelerated approval based on an improvement in knee extensor muscle strength, an intermediate clinical endpoint. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4 . References

1. Forzinity™ [package insert]. Needham, MA: Stealth BioTherapeutics Inc.; September 2025.

5 . Revision History

Date	Notes
1/10/2026	New program.

FSH

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412230
Guideline Name	FSH
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	10/20/2021 ; 06/15/2022 ; 09/21/2022 ; 12/14/2022 ; 08/18/2023 ; 08/18/2023 ; 04/17/2024 ; 10/01/2024 ; 06/18/2025 ; 06/18/2015 ; 9/17/2025

1 . Indications

Drug Name: Follistim AQ (follitropin beta)
Induction of ovulation and pregnancy in anovulatory infertile women Indicated for induction of ovulation and pregnancy in anovulatory infertile women in whom the cause of infertility is functional and not due to primary ovarian failure. **Pregnancy in normal ovulatory women** Indicated for pregnancy in normal ovulatory women undergoing controlled ovarian stimulation as part of an in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) cycle. **Induction of spermatogenesis in men** Indicated in males for induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism (HH) in whom the cause of infertility is not due to primary testicular failure. [3]

Drug Name: Gonal-f (follitropin alfa)
Induction of ovulation and pregnancy in oligo-anovulatory infertile women Indicated for the induction of ovulation and pregnancy in the oligo-anovulatory infertile patient in whom the cause of infertility is functional and not due to primary ovarian failure. **Development of multiple follicles** Indicated for the development of multiple follicles in ovulatory women participating in an Assisted Reproductive Technology (ART) program. **Induction of spermatogenesis in men** Indicated for the induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure. [4,5]
Drug Name: Gonal-f RFF (follitropin alfa), Gonal-F RFF Redi-Ject (follitropin alfa)
Induction of ovulation and pregnancy in oligo-anovulatory infertile women Indicated for the induction of ovulation and pregnancy in the oligo-anovulatory infertile patient in whom the cause of infertility is functional and not due to primary ovarian failure. **Development of multiple follicles** Indicated for the development of multiple follicles in ovulatory women participating in an Assisted Reproductive Technology (ART) program.

2 . Criteria

Product Name:Follistim AQ, Gonal-F, Gonal-F RFF, Gonal-F RFF Rediject [a]	
Diagnosis	Ovulation Induction
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ovulatory dysfunction

AND

2 - ONE of the following exists:

- Anovulation

- Oligo-ovulation
- Amenorrhea

AND

3 - Other specific causative factors (e.g., thyroid disease, hyperprolactinemia) have been excluded or treated

AND

4 - Infertility is not due to primary ovarian failure

AND

5 - For induction of ovulation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Follistim AQ, Gonal-F, Gonal-F RFF, Gonal-F RFF Rediject [a]	
Diagnosis	Controlled Ovarian Stimulation**
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (controlled ovarian stimulation)

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 ONE of the following exists:

- Diminished ovarian reserve
- Endometriosis
- Male factor infertility
- Tubal factor infertility
- Unexplained infertility
- Uterine factor infertility
- Ovulatory dysfunction
- Recurrent pregnancy loss
- Failure to achieve conception with other treatment modalities

AND

3.1.2 Will be used in conjunction with assisted reproductive technology (ART)

OR

3.2 BOTH of the following:

3.2.1 ONE of the following exists:

- Diminished ovarian reserve
- Mild to moderate male factor infertility
- Minimal to mild endometriosis
- Unilateral tubal factor infertility
- Unexplained infertility

AND

3.2.2 Will be used in conjunction with intrauterine insemination (IUI)

Notes	**NOTE: Requests for an infertility related diagnosis other than ovulati on induction for members in Iowa, New Jersey, New York, North Carol

	ina, Kansas, and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Follistim AQ, Gonal-F [a]	
Diagnosis	Male Hypogonadotropic Hypogonadism**
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of male primary hypogonadotropic hypogonadism

OR

1.2 Diagnosis of male secondary hypogonadotropic hypogonadism

AND

2 - For induction of spermatogenesis

AND

3 - Infertility is not due to primary testicular failure

Notes	**NOTE: Requests for an infertility related diagnosis other than ovulati on induction for members in Iowa, New Jersey, New York, North Carol ina, Kansas, and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: The body produces two types of gonadotropins, follicle-stimulating hormone (FSH) and luteinizing hormone (LH), both of which play a role in fertility and human reproduction. After they are produced by the pituitary gland, gonadotropins trigger production of other sex hormones which then promote production of egg and sperm. Gonadotropins are used in the treatment of infertility, a disease of the reproductive system defined as one of the following: • inability to achieve a successful pregnancy due to an individual's medical, sexual, or reproductive history; • failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse when the female partner is less than 35 years; • failure to achieve a pregnancy after 6 months or more of regular unprotected sexual intercourse when the female partner is 35 years or older Follistim AQ (follitropin beta) is indicated for induction of ovulation and pregnancy in anovulatory infertile women in whom the cause of infertility is functional and not due to primary ovarian failure. It is also indicated for pregnancy in normal ovulatory women undergoing controlled ovarian stimulation as part of an in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) cycle. In males, Follistim AQ is indicated for induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism (HH) in whom the cause of infertility is not due to primary testicular failure. Gonal-f, Gonal-f RFF and Gonal-f RFF Redi-Ject (follitropin alfa) are indicated for the induction of ovulation and pregnancy in oligo-anovulatory infertile women in whom the cause of infertility is functional and not due to primary ovarian failure. Gonal-f, Gonal-f RFF, and Gonal-f RFF Redi-ject are also indicated for the development of multiple follicles in ovulatory women participating in an Assisted Reproductive Technology (ART) program. Gonal-f is indicated for the induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism for whom the cause of infertility is not due to primary testicular failure. The clinically appropriate dosing for FSH agents is 450 IU/day or less when used for an ART cycle, or 225 IU/day or less when used for ovulation induction or controlled ovarian

stimulation, for not more than 14 days of treatment. Exceeding this daily dose and duration of treatment has not been proven to be efficacious in terms of pregnancy outcome.

Additional Clinical Programs:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. World Health Organization web site. https://www.who.int/health-topics/infertility#tab=tab. Accessed May 5, 2025.
2. American Society for Reproductive Medicine. Definitions of infertility and recurrent pregnancy loss: a committee opinion. Fertil Steril 2013;Jan;99(1):63
3. Follistim AQ [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; July 2023.
4. Gonal-f [package insert]. Rockland, MA: EMD Serono, Inc.; December 2020.
5. Gonal-f RFF [package insert]. Rockland, MA: EMD Serono, Inc.; November 2023.
6. Muasher SJ. Use of gonadotrophin-releasing hormone agonists in controlled ovarian hyperstimulation for in vitro fertilization. Clin Ther 1992;14(Suppl A):74-86.
7. Ferraretti A, Marca A, Fauser B, et al. ESHRE consensus on the definition of 'poor response' to ovarian stimulation for in vitro fertilization: the Bologna criteria. Human Reprod 2011; 26: 1616-24.
8. Andoh K, Mizunuma H, Liu X, et al. A comparative study of fixed-dose, stepdown, and low-dose step-up regimens of human menopausal gonadotropin for patients with polycystic ovary syndrome. Fertil Steril m1998: 70; 840-846.
9. Pal L, Jindal S, Witt B, Santoro N. Less is more: increased gonadotropin use for ovarian stimulation adversely influences clinical pregnancy and live birth after in vitro fertilization. Fertil Steril 2008;89:1694-701.
10. Fauser B, Nargund G, Anderson A, et al. Mild ovarian stimulation for IVF: 10 years later. Human Reprod 2010; 25: 2678-84.
11. Baart E, Martini E, Eijkemans M, et al. Milder ovarian stimulation for in-vitro fertilization reduces aneuploidy in the human preimplantation embryo: a randomized controlled trial. Human Reprod 2007; 22: 980-8.
12. Sunkara S, Rittenberg V, Raine-Fenning N, et al. Association between the number of eggs and live birth in IVF treatment: an analysis of 400,135 treatment cycles. Human Reprod 2011; 26: 1768-74.
13. The Practice Committee of the American Society for Reproductive Medicine. Use of exogenous gonadotropins in anovulatory women: a technical bulletin. Fertil Steril 2008;90:S7–12.
14. Practice Committee of the American Society for Reproductive Medicine. Electronic address: asrm@asrm.org. Definitions of infertility and recurrent pregnancy loss: a committee opinion. Fertil Steril. 2020;113(3):533-535. doi:10.1016/j.fertnstert.2019.11.025

5 . Revision History

Date	Notes
10/7/2025	Added New York to the ovulation induction operational note for 2026 i mplementation.

Gilotrif

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-248205
Guideline Name	Gilotrif
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	5/16/2025
P&T Revision Date:	

1 . Indications

Drug Name: Gilotrif (afatinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. Gilotrif is also indicated for the treatment of patients with metastatic, squamous NSCLC progressing after platinum-based chemotherapy. **NCCN Recommended** The National Cancer Comprehensive Network (NCCN) also recommends the use of Gilotrif in patients with advanced non-nasopharyngeal head and neck cancers with progression on or after platinum-containing chemotherapy. Additionally, the NCCN also recommends use of Gilotrif as a single-agent treatment for brain metastases in patients with EGFR sensitizing mutation positive NSCLC.

2 . Criteria

Product Name:Gilotrif [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

- Squamous disease progressing after previous platinum-based chemotherapy
- Tumors are positive for non-resistant epidermal growth factor receptor (EGFR) mutations

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Gilotrif [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Gilotrif therapy.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Gilotrif [a]	
Diagnosis	Non- Nasopharyngeal Head and Neck Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of advanced, non-nasopharyngeal head and neck cancer **AND** **2** - Disease has progressed on or after platinum-containing chemotherapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Gilotrif [a]	
Diagnosis	Non- Nasopharyngeal Head and Neck Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Gilotrif therapy.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Gilotrif [a]	
Diagnosis	Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of brain metastasis due to EGFR-sensitizing mutation positive non-small cell lung cancer	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Gilotrif [a]	
Diagnosis	Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Gilotrif therapy.	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Gilotrif [a]	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Gilotrif will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Gilotrif [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Gilotrif therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background:

Gilotrif® (afatinib) is a kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. Gilotrif is also indicated for the treatment of patients with metastatic, squamous NSCLC progressing after platinum-based chemotherapy. [1] The National Cancer Comprehensive Network (NCCN) also recommends the use of Gilotrif in patients with advanced non-nasopharyngeal head and neck cancers with progression on or after platinum-containing chemotherapy. Additionally, the NCCN also recommends use of Gilotrif as a single-agent treatment for brain metastases in patients with EGFR sensitizing mutation positive NSCLC. [2]

Limitations of Use: Safety and efficacy of Gilotrif were not established in patients whose tumors have resistant EGFR mutations.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Gilotrif [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed April 30, 2024.

5 . Revision History

Date	Notes
5/2/2025	Policy reviewed and approved for application to UnitedHealthcare Val ue & Balance Exchange for 7/2025 implementation.

GLP1 Receptor Agonists

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-248191
Guideline Name	GLP1 Receptor Agonists
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	12/14/2022
P&T Revision Date:	08/18/2023 ; 05/17/2024 ; 06/17/2024 ; 10/01/2024 ; 04/16/2025 ; 5/16/2025

1 . Indications

Drug Name: Mounjaro (tirzepatide), Rybelsus (semaglutide), Byetta (exenatide)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Drug Name: Bydureon BCise (exenatide extended-release)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years of age and older with type 2 diabetes mellitus.
Drug Name: Trulicity (dulaglutide), and Victoza (liraglutide)
Reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) Indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years of age and older with type 2 diabetes mellitus.
Drug Name: Ozempic (semaglutide)
Reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) Indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. **Type 2 Diabetes Mellitus** Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death** Indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.

2 . Criteria

Product Name:Byetta, Bydureon BCise, Exenatide (authorized generic of Byetta), Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza* [a]	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

OR

2 - For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Medications used for the purposes of weight loss are typically excluded from benefit coverage. Coverage is determined by the member's prescription drug benefit plan.

3 . Background

Benefit/Coverage/Program Information

Background:

Byetta (exenatide), Ozempic (semaglutide) and Rybelsus (semaglutide) are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Bydureon BCise (exenatide extended-release), Trulicity (dulaglutide) and Victoza (liraglutide) are indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years of age and older with type 2 diabetes mellitus. Ozempic, Trulicity, and Victoza are also indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. Finally, Ozempic carries an additional indication to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.

Mounjaro (tirzepatide) is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis

codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2024.
2. Mounjaro [package insert] Indianapolis, IN: Eli Lilly and Company; November 2024.
3. Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; January 2025.
4. Rybelsus [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; December 2024.
5. Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; November 2024.
6. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; February 2025.
7. American Diabetes Association. Standard of Medical Care in Diabetes - 2025. Diabetes Care 2025;48 (Supplement 1).
8. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan - 2022 Update. AACE Clinical Practice Guidelines. Endocr Pract. 2022;28: 923-1049.
9. Byetta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2024.
10. Exenatide [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; November 2024.

5 . Revision History

Date	Notes
4/30/2025	Added Byetta and Exenatide (authorized generic of Byetta) to policy. Removed AG of Victoza from policy, now available as true generic.

GnRH Antagonists

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412231
Guideline Name	GnRH Antagonists
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	12/15/2021 ; 09/21/2022 ; 12/14/2022 ; 08/18/2023 ; 08/18/2023 ; 04/17/2024 ; 10/01/2024 ; 06/18/2025 ; 9/17/2025

1 . Indications

Drug Name: Cetrotide (cetrorelix acetate), Fyremadel (ganirelix acetate)
Ovulation induction, controlled stimulation Indicated to inhibit premature luteinizing hormone (LH) surges in women undergoing controlled ovarian stimulation followed by insemination or assisted reproductive technology (ART).

2 . Criteria

Product Name:Brand Cetrotide, generic cetrorelix, Brand Fyremadel, generic ganirelix [a]	
Diagnosis	Controlled Ovarian Stimulation**

Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND

2 - ONE of the following exists:

- Unexplained infertility
- Endometriosis
- Male factor infertility
- Tubal factor infertility
- Diminished ovarian reserve
- Uterine factor infertility
- Ovulatory dysfunction
- Recurrent pregnancy loss
- Failure to achieve conception with other treatment modalities

AND

3 - For the development of one or more follicles (controlled ovarian stimulation)

AND

4 - Documentation of an approved assisted reproductive technology (ART) protocol

Notes	**NOTE: Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas, and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Cetrotide (cetrorelix acetate) and ganirelix acetate are synthetic decapeptides with gonadotropin-releasing hormone (GnRH) antagonist activity. These agents are indicated to inhibit premature luteinizing hormone (LH) surges in women undergoing controlled ovarian stimulation followed by insemination or assisted reproductive technology (ART). **Additional Clinical Programs:** • Supply limits may be in place. • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Cetrotide [package insert]. Rockland, MA: EMD Serono, Inc.; June 2024.
2. Ganirelix acetate [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; November 2024.
3. Sahakyan M, Harlow BL, Hornstein MD. Influence of age, diagnosis, and cycle number on pregnancy rates with gonadotropin-induced controlled ovarian hyperstimulation and intrauterine insemination. Fertil Steril 1999; 72: 500-504.
4. Ganirelix acetate [package insert]. Jersey City, NJ: Organon Global Inc.; February 2024.

5 . Revision History

Date	Notes
10/7/2025	Added New York to ovulation induction operation note for 2026 imple mentation.

Growth Hormone

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399216
Guideline Name	Growth hormone
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	2/19/2021
P&T Revision Date:	07/21/2021 ; 09/15/2021 ; 01/19/2022 ; 07/19/2023 ; 09/20/2023 ; 09/20/2023 ; 12/13/2023 ; 09/18/2024 ; 12/18/2024 ; 02/20/2025 ; 9/25/2025

1 . Indications

Drug Name: Somatropin
Pediatric growth hormone deficiency Indicated for the treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone **Growth hormone deficiency (GHD)** Indicated for the treatment of growth hormone deficiency (GHD) **Turner syndrome or Noonan syndrome** Indicated for short stature associated with Turner syndrome or Noonan syndrome **Idiopathic short stature (ISS)** indicated for the treatment of idiopathic short stature (ISS) **Short-stature homeobox (SHOX) gene deficiency** Indicated for short-stature or growth failure in short stature homeobox-containing gene homeobox (SHOX) gene deficiency

Prader-Willi syndrome Indicated for growth failure due to Prader-Willi syndrome.

Short stature in children small for gestational age Indicated for short stature in children born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years of age

Growth Failure associated with Chronic Renal Insufficiency Indicated for growth failure in children with chronic renal insufficiency up to the time of transplant

Replacement of endogenous growth hormone in adults Indicated for replacement of endogenous growth hormone in adults with confirmed growth hormone deficiency.

Drug Name: Ngenla (somatrogon)

Pediatric Growth Hormone Deficiency (GHD) Indicated for treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous GH.

Drug Name: Skytrofa (lonapegsomatropin-tcgd)

Pediatric Growth Hormone Deficiency (GHD) Indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).

Drug Name: Sogroya (somapacitan)

Pediatric Growth Hormone Deficiency (GHD) Indicated for the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone.

Adult Growth Hormone Deficiency Indicated for the replacement of endogenous GH in adults with growth hormone deficiency (GHD).

Drug Name: Serostim (somatropin)

Human Immunodeficiency Virus (HIV)-Associated Cachexia Indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance.

Drug Name: Zorbtive (somatropin)

Short Bowel Syndrome Indicated for the treatment of short bowel syndrome in adult patients receiving specialized nutritional support.

Drug Name: Increlex (mecasermin)

Severe primary insulin-like growth factor-1 (IGF-1) deficiency or growth hormone gene deletion Indicated for the treatment of growth failure in pediatric patients 2 years of age and

older with severe primary insulin-like growth factor-1 (IGF-1) deficiency or with GH gene deletion who have developed neutralizing antibodies to GH.

2 . Criteria

Product Name:Somatropin** [a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Congenital Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Infant is less than 12 months of age

AND

2 - Submission of medical records documenting evidence of growth failure confirmed by ALL of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

AND

3 - Submission of medical records documenting ONE of the following:

3.1 BOTH of the following:

- Hyopothalmic-pituitary defect (e.g., ectopic posterior pituitary, empty sella, hypoplastic pituitary, major congenital malformation, optic nerve hypoplasia, tumor or irradiation)
- Deficiency of at least one additional pituitary hormone

OR

3.2 ALL of the following:

- Neonatal hypoglycemia and/or micropenis
- Serum GH concentration less than or equal to 5 µg/L in the first 28 days of life
- Deficiency of at least one additional pituitary hormone
- Classical imaging triad (i.e., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk)

AND

4 - Submission of medical records documenting ONE of the following is below the age and gender adjusted normal range as provided by the physician's lab:

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

5 - Prescribed by an endocrinologist

AND

6 - Request does not exceed a maximum supply limit of 0.3mg/kg/week

Notes	**Please Note: The request for growth hormone (GH) injections to trea t idiopathic short stature (ISS) is not authorized. There is no consensu s in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Somatropin**[a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Congenital Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting a height increase of at least 2 cm/year over the previous year confirmed by ALL of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for length/height for age and gender

AND

2 - Submission of medical records documenting BOTH of the following:

- Expected adult height not attained
- Documentation of expected adult height goal (e.g. genetic potential)

AND

3 - Prescribed by an endocrinologist

AND

4 - Request does not exceed a maximum supply limit of 0.3mg/kg/week

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy.

	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Somatropin**[a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim), Ngenla, Skytrofa, Sogroya	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting diagnosis of pediatric GH deficiency

AND

2 - Submission of medical records documenting evidence of growth failure confirmed by ALL of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

AND

3 - Submission of medical records documenting open epiphyses in the last 12 months

AND

4 - Submission of medical records documenting Tanner stage less than or equal to 4

AND

5 - Submission of medical records documenting BOTH of the following:

5.1 Patient has undergone TWO of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

5.2 Peak GH responses to each agent is less than 10 mcg/L

AND

6 - If patient has a history of malignancy, ONE of the following:

- Patient is in remission
- Patient has been stable for at least 12 months

AND

7 - Prescribed by an endocrinologist

AND

8 - ONE of the following:

8.1 If the request is for Ngenla, request does not exceed a maximum supply limit of 0.66 mg/kg/week

OR

8.2 If the request is for Somatropin, Skytrofa, or Sogroya, ONE of the following:

8.2.1 Request does not exceed a maximum supply limit of 0.3 mg/kg/week

OR

8.2.2 ALL of the following:

8.2.2.1 ONE of the following:

- Poor catch-up growth while on standard dosing
- IGF-1 less than 2 standard deviations from the mean while on standard dosing

AND

8.2.2.2 Tanner Stage 2 or greater

AND

8.2.2.3 Request does not exceed a maximum supply limit of 0.7 mg/kg/week

Notes	**Please Note: The request for growth hormone (GH) injections to trea t idiopathic short stature (ISS) is not authorized. There is no consensu s in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. Note: If patient is a Transition Phase Adolescent or Adult who had chil dhood onset GH deficiency, utilize criteria for Transition Phase Adoles cent or Adult GH Deficiency. [a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Somatropin**[a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim), Ngenla, Skytrofa, Sogroya	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting a height increase of at least 2 cm/year over the previous year confirmed by ALL of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for length/height for age and gender

AND

2 - Submission of medical records documenting BOTH of the following:

- Expected adult height not attained
- Documentation of expected adult height goal (e.g., genetic potential)

AND

3 - Prescribed by an endocrinologist

AND

4 - ONE of the following:

4.1 If the request is for Ngenla, request does not exceed a maximum supply limit of 0.66 mg/kg/week

OR

4.2 If the request is for Somatropin, Skytrofa, or Sogroya, ONE of the following:

4.2.1 Request does not exceed a maximum supply limit of 0.3 mg/kg/week

OR **4.2.2** ALL of the following: **4.2.2.1** ONE of the following: • Poor catch-up growth while on standard dosing • IGF-1 less than 2 standard deviations from the mean while on standard dosing **AND** **4.2.2.2** Tanner Stage 2 or greater **AND** **4.2.2.3** Request does not exceed a maximum supply limit of 0.7 mg/kg/week

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. Note: If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Somatropin**[a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting ONE of the following:

1.1 Genetic mutation

OR

1.2 Deficiency of THREE of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

OR

1.3 Irreversible structural hypothalamic-pituitary disease

OR

1.4 Panhypopituitarism

AND

2 - Submission of medical records documenting ONE of the following:

2.1 IGF-1 level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.2 BOTH of the following:

2.2.1 Patient has undergone ONE of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- Insulin tolerance test (ITT)
- GH-releasing hormone-arginine test (GHRH+ARG)
- Glucagon stimulation test (GST)
- Macimorelin

AND

2.2.2 ONE of the following peak GH values:

- ITT less than or equal to 5.1 µg/L
- GHRH+ARG less than or equal to 11 µg/L
- Glucagon less than or equal to 3 µg/L
- Macimorelin less than or equal to 2.8 ng/mL

AND

3 - Prescribed by an endocrinologist

AND

4 - ONE of the following:

4.1 Request does not exceed a maximum supply limit of 0.3mg/kg/week

OR

4.2 ALL of the following:

4.2.1 One of the following:

- Poor catch-up growth while on standard dosing
- IGF-1 less than 2 standard deviations from the mean while on standard dosing

AND

4.2.2 Tanner Stage 2 or greater

AND

4.2.3 Request does not exceed a maximum supply limit of 0.7 mg/kg/week

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. Note: Use this criteria for patients diagnosed with GHD in childhood during the transition period from puberty to adulthood (the period from mid to late teens until 6 to 7 years after achievement of adult height) [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Somatropin**[a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

AND

2 - Prescribed by an endocrinologist

AND

3 - ONE of the following:

3.1 Request does not exceed a maximum supply limit of 0.3mg/kg/week

OR

3.2 ALL of the following:

3.2.1 ONE of the following:

- Poor catch-up growth while on standard dosing
- IGF-1 less than 2 standard deviations from the mean while on standard dosing

AND

3.2.2 Tanner Stage 2 or greater

AND

3.2.3 Request does not exceed a maximum supply limit of 0.7 mg/kg/week

Notes	**Please Note: The request for growth hormone (GH) injections to trea t idiopathic short stature (ISS) is not authorized. There is no consensu s in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. Note: Use this criteria for patients diagnosed with GHD in childhood d uring the transition period from puberty to adulthood (the period from mid to late teens until 6 to 7 years after achievement of adult height) [a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Skytrofa, Sogroya, Somatropin**[a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting a diagnosis of adult growth hormone deficiency (GHD) as a result of ONE of the following:

- Known hypothalamic or pituitary disease
- Panhypopituitarism
- History of GHD in childhood

AND

2 - Submission of medical records documenting ONE of the following:

2.1 IGF-1 level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.2 ALL of the following:

2.2.1 Patient does not have a low IGF-1

AND

2.2.2 Patient has undergone ONE of the following GH stimulation tests:

- GH-releasing hormone-arginine test (GHRH+ARG)
- Glucagon stimulation test (GST)
- Macimorelin

AND

2.2.3 ONE of the following peak GH values:

- GHRH+ARG less than or equal to 11 µg/L
- Glucagon less than or equal to 3 ng/mL

- Macimorelin less than or equal to 2.8 ng/mL

AND

3 - ONE of the following:

3.1 Diagnosis of panhypopituitarism

OR

3.2 Other diagnosis AND not used in combination with the following:

- Aromatase inhibitors [e.g., Arimidex (anastrozole), Femara (letrozole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

4 - Prescribed by an endocrinologist

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Skytrofa, Sogroya, Somatropin**[a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting an IGF-1level within the past 12 months

AND

2 - ONE of the following:

2.1 Diagnosis of panhypopituitarism

OR

2.2 Other diagnosis AND not used in combination with the following

- Aromatase inhibitors [e.g., Arimidex (anastrazole), Femara (letrazole)]
- Androgens [e.g., Delatestryl (testoseterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

3 - Prescribed by an endocrinologist

Notes	**Please Note: The request for growth hormone (GH) injections to trea t idiopathic short stature (ISS) is not authorized. There is no consensu s in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Somatropin** [a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting BOTH of the following:

- Diagnosis of Prader-Willi Syndrome
- Diagnosis confirmed by genetic testing

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient is less than 18 years of age

AND

2.1.2 Submission of medical records documenting evidence of growth failure confirmed by ALL of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

OR

2.2 Patient is greater than or equal to 18 years of age

AND

3 - Patient does not have ANY of the following:

- Active malignancy

- Severe obesity (weight greater than 225 percent of ideal body weight)
- Severe respiratory impairment

AND

4 - Prescribed by an endocrinologist

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Somatropin** [a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Patient is less than 18 years of age

AND

1.1.2 Submission of medical records documenting a height increase of at least 2 cm/year over the previous year of treatment as documented by ALL of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth charts for length/height for age and gender

AND

1.1.3 Submission of medical records documenting BOTH of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

OR

1.2 BOTH of the following:

- Patient is greater than or equal to 18 years of age
- Submission of medical records documenting a positive response to therapy (e.g., reduction in fat mass, increase in lean body mass, improved strength and exercise tolerance)

OR

2 - Prescribed by an endocrinologist

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Somatropin** [a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting a diagnosis of growth failure associated with SGA

AND

2 - Submission of medical records documenting diagnosis has been confirmed by ALL of the following:

2.1 BOTH of the following:

- Growth charts for length/height and weight for gestational age and gender at birth
- Documentation that birth length/height and/or weight ≥ 2 SD below mean for gestational age

AND

2.2 Infant growth charts for length/height and weight for age and gender between birth and 24 to 36 months of age do not show evidence of catch-up growth in length/height and/or weigh (i.e., length/height or weight remained ≥ 2 SD below mean for age and gender from birth to age 2 to 3)

AND

2.3 Documentation that current length/height and/or weight remains ≥ 2 SD below mean for age and gender

AND

2.4 Calculated growth velocity

AND

3 - Prescribed by an endocrinologist

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Somatropin** [a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting a height increase of at least 2 cm/year over the previous year confirmed by ALL of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for length/height for age and gender

AND

2 - Submission of medical records documenting BOTH of the following:

- Expected adult height not attained

- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Somatropin**[a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting ONE of the following:

1.1 BOTH of the following:

- Diagnosis of Turner Syndrome
- Diagnosis confirmed by genetic testing

OR

1.2 BOTH of the following:

- Diagnosis of Noonan Syndrome

- Diagnosis confirmed by the presence of clinical features consistent with Noonan Syndrome (e.g., distinct facial features such as high forehead, hypertelorism, down slanting palpebral fissures with high arched eyebrows, epicanthic folds, full upper lip with a depressed nasal bridge, low set ears, blue irises, ptosis and neck webbing, pulmonary valve stenosis, hypertrophic cardiomyopathy, pectus carinatum/excavatum, mild developmental delay, cryptorchidism, lymphatic dysplasia)

AND

2 - Submission of medical records documenting ALL of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

AND

3 - Submission of medical records documenting open epiphyses in the last 12 months

AND

4 - Submission of medical records documenting Tanner staging less than equal to 4

AND

5 - Prescribed by an endocrinologist

Notes	**Please Note: The request for growth hormone (GH) injections to trea t idiopathic short stature (ISS) is not authorized. There is no consensu s in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Somatropin**[a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting a height increase of at least 2 cm/year over the previous year confirmed by ALL of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for height for age and gender

AND

2 - Submission of medical records documenting BOTH of the following:

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Somatropin**[a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting BOTH of the following:

- Diagnosis of short-stature homeobox (SHOX) gene deficiency
- Diagnosis confirmed by genetic testing

AND

2 - Submission of medical records documenting ALL of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

AND

3 - Submission of medical records documenting open epiphyses in the last 12 months

AND

4 - Submission of medical records documenting Tanner stage less than or equal to 4

AND

5 - Prescribed by an endocrinologist

Notes	**Please Note: The request for growth hormone (GH) injections to trea t idiopathic short stature (ISS) is not authorized. There is no consensu s in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Somatropin** [a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting a height increase of at least 2 cm/year over the previous year confirmed by ALL of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for height for age and gender

AND

2 - Submission of medical records documenting both of the following:

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	**Please Note: The request for growth hormone (GH) injections to trea t idiopathic short stature (ISS) is not authorized. There is no consensu s in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Somatropin**[a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting ALL of the following:

1.1 Diagnosis of chronic renal insufficiency

AND

1.2 Documentation of ALL of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

AND

1.3 Documentation of open epiphyses in the last 12 months

AND

1.4 Tanner stage less than or equal to 4

AND

2 - Patient has not yet had a renal transplant

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Somatropin** [a] (Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, and Serostim)	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting a height increase of at least 2 cm/year over the previous year confirmed by ALL of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for height for age and gender

AND

2 - Submission of medical records documenting BOTH of the following:

- Expected adult height not attained
- Expected adult height goal

AND

3 - Patient has not yet had a renal transplant

AND

4 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Serostim**[a]	
Diagnosis	Human Immunodeficiency Virus (HIV)-Associated Cachexia (Serostim only)

Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Serostim will be approved based on submission of medical records documenting ALL of the following criteria:

1.1 Diagnosis of HIV-associated wasting syndrome or cachexia

AND

1.2 Involuntary weight loss of greater than or equal to 10%

AND

1.3 ONE of the following:

1.3.1 Chronic diarrhea (2 loose stools daily for more than 30 days)

OR

1.3.2 BOTH of the following:

- Chronic weakness
- Fever

AND

1.4 Symptoms lasting greater than or equal to 30 days (intermittent or constant)

AND

1.5 Absence of a concurrent condition other than HIV infection that may cause these findings

(e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy except for Kaposi's sarcoma limited to skin or mucous membranes)

AND

1.6 A nutritional evaluation has been completed since onset of wasting first occurred

AND

1.7 Patient's anti-retroviral therapy has been optimized to decrease the viral load

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Serostim** [a]	
Diagnosis	Human Immunodeficiency Virus (HIV)-Associated Cachexia (Serostim only)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Serostim will be approved based on submission of medical records documenting BOTH of the following criteria:

1.1 Documentation of a positive response to therapy (i.e., greater than or equal to 2% increase in body weight and/or body cell mass)

AND

1.2 ONE of the following targets or goals has not been achieved:

- Weight
- Body cell mass (BCM)
- Body mass index (BMI)

Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zorbtive**[a]	
Diagnosis	Short Bowel Syndrome (Zorbtive only)
Approval Length	4 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Zorbtive will be approved based on submission of medical records documenting ALL of the following criteria:

1.1 Diagnosis of Short Bowel Syndrome

AND

1.2 Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements

AND

1.3 Patient has not previously received 4 weeks of treatment with Zorbtive	
Notes	Note: Treatment with Zorbtive will not be authorized beyond 4 weeks. Administration for more than 4 weeks has not been adequately studied. **Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Increlex**[a]	
Diagnosis	Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion (Increlex only)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting all of the following:

1.1 Diagnosis of severe primary IGF-1 deficiency (PIGFD)

AND

1.2 Documentation of height below -3.0 SD mean for age and gender

AND

1.3 Documentation of IGF-1 below -3.0 SD mean for age and gender

AND

1.4 Documentation of BOTH of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Calculated growth velocity

AND

1.5 ONE of the following:

1.5.1 Patient is unresponsive to a trial of growth hormone therapy

OR

1.5.2 Documentation of ONE of the following:

- Very low or undetectable level of GHBP
- Very low or undetectable level of GHR mutations known to cause Laron syndrome/GH insensitivity syndrome
- GH1 gene deletion (GHD type 1A)
- GH-neutralizing antibodies
- STT5b gene mutation
- IGF-1 gene deletion or mutation

AND

2 - Other causes of low IGF-I levels have been ruled out (e.g., growth hormone deficiency, undernutrition, hepatic disease)

AND

3 - Patient will not be treated with concurrent growth hormone therapy

AND

4 - Prescribed by an endocrinologist	
Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Increlex**[a]	
Diagnosis	Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion (Increlex only)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting a height increase of at least 2 cm/year over the previous year of treatment as confirmed by ALL of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for height for age and gender

AND

2 - Submission of medical records documenting BOTH of the following:

- Expected adult height not obtained
- Expected adult height goal

AND

3 - Patient is not treated with concurrent growth hormone therapy **AND** **4** - Prescribed by an endocrinologist	
Notes	**Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Somatropin (Genotropin®, Humatrope®, Norditropin®, Nutropin AQ NuSpin®, Omnitrope®, Saizen®, Zomacton®) is indicated for the treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone (GH), growth hormone deficiency (GHD), short stature associated with Turner syndrome or Noonan syndrome, idiopathic short stature (ISS), short-stature or growth failure in short stature homeobox-containing gene homeobox (SHOX) gene deficiency, growth failure due to Prader-Willi syndrome, short stature in children born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years of age, and chronic kidney disease (CKD) up to the time of renal transplantation., growth failure in children with chronic renal insufficiency up to the time of transplant, short bowel syndrome in patients receiving specialized nutritional support, and HIV-associated wasting. Somatropin is also indicated for replacement of endogenous GH in adults with confirmed GHD. Ngenla™ (somatrogon-ghla), is indicated for the treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous GH.

Skytrofa™ (lonapegsomatropin-tcgd) is indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous GH. It is also indicated for the replacement of endogenous GH in adults with GHD.

Sogroya® (somapacitan-beco) is indicated for the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous GH. It is also indicated for the replacement of endogenous GH in adults with GHD.

Serostim® (somatropin) is indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance.

Zorbtive® (somatropin) is indicated for the treatment of short bowel syndrome in adult patients receiving specialized nutritional support.

Increlex® (mecasermin) is indicated for the treatment of growth failure in pediatric patients 2 years of age and older with severe primary insulin-like growth factor-1 (IGF-1) deficiency or with GH gene deletion who have developed neutralizing antibodies to GH.

***Educational Statement**

Documentation of previous height, current height and goal expected adult height will be required for renewal.

Additional Clinical Rules

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

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5. Omnitrope [package insert]. Princeton, NJ: Sandoz, Inc.; March 2024.
6. Saizen [package insert]. Rockland, MA: EMD Serono, Inc.; February 2020.
7. Zomacton [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; April 2024
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9. Skytrofa [package insert]. Princeton, NJ: Acendis Pharma Endocrinology, Inc.; July 2025.
10. Sogroya [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; April 2023.
11. Serostim [package insert]. Rockland, MA: EMD Serono, Inc.; June 2019.
12. Zorbtive [package insert]. Rockland, MA: EMD Serono, Inc.; September 2019.
13. Increlex [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; March 2024.
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5 . Revision History

Date	Notes
9/22/2025	Added levodopa as acceptable GH stimulation test for pediatric GHD . Added adult GHD as covered indication for Skytrofa. Updated SGA i nitial authorization criteria. Removed obsolete Saizenprep. Updated background and references.

Haegarda

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-555210
Guideline Name	Haegarda
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/18/2023
P&T Revision Date:	03/20/2024 ; 3/18/2026

1 . Indications

Drug Name: Haegarda (C1 esterase inhibitor, human)
Prophylaxis of HAE attacks Haegarda is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) (C1-INH) indicated for routine prophylaxis to prevent hereditary angioedema (HAE) attacks in patients 6 years of age and older.

2 . Criteria

Product Name:Haegarda [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - ALL of the following:

- Prescribed for the prophylaxis of HAE attacks
- Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Andembry, Cinryze, Dawnzera, Orladeyo, Takhzyro)
- Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Haegarda

AND

3 - Prescribed by ONE of the following:

- Immunologist

• Allergist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Haegarda [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Haegarda therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Ekterly, Firazyr, icatibant, Ruconest) as determined by claims information, while on Haegarda therapy

AND

3 - BOTH of the following:

- Prescribed for the prophylaxis of HAE attacks
- Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Andembry, Cinryze, Dawnzera, Orladeyo, Takhzyro)

AND

4 - Prescribed by ONE of the following:

- Immunologist

• Allergist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Haegarda is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) (C1-INH) indicated for routine prophylaxis to prevent hereditary angioedema (HAE) attacks in patients 6 years of age and older. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limitations may be in place.

4 . References

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5 . Revision History

Date	Notes
3/18/2026	Annual review. Updated list of examples of prophylactic and acute H AE treatments. Updated references.

Harliku

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436511
Guideline Name	Harliku
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	11/21/2025
P&T Revision Date:	

1 . Indications

Drug Name: Harliku (nitisinone)
Reduction of urine homogentisic acid (HGA) Indicated for the reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU).

2 . Criteria

Product Name:Harliku [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of alkaptonuria

AND

2 - Patient is ≥ 18 years old

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) confirming ONE of the following:

- Urinary homogentisic acid (HGA) excretion > 0.4g/24 hours
- Biallelic mutation in homogentisate 1,2-dioxygenase (HGD) gene confirmed by genetic testing

AND

4 - Harliku will not be used in combination with ANY of the following:

- generic nitisinone
- Nityr
- Orfadin

AND

5 - Prescribed by or in consultation with a geneticist, metabolic disease specialist, or rheumatologist.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Harliku [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Harliku therapy (e.g., reduced urinary HGA levels, improvement in joint symptoms)

AND

2 - Harliku will not be used in combination with ANY of the following:

- generic nitisinone
- Nityr
- Orfadin

AND

3 - Prescribed by or in consultation with a geneticist, metabolic disease specialist, or rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background:

Harliku™ (nitisinone) is a hydroxyphenyl-pyruvate dioxygenase inhibitor indicated for the reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU).

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place**.**

4 . References

1. Harliku [package insert]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd.; June 2025.
2. Ranganath LR, Milan AM, Hughes AT, et al. Suitability of nitisinone in alkaptonuria 1 (SONIA 1): an international, multicentre, randomised, open-label, no-treatment controlled, parallel-group, dose-response study to investigate the effect of once daily nitisinone on 24-h urinary homogentisic acid excretion in patients with alkaptonuria after 4 weeks of treatment. Ann Rheum Dis. 2016;75(2):362-367.
3. Ranganath LR, Psarelli EE, Arnoux JB, et al. Efficacy and safety of once-daily nitisinone for patients with alkaptonuria (SONIA 2): an international, multicentre, open-label, randomised controlled trial. Lancet Diabetes Endocrinol. 2020;8(9):762-772.
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5 . Revision History

Date	Notes
11/3/2025	New program.

HCG

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412232
Guideline Name	HCG
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	10/20/2021 ; 11/19/2021 ; 09/21/2022 ; 08/18/2023 ; 11/17/2023 ; 04/17/2024 ; 10/01/2024 ; 12/18/2024 ; 06/18/2025 ; 9/17/2025

1 . Indications

Drug Name: Novarel (chorionic gonadotropin), Pregnyl (chorionic gonadotropin)
Ovulation Induction Novarel (chorionic gonadotropin) and Pregnyl (chorionic gonadotropin) are indicated for induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with human menotropins. They are also indicated for prepubertal cryptorchidism not due to anatomic obstruction and selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males. [4-5]
Drug Name: Ovidrel (choriogonadotropin alfa)
Ovulation Induction Ovidrel (choriogonadotropin alfa) is indicated for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated with follicle stimulating hormones as part of an Assisted Reproductive Technology (ART) program such as in vitro fertilization

and embryo transfer. It is also indicated for the induction of ovulation and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure. [6]
Drug Name: Novarel (chorionic gonadotropin), Pregnyl (chorionic gonadotropin), Ovidrel (choriogonadotropin alfa)
Prepubertal Cryptorchidism hCG may also be used to treat cryptorchidism in boys because hCG is thought to induce testicular descent in situations when descent would have occurred at puberty. hCG thus may help to predict whether or not orchiopexy will be needed in the future. Although, in some cases, descent following hCG administration is permanent, in most cases the response is temporary. [1-3] **Hypogonadotropic Hypogonadism** hCG is also used to induce puberty in boys and to treat androgen deficiency in hypogonadotropic hypogonadism. However, the major use of hCG preparations in males is in the initiation and maintenance of spermatogenesis in hypogonadotropic men who desire fertility. [1-3]

2 . Criteria

Product Name:Novarel, Chorionic Gonadotropin, Ovidrel, Pregnyl [a]	
Diagnosis	Ovulation Induction
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anovulatory infertility

AND

2 - Infertility is not due to primary ovarian failure

AND

3 - For induction of ovulation

AND **4** - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropin, clomiphene citrate, letrozole)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Novarel, Chorionic Gonadotropin, Ovidrel, Pregnyl [a]	
Diagnosis	Controlled Ovarian Hyperstimulation**
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (controlled ovarian hyperstimulation)

AND

3 - Patient has been or will be pre-treated with a follicular stimulating agent (e.g., gonadotropin, clomiphene citrate, letrozole)

Notes	**NOTE: Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Novarel, Chorionic Gonadotropin, Ovidrel, Pregnyl [a]	
Diagnosis	Prepubertal Cryptorchidism**
Approval Length	6 Week(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction	
Notes	**NOTE: Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Novarel, Chorionic Gonadotropin, Ovidrel, Pregnyl [a]	
Diagnosis	Hypogonadotropic Hypogonadism**
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hypogonadism secondary to pituitary deficiency **AND** **2** - Low testosterone (below normal reference level provided by the physician's laboratory) **AND** **3** - ONE of the following:	

• Low LH (below normal reference level provided by the physician's laboratory) • Low FSH (below normal reference level provided by the physician's laboratory)

Notes	**NOTE: Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Novarel, Chorionic Gonadotropin, Ovidrel, Pregnyl [a]	
Diagnosis	Hypogonadotropic Hypogonadism**
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	**NOTE: Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: The body produces two types of gonadotropins, follicle-stimulating hormone (FSH) and luteinizing hormone (LH),both of which play a role in fertility and human reproduction. After they are produced by the pituitary gland, gonadotropins trigger production of other sex

hormones which then promote production of egg and sperm. Produced in pregnant women by the placenta and extracted from the urine, human chorionic gonadotropin (hCG) is similar in chemical structure and function to LH.

hCG is routinely used to trigger ovulation in the treatment of infertility, a disease of the reproductive system defined as one of the following:

- inability to achieve a successful pregnancy due to an individual's medical, sexual, or reproductive history;
- failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse when the female partner is less than 35 years;
- failure to achieve a pregnancy after 6 months or more of regular unprotected sexual intercourse when the female partner is 35 years or older

hCG may also be used to treat cryptorchidism in boys because hCG is thought to induce testicular descent in situations when descent would have occurred at puberty. hCG thus may help to predict whether or not orchiopexy will be needed in the future. Although, in some cases, descent following hCG administration is permanent, in most cases the response is temporary. hCG is also used to induce puberty in boys and to treat androgen deficiency in hypogonadotropic hypogonadism. However, the major use of hCG preparations in males is in the initiation and maintenance of spermatogenesis in hypogonadotropic men who desire fertility.

Novarel (chorionic gonadotropin) and Pregnyl (chorionic gonadotropin) are indicated for induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with human menotropins. They are also indicated for prepubertal cryptorchidism not due to anatomic obstruction and selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males.

Ovidrel (choriogonadotropin alfa) is indicated for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated with follicle stimulating hormones as part of an Assisted Reproductive Technology (ART) program such as *in vitro* fertilization and embryo transfer. It is also indicated for the induction of ovulation and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure.

Additional Clinical Rules:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. World Health Organization web site. https://www.who.int/health-topics/infertility#tab=tab. Accessed May 5, 2025.
2. American Society for Reproductive Medicine. Definitions of infertility and recurrent pregnancy loss: a committee opinion. Fertil Steril 2013;Jan;99(1):63
3. Petak SM, Nankin HR, Spark RF, Swerdloff RS, Rodriguez-Rigau LJ. American Association of Clinical Endocrinologists Medical Guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients – 2002 update. Endocr Pract. 2002;8:440-456.
4. Novarel [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; May 2023.
5. Pregnyl [package insert]. Jersey City, NJ: Organon & Co; March 2025.
6. Ovidrel [package insert]. Rockland, MA: EMD Serono, Inc.; February 2022.

5 . Revision History

Date	Notes
10/7/2025	Added New York to ovulation induction operation note for 2026 imple mentation.

Hepatitis C Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-458246
Guideline Name	Hepatitis C Agents
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 08/20/2021 ; 09/15/2021 ; 02/18/2022 ; 06/15/2022 ; 07/20/2022 ; 11/17/2023 ; 07/16/2025 ; 10/15/2025

1 . Indications

Drug Name: Epclusa (sofobuvir/velpatasvir)
Hepatitis C Indicated for the treatment of adult and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis, or with decompensated cirrhosis in combination with ribavirin.
Drug Name: Harvoni (ledipasvir/sofosbuvir) and Harvoni Pak
Hepatitis C Indicated for the treatment of HCV in adults and pediatric patients 3 years of age and older for genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis, genotype 1 infection with decompensated cirrhosis, in combination with ribavirin, or with genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin.
Drug Name: Mavyret (glecaprevir/pibrentasvir)

Hepatitis C Indicated for the treatment of adult and pediatric patients 3 years and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). **Hepatitis C** Indicated for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.
Drug Name: Sovaldi (sofosbuvir) and Sovaldi Pak
Hepatitis C Indicated for the treatment of adult patients with genotype 1, 2, 3, or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen and pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV without cirrhosis or with compensated cirrhosis in combination with ribavirin.
Drug Name: Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
Hepatitis C Indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor or genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.
Drug Name: Zepatier (elbasvir/grazoprevir)
Hepatitis C Indicated for treatment of chronic HCV genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg. **Hepatitis C** Indicated for use with ribavirin in certain patient populations.

2 . Criteria

Product Name:Mavyret, Mavyret Pak [a]	
Diagnosis	Acute Hepatitis C
Approval Length	8 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of acute hepatitis C infection

AND

2 - Patient is treatment-naïve

AND

3 - Patient is not receiving Mavyret in combination with another hepatitis C virus (HCV) direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir)]

AND

4 - Provider attests to BOTH of the following:

- It is inappropriate for the patient to delay treatment to allow for potential spontaneous clearance of HCV
- Patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mavyret, Mavyret Pak [a]	
Diagnosis	Chronic Hepatitis C
Approval Length	refer to Chart 1 - Mavyret
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

AND

3 - ALL of the following:

- The request is for Mavyret
- Patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir)]
- The requested regimen is an approvable regimen, as outlined below, based on patient genotype and characteristics

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Epclusa, sofosbuvir/velpatasvir (AG of Epclusa), Epclusa Pak [a]	
Diagnosis	Chronic Hepatitis C
Approval Length	refer to Chart 2 -Epclusa
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

AND

3 - ALL of the following:

- The request is for Epclusa or sofosbuvir/velpatasvir (AG of Epclusa)
- Patient is not receiving Epclusa in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), Sovaldi (sofosbuvir)]
- The requested regimen is an approvable regimen, as outlined below, based on patient genotype and characteristics

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Harvoni, ledipasvir/sofosbuvir (AG of Harvoni), or Harvoni Pak [a]	
Diagnosis	Chronic Hepatitis C
Approval Length	refer to Chart 3 - Harvoni
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

AND

3 - ALL of the following:

- The request is for Harvoni, ledipasvir/sofosbuvir (AG of Harvoni), or Harvoni Pak
- Patient is genotype 1, 4, 5, or 6

- Patient is not receiving Harvoni or ledipasvir/sofosbuvir (AG of Harvoni) in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Mavyret (glecaprevir/pibrentasvir), Sovaldi (sofosbuvir)]
- The requested regimen is an approvable regimen, as outlined in Chart 3 - Harvoni, based on patient genotype and characteristics

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Sovaldi or Sovaldi Pak [a]	
Diagnosis	Chronic Hepatitis C
Approval Length	refer to Chart 4 - Sovaldi
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

AND

3 - ALL of the following

- The request is for Sovaldi or Sovaldi Pak
- Patient is genotype 1, 2, 3, or 4
- Patient is not receiving Sovaldi in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir)]
- The requested regimen is an approvable regimen, as outlined in Chart 4 - Sovaldi, based on patient genotype and characteristics

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vosevi [a]	
Diagnosis	Chronic Hepatitis C
Approval Length	refer to Chart 6 - Vosevi
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

AND

3 - ALL of the following

3.1 The request is for Vosevi

AND

3.2 The patient is without cirrhosis or has compensated cirrhosis (Child-Pugh A)

AND

3.3 Patient is not receiving Vosevi in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), Sovaldi (sofosbuvir)]

AND

3.4 The requested regimen is an approvable regimen, as outlined below, based on patient genotype and characteristics

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zepatier [a]	
Diagnosis	Chronic Hepatitis C
Approval Length	refer to Chart 7 - Zepatier
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

AND

3 - ALL of the following

- The request is for Zepatier
- Patient is genotype 1a, 1b, or 4
- Patient is not receiving Zepatier in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), Sovaldi (sofosbuvir)]
- The requested regimen is an approvable regimen, as outlined in Chart 7 - Zepatier, based on patient genotype and characteristics

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Chart 1 - Mavyret

Treatment Naïve Patients

HCV Genotype	Treatment Duration	
	No cirrhosis	Compensated cirrhosis (Child-Pugh A)
1, 2, 3, 4, 5, or 6	8 weeks	8 weeks

Treatment Experienced Patients

		Treatment Duration	
HCV Genotype	**Patients previously treated with a regimen containing:**	**No cirrhosis**	**Compensated cirrhosis (Child-Pugh A)**
1	An NS5A inhibitor[1] without prior treatment with an NS3/4A protease inhibitor	16 weeks	16 weeks
	An NS3/4A PI[2] without prior treatment with an NS5A inhibitor	12 weeks	12 weeks
1, 2, 4, 5, or 6	PRS[3]	8 weeks	12 weeks
3	PRS[3]	16 weeks	16 weeks

Kidney or LiverTransplant Recipients

HCV Genotype	Treatment Duration	
	No cirrhosis	Compensated cirrhosis (Child-Pugh A)
1, 2, 3, 4, 5, or 6	12 week	12 weeks

1. In clinical trials, subjects were treated with prior regimens containing ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.

2. In clinical trials, subjects were treated with prior regimens containing simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin.

3. PRS = prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.

Chart 2 - Epclusa

Patient Population	Recommended Treatment Regimen
Patients without cirrhosis and patients with compensated cirrhosis (Child-Pugh A)	EPCLUSA for 12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	EPCLUSA + ribavirin for 12 weeks

Chart 3 - Harvoni

Recommended treatment regimen and duration:

Genotype	Patient Population	Regimen and Duration
Genotype 1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks*
	Treatment-experienced without cirrhosis	HARVONI 12 weeks
	Treatment-experienced with compensated cirrhosis (Child-Pugh A)	HARVONI 24 weeks**

	Treatment-naïve and treatment-experienced with decompensated cirrhosis (Child-Pugh B or C)	HARVONI + ribavirin 12 weeks
Genotype 1 or 4	Treatment-naïve and treatment-experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	HARVONI + ribavirin 12 weeks
Genotype 4, 5, or 6	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks

*HARVONI for 8 weeks can be considered in treatment-naïve genotype 1 patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL

**HARVONI + ribavirin for 12 weeks can be considered in treatment-experienced genotype 1 patients with cirrhosis who are eligible for ribavirin

Chart 4 - Sovaldi

Recommended Adult Treatment Regimen and Duration

	Adult Patient Population	**Regimen and Duration**
Genotype 1 or 4	Treatment naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + peginterferon alfa + ribavirin 12 weeks
Genotype 2	Treatment naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + ribavirin 12 weeks
Genotype 3	Treatment naïve and treatment experienced without cirrhosis or with	SOVALDI + ribavirin 24 weeks

	compensated cirrhosis (Child-Pugh A)	

SOVALDI in combination with ribavirin for 24 weeks can be considered for adult patients with genotype 1 infection who are interferon ineligible.

SOVALDI should be used in combination with ribavirin for treatment of HCV in adult patients with hepatocellular carcinoma awaiting liver transplantation for up to 48 weeks or until liver transplantation, whichever occurs first.

Recommended Treatment Regimen and Duration for Pediatric Patients 3 Years of Age and Older

	Pediatric Patient Population 3 Years of Age and Older	**Regimen and Duration**
Genotype 2	Treatment naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + ribavirin 12 weeks
Genotype 3	Treatment naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + ribavirin 24 weeks

Chart 6- Vosevi

Genotype	**Patients previously treated with an HCV regimen containing:**	**VOSEVI Duration**
1, 2, 3, 4, 5, or 6	An NS5A inhibitor[1]	12 weeks
1a or 3	Sofosbuvir without an NS5A inhibitor[2]	12 weeks

1. In clinical trials, prior NS5A inhibitor experience included daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir.

2. In clinical trials, prior treatment experience included sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir).

Chart 7 - Zepatier

Dosage Regimens and Durations for ZEPATIER in Patients with Genotype 1 or 4 HCV with or without Cirrhosis

Patient Population	Treatment	Duration
Genotype 1a: treatment naïve or PegIFN/RBV experienced* without baseline NS5A polymorphisms+	ZEPATIER	12 weeks
Genotype 1a: treatment naïve or PegIFN/RBV experienced* with baseline NS5A polymorphisms+	ZEPATIER + ribavirin	16 weeks
Genotype 1b: treatment naïve or PegIFN/RBV experienced*	ZEPATIER	12 weeks
Genotype 1a or 1b: PegIFN/RBV/PI experienced++	ZEPATIER + ribavirin	12 weeks
Genotype 4: treatment naïve	ZEPATIER	12 weeks
Genotype 4: PegIFN/RBV experienced*	ZEPATIER + ribavirin	16 weeks

*Peginterferon alfa + ribavirin

+Polymorphisms at amino acid positions 28, 30, 31, or 93

++Peginterferon alfa + ribavirin + HCV NS3/4 A protease inhibitor

Background

Epclusa (sofosbuvir/velpatasvir) is indicated for the treatment of adult and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6

infection without cirrhosis or with compensated cirrhosis, or with decompensated cirrhosis in combination with ribavirin.

Harvoni and Harvoni Pak (ledipasvir/sofosbuvir) are indicated for the treatment of HCV in adults and pediatric patients 3 years of age and older for genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis, genotype 1 infection with decompensated cirrhosis, in combination with ribavirin, or with genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin.

Mavyret (glecaprevir/pibrentasvir) is indicated for the treatment of adult and pediatric patients 3 years and older with acute or chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). Mavyret is also indicated for the treatment of adult and pediatric patients 3 years and older or with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

Sovaldi and Solvandi Pak (sofosbuvir) are indicated for the treatment of adult patients with genotype 1, 2, 3, or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen and pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV without cirrhosis or with compensated cirrhosis in combination with ribavirin.

Vosevi (sofosbuvir/velpatasvir/voxilaprevir) is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor or genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.

Zepatier (elbasvir/grazoprevir) is indicated for treatment of chronic HCV genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg. Zepatier is indicated for use with ribavirin in certain patient populations.

Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may be in place.

4 . References

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2022.
2. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
3. Mavyret [package insert]. North Chicago, IL: AbbVie, Inc.; June 2025.
4. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2024.
5. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.
6. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co.; May 2022.
7. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. https://www.hcvguidelines.org/. Accessed September 8, 2025.

5 . Revision History

Date	Notes
12/1/2025	Simplified Vosevi criteria without change to clinical intent. Removed Zepatier as an example therapy due to removal from market but retai ned criteria as it is not yet obsolete. Updated references.

Hetlioz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-555211
Guideline Name	Hetlioz
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	05/21/2021 ; 12/15/2021 ; 12/14/2022 ; 12/14/2022 ; 01/17/2024 ; 03/19/2025 ; 3/18/2026

1 . Indications

Drug Name: Hetlioz (tasimelteon)
Non-24-hour sleep-wake disorder Indicated for the treatment of non-24-hour sleep-wake disorder in adults and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older. Hetlioz LQ is an oral suspension and is indicated for the treatment of nighttime sleep disturbances in SMS in pediatric patients 3 years to 15 years of age.

2 . Criteria

Product Name:Brand Hetlioz, generic tasimelteon, Hetlioz LQ [a]

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Diagnosis of non-24-hour sleep wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome)
- Patient is totally blind (has no light perception)
- Prescribed by or in consultation with a specialist in sleep disorders

OR

2 - BOTH of the following:

- Diagnosis of nighttime sleep disturbances in Smith-Magenis-Syndrome (SMS)
- Prescribed by or in consultation with a specialist in sleep disorders

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Brand Hetlioz, generic tasimelteon, Hetlioz LQ [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Hetlioz or Hetlioz LQ therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply

3 . Background

Benefit/Coverage/Program Information
Background: Hetlioz is a melatonin receptor agonist indicated for the treatment of non-24-hour sleep-wake disorder in adults and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older. Hetlioz LQ is an oral suspension and is indicated for the treatment of nighttime sleep disturbances in SMS in pediatric patients 3 years to 15 years of age. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc.; January 2024.
2. American Academy of Sleep Medicine. (2015). Clinical practice guideline for the treatment of intrinsic circadian rhythm sleep–wake disorders: Advanced sleep–wake phase disorder (ASWPD), delayed sleep–wake phase disorder (DSWPD), non 24 hour sleep–wake rhythm disorder (N24SWD), and irregular sleep–wake rhythm disorder (ISWRD): An update for 2015. American Academy of Sleep Medicine.
3. Auger RR, Burgess HJ, Emens JS, et al. Clinical Practice Guidelines for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Phase Disorder (DSWPD), Non-24-Hour Sleep-Wak Rhythm Disorder (N24SWD), and Irregular Sleep-Wake Rhythm Disorder (ISWRD) J Clin Sleep Med 2015;11(10):1199 –1236.
4. Rajaratnam SM, Polymeropoulos MH, Fisher DM, et al. Melatonin agonist tasimelteon (VEC-162) for transient insomnia after sleep-time shift: two randomised controlled multicentre trials. Lancet. 2009 Feb 7;373(9662):482-91.

5 . Revision History

Date	Notes
3/18/2026	Annual review. Updated references.

Hycamtin

Prior Authorization Guideline

Guideline ID	GL-436512
Guideline Name	Hycamtin
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 08/19/2022 ; 11/18/2022 ; 11/17/2023 ; 11/22/2024 ; 11/21/2025

1 . Indications

Drug Name: Hycamtin (topotecan hydrochloride)
Relapsed small cell lung cancer Indicated for the treatment of patients with relapsed small cell lung cancer.

2 . Criteria

Product Name:Hycamtin [a]	
Diagnosis	Small cell lung cancer (SCLC)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of small cell lung cancer (SCLC)

AND

2 - Patient has experienced a relapse of disease after initial first-line chemotherapy (e.g., cisplatin with etoposide)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Hycamtin [a]	
Diagnosis	Small cell lung cancer (SCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Hycamtin therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Hycamtin [a]	
Diagnosis	Merkel cell carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Merkel cell carcinoma

AND

2 - Patient has a contraindication to or disease has progressed on anti-PD-L1 or anti-PD-1 therapy

AND

3 - ONE of the following:

- Disease is regional N+
- Disease is M1 disseminated

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Hycamtin [a]	
Diagnosis	Merkel cell carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Hycamtin therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Hycamtin [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Hycamtin will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Hycamtin [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Hycamtin (topotecan hydrochloride) is a topoisomerase inhibitor indicated for the treatment of patients with relapsed small cell lung cancer. The National Cancer Comprehensive Network (NCCN) also recommends Hycamtin may be considered as single-agent treatment (useful in certain circumstances) for M1 disseminated or regional N+ disease with or without surgery and/or radiation therapy if anti-PD-L1 or anti-PD-1 therapy is contraindicated or disease has progressed on anti-PD-L1 or anti-PD-1 therapy. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Hycamtin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2018.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 1, 2025.

5 . Revision History

Date	Notes
11/3/2025	Annual review. Updated Merkel cell carcinoma criteria based on curr ent NCCN recommendations. Updated background.

Ibrance

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-516229
Guideline Name	Ibrance
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	2/16/2024
P&T Revision Date:	05/21/2021 ; 05/20/2022 ; 08/19/2022 ; 02/17/2023 ; 02/20/2025 ; 2/20/2026

1 . Indications

Drug Name: Ibrance (palbociclib)
Breast cancer Indicated for the treatment of hormone receptor (HR)-positive human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy, or in combination with Faslodex (fulvestrant) in patients with disease progression following endocrine therapy.

2 . Criteria

Product Name:Ibrance [a]

Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, recurrent, or metastatic breast cancer

AND

2 - Disease is hormone-receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - One of the following:

4.1 Used in combination with an aromatase inhibitor (e.g. anastrozole, letrozole, exemestane)

OR

4.2 Used in combination with Faslodex (fulvestrant)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ibrance [a]	
Diagnosis	Breast Cancer

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Ibrance therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ibrance [a]	
Diagnosis	Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of unresectable retroperitoneal WD-DDLS	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ibrance [a]	
Diagnosis	Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Ibrance therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ibrance [a]	
Diagnosis	Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Diagnosis of endometrial carcinoma
- Disease is recurrent or metastatic
- Used in combination with letrozole

OR

2 - ALL of the following

2.1 Diagnosis of uterine sarcoma

AND

2.2 Positive for CDK4 gene amplification

AND

2.3 Disease is ONE of the following:

• Advanced • Inoperable • Recurrent/metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ibrance [a]	
Diagnosis	Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Ibrance therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ibrance [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Ibrance will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ibrance [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Ibrance therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Ibrance® (palbociclib) is a kinase inhibitor indicated for the treatment of hormone receptor (HR)-positive human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy, or in combination with Faslodex® (fulvestrant) in patients with disease progression following endocrine therapy. The use of an aromatase inhibitor in men with breast cancer is ineffective without concomitant suppression of testicular steroidogenesis. The National Comprehensive Cancer Network (NCCN) recommends the use of Ibrance as single-agent therapy for

unresectable retroperitoneal well-differentiated/dedifferentiated liposarcoma (WD-DDLS), recurrent or metastatic endometrial carcinoma, and in certain uterine sarcomas.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Ibrance capsule [package insert]. New York, NY: Pfizer Labs; September 2023.
2. Ibrance tablets [package insert]. New York, NY: Pfizer Labs; September 2023.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed December 16, 2025.

5 . Revision History

Date	Notes
2/10/2026	Annual review. Updated coverage criteria to include new section for u terine neoplasms. Updated references.

Iclusig

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436513
Guideline Name	Iclusig
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	11/19/2021
P&T Revision Date:	08/19/2022 ; 11/18/2022 ; 11/17/2023 ; 11/22/2024 ; 11/21/2025

1 . Indications

Drug Name: Iclusig (ponatinib)
Chronic Myeloid Leukemia (CML) Indicated for treatment of patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia or Ph+ ALL for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated. [1] **Acute Lymphoblastic Leukemia (Ph+ ALL)** Indicated for treatment of patients with T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). **Myeloid/Lymphoid Neoplasms** Indicated for the treatment of myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 or ABL1 rearrangements.

2 . Criteria

Product Name:Iclusig [a]	
Diagnosis	Chronic Myelogenous / Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myelogenous/ myeloid leukemia (CML)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Disease is in the chronic phase

AND

2.1.2 ONE of the following:

- Patient with resistance or intolerance to TWO or more tyrosine kinase inhibitor (TKI) therapies [e.g., imatinib mesylate, Sprycel (dasatinib), or Tasigna (nilotinib)]^
- Patient has no identifiable BCR::ABL1 mutations

OR

2.2 Confirmed documentation of T315I mutation

OR

2.3 Both of the following:

• Disease is in the accelerated or blast phase • No other kinase inhibitors are indicated	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines.

Product Name:Iclusig [a]	
Diagnosis	Chronic Myelogenous / Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Iclusig therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Iclusig [a]	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL)	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Iclusig [a]	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Iclusig therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Iclusig [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia **AND** **2** - ONE of the following:	

• Patient has a FGFR1 rearrangement • Patient has an ABL1 rearrangement

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Iclusig [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Iclusig therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Iclusig [a]	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of gastrointestinal stromal tumor (GIST)	

AND

2 - Disease is ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Recurrent/metastatic disease after progression on approved therapies (e.g. imatinib, sunitinib, regorafenib, and standard dose ripretinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Iclusig [a]	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Iclusig therapy.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Iclusig [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Iclusig will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Iclusig [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Iclusig therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Iclusig (ponatinib) is a kinase inhibitor indicated for the treatment of patients with newly diagnosed Philadelphia chromosome-positive acute Lymphoblastic Leukemia (Ph+ ALL), in combination with chemotherapy, as monotherapy in Ph+ ALL for whom no other kinase inhibitors are indicated, or T315I-positive Ph+ ALL. Iclusig is also indicated in chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior

kinase inhibitors, accelerated phase (AP) or blast phase (BP) CML for whom no other kinase inhibitors are indicated, chronic phase CML with no identifiable BCR::ABL1 mutations, or T315I-positive CML (chronic phase, accelerated phase, or blast phase).

The National Comprehensive Cancer Network (NCCN) also recommends Iclusig for the treatment of myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 or ABL1 rearrangements, and gastrointestinal stromal tumors .

Additional Clinical Programs:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Iclusig [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc; March 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed September 18, 2025.

5 . Revision History

Date	Notes
11/3/2025	Annual review. Updated CML criteria based on NCCN recommendations. Updated background and references.

Idhifa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399220
Guideline Name	Idhifa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	09/21/2022 ; 09/20/2023 ; 09/18/2024 ; 9/25/2025

1 . Indications

Drug Name: Idhifa (enasidenib)
Relapsed or refractory acute myeloid leukemia (AML) Indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test.

2 . Criteria

Product Name:Idhifa [a]	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is IDH2 mutation-positive

AND

3 - ONE of the following:

- Disease is relapsed or refractory
- Used as low-intensity treatment induction when not a candidate for intensive induction therapy
- Used for consolidation therapy as continuation of low-intensity regimen used for induction
- Used as follow-up after induction therapy following response to previous lower intensity therapy with the same regimen

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Idhifa [a]	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Idhifa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Idhifa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Idhifa will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Idhifa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Idhifa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Idhifa (enasidenib) is an isocitrate dehydrogenase-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test. The National Cancer Comprehensive Network (NCCN) also recommends the use of Idhifa as a single agent, or in combination with azacitidine, in patients with IDH2-mutated AML for treatment induction when not a candidate for intensive induction therapy, as follow-up after induction therapy following response to previous lower intensity therapy with the same regimen, or as consolidation therapy as continuation of low-intensity regimen used for induction. Idhifa has a black box warning for differentiation syndrome with or without concomitant hyperleukocytosis. Please see full prescribing information for additional details. **Additional Clinical Programs:** • Supply limits may be in place. • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Idhifa [package insert]. Summit, NJ: Celgene Corporation; January 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed July 26, 2024.

5 . Revision History

Date	Notes
9/17/2025	Annual review. No changes to coverage criteria. Updated references.

Imbruvica

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-405348
Guideline Name	Imbruvica
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 10/20/2021 ; 10/19/2022 ; 10/18/2023 ; 10/16/2024 ; 10/15/2025

1 . Indications

Drug Name: Imbruvica (ibrutinib)
Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL). **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma with 17p deletion** Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) with 17p deletion **Waldenström's Macroglobulinemia** Indicated for the treatment of adult patients with Waldenström's macroglobulinemia. **Chronic Graft versus Host Disease** Indicated for the treatment of patients with chronic graft-versus-host disease after failure of one or more lines of systemic therapy.

Other Uses The National Cancer Comprehensive Network (NCCN) also recommends the use of Imbruvica for the B-cell lymphoma types: extranodal marginal zone lymphoma (EMZL) of the stomach and of nongastric sites (noncutaneous), mantle cell lymphoma (MCL),gastric and nongastric MALT, diffuse large B-cell, AIDSHIV-related B-cell, high grade B-cell lymphoma, and post-transplant lymphoproliferative disorders. NCCN also recommends its use for primary CNS lymphoma and hairy cell leukemia.

2 . Criteria

Product Name:Imbruvica [a]	
Diagnosis	B-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of mantle cell lymphoma (MCL)

AND

1.2 ONE of the following:

- Patient has received at least one prior therapy for MCL
- Used in pre-treatment therapy in combination with Rituxan (rituximab) to limit the number of cycles with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen

OR

2 - Diagnosis of ONE of the following:

- Chronic Lymphocytic Leukemia (CLL)

- Small Lymphocytic Lymphoma (SLL)

OR

3 - BOTH of the following:

3.1 Diagnosis of ONE of the following:

- Post-transplant lymphoproliferative disorders
- Extranodal marginal zone lymphoma (EMZL) of the stomach
- EMZL of nongastric sites (noncutaneous)
- Diffuse large B-cell lymphoma (non-germinal center DLBCL)
- HIV-related B-cell lymphoma
- High grade B-cell lymphoma
- Hairy cell leukemia
- Nodal or splenic marginal zone lymphoma (MZL)

AND

3.2 Used as second-line or a subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Imbruvica [a]	
Diagnosis	B-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Imbruvica therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Imbruvica [a]	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Imbruvica [a]	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Imbruvica therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Imbruvica [a]	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic graft versus host disease **AND** **2** - History of failure of at least one other systemic therapy (e.g. corticosteroids, mycophenolate, etc.)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Imbruvica [a]	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient shows evidence of positive clinical response while on Imbruvica therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Imbruvica [a]	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary CNS lymphoma

AND

2 - One of the following:

- Used as second-line or a subsequent therapy
- Used as induction therapy if patient is unsuitable or intolerant to high-dose methotrexate

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Imbruvica [a]	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Imbruvica therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Imbruvica [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Imbruvica will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Imbruvica [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Imbruvica therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Imbruvica (ibrutinib) is a kinase inhibitor indicated for the treatment of adult patients with the following: chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL); CLL/SLL with 17p deletion; and Waldenström's macroglobulinemia (WM). Imbruvica is also FDA

approved for the treatment of adult and pediatric patients age 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.

The National Cancer Comprehensive Network (NCCN) also recommends the use of Imbruvica for the B-cell lymphoma types: extranodal marginal zone lymphoma (EMZL) of the stomach and of nongastric sites (noncutaneous), mantle cell lymphoma (MCL), diffuse large B-cell, HIV-related B-cell, high grade B-cell lymphoma, and post-transplant lymphoproliferative disorders. NCCN also recommends its use for primary CNS lymphoma and hairy cell leukemia.

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limits may be in place.

4 . References

1. Imbruvica [package insert]. South San Francisco, CA: Pharmacyclics, LLC. December 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia. Accessed September 10, 2025

5 . Revision History

Date	Notes
9/30/2025	Annual review. Simplified criteria for non-germinal center diffuse large B-cell lymphoma. Updated references.

Ingrezza

Prior Authorization Guideline

Guideline ID	GL-237192
Guideline Name	Ingrezza
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	6/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	11/16/2018 ; 02/19/2021 ; 06/16/2021 ; 06/21/2023 ; 07/19/2023 ; 10/18/2023 ; 12/18/2024 ; 4/16/2025

1 . Indications

Drug Name: Ingrezza (valbenazine)
Tardive dyskinesia Indicated for the treatment of adults with tardive dyskinesia.

2 . Criteria

Product Name:Ingrezza [a]	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia

AND

2 - One of the following:

- Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication
- Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ingrezza [a]	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ingrezza therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ingrezza [a]	
Diagnosis	Chorea associated with Huntington’s disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea associated with Huntington's disease

AND

2 - Prescribed by or in consultation with ONE of the following:

- Neurologist
- Psychiatrist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ingrezza [a]	
Diagnosis	Chorea associated with Huntington’s disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Ingrezza therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Ingrezza is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Ingrezza [package insert]. San Diego, CA: Neurocrine Biosciences, Inc. February 2025.
2. Hauser RA, Factor SA, Marder SR, et al. Kinect 3: A phase 3 randomized, double-blind, placebo-controlled trial of valbenazine for tardive dyskinesia. American Journal of Psychiatry. May 2017. 174:5.

5 . Revision History

Date	Notes
4/7/2025	Annual review with no change to clinical criteria. References updated .

Inlyta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-374428
Guideline Name	Inlyta
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	09/21/2022 ; 09/20/2023 ; 09/18/2024 ; 9/25/2025

1 . Indications

Drug Name: Inlyta (axitinib)
Advanced renal cell carcinoma (RCC) Indicated for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy. Indicated in combination with either avelumab or pembrolizumab for the first-line treatment of patients with advanced RCC. **Off Label Uses: Other indications** The NCCN also recommends Inlyta in thymic carcinomas in certain settings for those unable to tolerate first-line therapy, for recurrent, advanced, or metastatic disease, and as second-line therapy, in combination with avelumab. NCCN also recognizes Inlyta as preferred therapy in combination with pembrolizumab for treatment of alveolar soft part sarcoma (ASPS) and as first-line treatment of relapsed or stage IV renal cell carcinoma.

2 . Criteria

Product Name:Inlyta [a]	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following

1.1 Diagnosis of advanced renal cell carcinoma

AND

1.2 ONE of the following:

1.2.1 Patient has failed one prior systemic therapy

OR

1.2.2 Inlyta will be used in combination with Bavencio (avelumab) or Keytruda (pembrolizumab)

OR

2 - Diagnosis of relapsed or stage IV renal cell carcinoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Inlyta [a]	
Diagnosis	Renal Cell Carcinoma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inlyta therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Inlyta [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Follicular Carcinoma
- Oncocytic Carcinoma
- Papillary Carcinoma

AND

2 - Disease is ONE of the following:

- Recurrent and unresectable
- Persistent
- Metastatic

AND **3** - Disease is not amenable to radioactive iodine treatment

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Inlyta [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Inlyta therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Inlyta [a]	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of salivary gland tumor	

AND

2 - Disease is ONE of the following:

- Recurrent and unresectable
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Inlyta [a]	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inlyta therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Inlyta [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of alveolar soft part sarcoma (ASPS) **AND** **2** - Inlyta will be used in combination with Keytruda (pembrolizumab)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Inlyta [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Inlyta therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Inlyta [a]	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Thymic Carcinoma

AND

2 - ONE of the following:

- Used as first-line therapy for those who cannot tolerate first-line combination regimens
- Used as second-line therapy

AND

3 - Used in combination with Bavencio (avelumab)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Inlyta [a]	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inlyta therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Inlyta [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Inlyta will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Inlyta [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Inlyta therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Inlyta® (axitinib) is a kinase inhibitor indicated for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy. It is also indicated in

combination with either avelumab or pembrolizumab for the first-line treatment of patients with advanced RCC.[1] The NCCN (National Comprehensive Cancer Network) recommends the use of Inlyta for treatment of unresectable, metastatic, or recurrent salivary gland tumors and follicular, oncocytic, and papillary carcinomas. The NCCN also recommends Inlyta in thymic carcinomas in certain settings for those unable to tolerate first-line therapy, for recurrent, advanced, or metastatic disease, and as second-line therapy, in combination with avelumab. NCCN also recognizes Inlyta as preferred therapy in combination with pembrolizumab for treatment of alveolar soft part sarcoma (ASPS) and as first-line treatment of relapsed or stage IV renal cell carcinoma.[2]

Additional Clinical Programs:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Inlyta [package insert]. New York, NY: Pfizer, Inc.; July 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 30, 2025.

5 . Revision History

Date	Notes
9/3/2025	Annual review. Added new criteria for Thymic carcinoma based on N CCN recommendations. Updated background. Updating footnote of p olicy with no changes to clinical intent.

Interferon Alfa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412233
Guideline Name	Interferon Alfa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 11/19/2021 ; 08/19/2022 ; 10/19/2022 ; 12/13/2023 ; 02/16/2024 ; 10/01/2024 ; 9/17/2025

1 . Indications

Drug Name: Pegasys (peginterferon alfa-2a)
Chronic hepatitis C Indicated for the treatment of chronic hepatitis C (CHC) as part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs in patients 5 years of age and older with compensated liver disease. Pegasys monotherapy is indicated for CHC only if patient has contraindication to or significant intolerance to other HCV antiviral drugs. **HBeAg positive and HBeAg negative chronic hepatitis B** Indicated in the treatment of adult patients with HBeAg positive and HBeAg negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation.

2 . Criteria

Product Name:Pegasys [a]	
Diagnosis	Treatment of Chronic Hepatitis B
Approval Length	48 Week(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic Hepatitis B infection **AND** **2** - Patient does not have decompensated liver disease*	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Defined as Child-Pugh Class B or C

Product Name:Pegasys [a]	
Diagnosis	Treatment of Chronic Hepatitis C
Approval Length	48 Week(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic hepatitis C infection **AND** **2** - Patient does not have decompensated liver disease*	

AND **3** - Will be used as part of a combination antiviral treatment regimen

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Defined as Child-Pugh Class B or C

Product Name:Pegasys [a]	
Diagnosis	For Diagnoses Other Than Hepatitis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Chronic myeloid leukemia (CML)
- Hairy cell leukemia
- Erdheim-Chester disease (ECD)
- Myeloproliferative neoplasms (MPNs) such as essential thrombocythemia (ET), polycythemia vera (PV), or myelofibrosis (MF)
- Mycosis fungoides/Sezary syndrome
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders
- Systemic mastocytosis
- Adult T-cell leukemia/lymphoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Pegasys, [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Guideline Type	Prior Authorization
Approval Criteria **1** - The drug will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Pegasys (peginterferon alfa-2a) is an inducer of the innate immune response indicated for the treatment of chronic hepatitis C (CHC) as part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs in patients 5 years of age and older with compensated liver disease. Pegasys monotherapy is indicated for CHC only if patient has contraindication to or significant intolerance to other HCV antiviral drugs. Pegasys is indicated in the treatment of adult patients with HBeAg positive and HBeAg negative chronic hepatitis B (CHB) infection who have compensated liver disease and evidence of viral replication and liver inflammation. It is also indicated for the treatment of non-cirrhotic pediatric patients 3 years of age and older with HBeAg-positive CHB and evidence of viral replication and elevations in serum alanine aminotransferase (ALT). [3]

The National Comprehensive Cancer Network (NCCN) also recommends the use of Pegasys (peginterferon alfa-2a) in patients with chronic myeloid leukemia (CML), Erdheim-Chester disease (ECD), myeloproliferative neoplasms (MPNs) such as essential thrombocytopenia (ET), polycythemia vera (PV), and myelofibrosis (PM), and systemic mastocytosis, as well as mycosis fungoides/Sezary syndrome, hairy cell leukemia, primary cutaneous CD30+ T-cell lymphoproliferative disorders, and adult T-cell leukemia/lymphoma. [2,6-9]

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4 . References

1. The NCCN Drugs and Biologics Compendium (NCCN Compendiu). Accessed August 20, 2024 at https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia
2. Pegasys [package insert]. South San Francisco, CA: Genetech USA, Inc.; March 2021.

5 . Revision History

Date	Notes
10/7/2025	Removed Intron A as it is discontinued. Updated references.

Interstitial Lung Disease Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-516230
Guideline Name	Interstitial Lung Disease Agents
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	04/21/2021 ; 09/15/2021 ; 04/20/2022 ; 09/21/2022 ; 03/15/2023 ; 08/18/2023 ; 03/20/2024 ; 05/16/2025 ; 2/20/2026

1 . Indications

Drug Name: Esbriet (pirfenidone)
Idiopathic Pulmonary Fibrosis (IPF) Indicated for the treatment of idiopathic pulmonary fibrosis (IPF).
Drug Name: Ofev (nintedanib)
Idiopathic Pulmonary Fibrosis (IPF) Indicated for in the treatment of idiopathic pulmonary fibrosis (IPF). **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)** Indicated for slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD). **Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype**

Indicated for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype
Drug Name: Jascayd (nerandomilast)
Idiopathic Pulmonary Fibrosis (IPF) Indicated for in the treatment of idiopathic pulmonary fibrosis (IPF). **Progressive Pulmonary Fibrosis** Indicated for the treatment of progressive pulmonary fibrosis in adult patients.

2 . Criteria

Product Name:Brand Esbriet, Jascayd, Ofev, generic pirfenidone [a]	
Diagnosis	Idiopathic Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by BOTH of the following:

1.1 Exclusion of other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity), as documented by ICD-10 Code J84.112 (Idiopathic pulmonary fibrosis)

AND

1.2 ONE of the following:

- In patients NOT subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF [5]
- In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern reveal IPF or probable IPF [5]

AND

2 - ONE of the following:

2.1 The request is for Esbriet, Esbriet is not used in combination with Ofev.

OR

2.2 The request is for Ofev, Ofev is not used in combination with Esbriet.

OR

2.3 The request is for Jascayd, ONE of the following:

- History of trial and failure, or intolerance, to Esbriet or Ofev
- Contraindication to both Esbriet and Ofev

AND

3 - Prescribed by a pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Esbriet, Jascayd, Ofev, generic pirfenidone [a]	
Diagnosis	Idiopathic Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - ONE of the following:

- The request is for Esbriet, Esbriet is not used in combination with Ofev
- The request is for Ofev, Ofev is not used in combination with Esbriet
- The request is for Jascayd

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ofev, Jascayd [a]	
Diagnosis	Progressive Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of progressive pulmonary fibrosis

AND

2 - At least TWO of the following criteria occurring within the past 12 months with no alternative explanation:

2.1 Worsening respiratory symptoms

OR

2.2 Physiological evidence of disease progression demonstrated by ONE of the following:

- Absolute decline in forced vital capacity (FVC) ≥ 5% predicted

- Absolute decline in diffusing capacity of the lungs for carbon monoxide (DLco) (corrected for Hb) ≥ 10% predicted

OR

2.3 Radiological evidence of disease progression by at least ONE of the following via HRCT:

- Increased extent or severity of traction bronchiectasis/bronchiolectasis
- Increased extent or increased coarseness of reticular abnormality
- Increased lobar volume loss
- New ground-glass opacity with traction bronchiectasis
- New fine reticulation
- New or increased honeycombing

AND

3 - Prescribed by a pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ofev, Jascayd [a]	
Diagnosis	Progressive Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by a pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ofev [a]	
Diagnosis	Systemic sclerosis-associated interstitial lung disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by BOTH of the following criteria:

1.1 ONE of the following:

1.1.1 Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

OR

1.1.2 At least TWO of the following:

- Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
- Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
- Telangiectasia
- Abnormal nailfold capillaries
- Pulmonary arterial hypertension
- Raynaud's phenomenon
- SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

AND

1.2 Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on HRCT, involving at least 10% of the lungs

AND **2** - Ofev is not being used in combination with Esbriet or pirfenidone **AND** **3** - Prescribed by a pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ofev [a]	
Diagnosis	Systemic sclerosis-associated interstitial lung disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ofev therapy

AND

2 - Ofev is not being used in combination with Esbriet or pirfenidone

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Esbriet (pirfenidone) is a pyridone inhibitor, Jascayd (nerandomilast) is a phosphodiesterase 4 (PDE4) inhibitor, and Ofev (nintedanib) is a kinase inhibitor that are indicated for the treatment of idiopathic pulmonary fibrosis (IPF). Ofev is also indicated for slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) and for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype. Jascayd is also indicated for the treatment of progressive pulmonary fibrosis in adult patients. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Esbriet [Prescribing Information]. South San Francisco, CA. Genentech USA, Inc. February 2023.
2. King TE, Bradford WZ, Castro-Benardini S, et al. A phase 3 trial of pirfenidone in patients with idiopathic pulmonary fibrosis. N Engl J Med. 2014;370:2083-92.
3. Noble PW, Albera C, Bradford WZ, et al. Pirfenidone in patients with idiopathic pulmonary fibrosis (CAPACITY): two randomized trials. Lancet. 2011;377:1760-69.
4. Ofev [Prescribing Information]. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals. October 2024.
5. Richeldi L, du Boise RM, Raghu G, et al. Efficacy and safety of nintedanib in idiopathic pulmonary fibrosis. N Engl J Med. 2014 May 29;370(22):2071-82.
6. Richeldi L, Cottin V, Flaherty KR, et al. Design of the INPULSIS trials: two phase 3 trials of nintedanib in patients with idiopathic pulmonary fibrosis. Resp Med. 2014;108:1023-1030.
7. Raghu G, Remy-Jardin M, Richeldi L, et al. Idiopathic Pulmonary Fibrosis (an Update) and Progressive Pulmonary Fibrosis in Adults: An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. Am J Respir Crit Care Med. 2022;205(9):e18-e47. doi:10.1164/rccm.202202-0399ST
8. Jascayd [Prescribing Information]. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. October 2024.
9. Lee, SJ. Overview of the Management of Adults with Interstitial Lung Disease. In: UpToDate, Dieffenbach P (Ed), UpToDate, Waltham, MN. Accessed on January 5, 2026.

5 . Revision History

Date	Notes
2/10/2026	Addition of Jascayd to program and addition of coverage criteria for p rogressive pulmonary fibrosis. Updated coverage criteria for idiopathi c pulmonary fibrosis to include Jascayd. Updated Ofev coverage crit eria by removing chronic fibrosing interstitial lung disease with progre ssive phenotype and including Ofev into the section for progressive p ulmonary fibrosis. Updated references.

Iqirvo

Prior Authorization Guideline

Guideline ID	GL-154206
Guideline Name	Iqirvo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2024
P&T Approval Date:	9/18/2024
P&T Revision Date:	

1 . Indications

Drug Name: Iqirvo (elafibranor)
Primary biliary cholangitis Indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.

2 . Criteria

Product Name:Iqirvo [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of primary biliary cholangitis

AND

2 - Patient does not have decompensated cirrhosis

AND

3 - ONE of the following^:

3.1 BOTH of the following:

- Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)
- Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)

OR

3.2 History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol)

AND

4 - Patient is not receiving Iqirvo in combination with Livdelzi (seladelpar) or Ocaliva (obeticholic acid)

AND

5 - Prescribed by one of the following:

- Hepatologist

• Gastroenterologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Iqirvo [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in ALP level from pre-treatment baseline (i.e., prior to Iqirvo therapy)

AND

2 - Patient does not have decompensated cirrhosis

AND

3 - Patient is not receiving Iqirvo in combination with Livdelzi (seladelpar) or Ocaliva (obeticholic acid)

AND

4 - Prescribed by one of the following:

- Hepatologist
- Gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Iqirvo (elafibranor) is a peroxisome proliferator-activated receptor (PPAR) agonist indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. This indication is approved under accelerated approval based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Use of Iqirvo is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy). [1] **Additional Clinical Rules:** • Supply limits may be in place. • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Iqirvo [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2024.

5 . Revision History

Date	Notes

9/3/2024	New program

Iressa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-405349
Guideline Name	Iressa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	10/20/2021 ; 10/19/2022 ; 06/21/2023 ; 10/18/2023 ; 10/16/2024 ; 10/15/2025

1 . Indications

Drug Name: Iressa (gefitinib)
Non-small cell lung cancer (NSCLC) Indicated as first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. **Off Label Uses: National Cancer Comprehensive Network (NCCN)** The National Cancer Comprehensive Network (NCCN) also recommends the use of Iressa in patients with NSCLC with EGFR S768I, L861Q, and/or G719X mutation positive tumors as well as patients with NSCLC with a known sensitizing EGFR mutation and associated brain metastases.

2 . Criteria

Product Name:Brand Iressa, generic gefitinib [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g, exon 20 S768I mutation, exon 18 G719X mutation, exon 21 L861Q mutation)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Iressa, generic gefitinib [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Iressa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Iressa, generic gefitinib [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of central nervous system (CNS) cancer with metastatic lesions

AND

2 - Iressa is active against primary (NSCLC) tumor with a known EGFR sensitizing mutation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Iressa, generic gefitinib [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Iressa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Iressa, generic gefitinib [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Iressa will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Iressa, generic gefitinib [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to Iressa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Iressa (gefitinib) is a tyrosine kinase inhibitor indicated as first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations [1] The National Cancer Comprehensive Network (NCCN) also recommends the use of Iressa in patients with NSCLC with EGFR S768I, L861Q, and/or G719X mutation positive tumors as well as patients with NSCLC with a known sensitizing EGFR mutation and associated brain metastases.[2] **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Iressa [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia . Accessed September 10, 2025.

5 . Revision History

Date	Notes
9/30/2025	Annual review. Added coverage criteria for recurrent or advanced NS CLC per NCCN recommendations. Updated reauthorization criteria w ording. Updated references.

Iron Chelators

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126557
Guideline Name	Iron Chelators
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 06/16/2021 ; 09/15/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Exjade (deferasirox), Jadenu (deferasirox)
Chronic iron overload due to blood transfusions (transfusional iron overload) Indicated for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older. The safety and efficacy of Exjade and Jadenu, when administered with other iron chelation therapy, have not been established. **Chronic iron overload due to non-transfusion dependent thalassemia syndromes** Indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion dependent thalassemia syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (dw) and a serum ferritin greater than 300 mcg/L.

2 . Criteria

Product Name:Brand Exjade, Brand Jadenu, generic deferasirox [a]	
Diagnosis	Chronic Iron Overload Due to Blood Transfusions (i.e., Transfusional Iron Overload)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic iron overload (e.g., sickle cell anemia, thalassemia, etc.) due to blood transfusion	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Exjade, Brand Jadenu, generic deferasirox [a]	
Diagnosis	Chronic Iron Overload Due to Blood Transfusions (i.e., Transfusional Iron Overload)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Exjade, Brand Jadenu, generic deferasirox [a]

Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndromes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic iron overload in non-transfusion dependent thalassemia (NTDT) syndrome

AND

2 - Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with Exjade or Jadenu

AND

3 - Patient has serum ferritin levels consistently greater than 300 mcg/L prior to initiation of treatment with Exjade or Jadenu

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Exjade, Brand Jadenu, generic deferasirox [a]	
Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndromes
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Exjade (deferasirox) and Jadenu (deferasirox) are iron chelating agents indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older. The safety and efficacy of deferasirox, when administered with other iron chelation therapy, have not been established. It is recommended that therapy with deferasirox be started when a patient has evidence of chronic transfusional iron overload, such as the transfusion of approximately 100 mL/kg of packed red blood cells (approximately 20 units for a 40-kg patient) and a serum ferritin consistently >1000 mcg/L. Deferasirox is also indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion dependent thalassemia (NTDT) syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L. This indication is based on achievement of an LIC less than 5 mg Fe/g dw. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Step therapy may be in place.

4 . References

1. Exjade [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

2. Jadenu [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

5 . Revision History

Date	Notes
6/21/2023	Updated references. Removed formulation notations because policy applies to all formulations of targeted drugs.
6/21/2023	Annual review. Added state mandate language.

Jakafi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436462
Guideline Name	Jakafi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	
P&T Revision Date:	11/21/2025

1 . Indications

Drug Name: Jakafi (ruxolitinib)
Myelofibrosis Indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults. **Polycythemia vera** Indicated in adult patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea. **Graft versus host disease (GVHD)** Indicated for the treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older and chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

2 . Criteria

Product Name:Jakafi [a]	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Symptomatic lower-risk myelofibrosis
- Intermediate or higher-risk myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

OR

2 - All of the following:

2.1 Diagnosis of myelofibrosis-associated anemia

AND

2.2 Presence of symptomatic splenomegaly and/or constitutional symptoms

AND

2.3 Given in combination with ONE of the following:

- Reblozyl (luspatercept)
- Erythropoetin stimulating agent (ESA) if serum EPO < 500 mU/mL
- Danazol

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name:Jakafi [a]	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name:Jakafi [a]	
Diagnosis	Polycythemia vera
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of polycythemia vera

AND

2 - History of failure, inadequate response, contraindication, or intolerance to one of the following^:

- Hydroxyurea
- Interferon therapy (e.g., Intron A, Pegasys)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy. ^Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines

Product Name:Jakafi [a]	
Diagnosis	Polycythemia vera
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name:Jakafi [a]	
Diagnosis	Essential thrombocythemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of essential thrombocythemia

AND

2 - Inadequate response or loss of response to ONE of the following:

- Hydroxyurea
- Pegasys (peginterferon alfa-2a)
- Agrylin (Anagrelide)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name:Jakafi [a]	
Diagnosis	Essential thrombocythemia
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name:Jakafi [a]	
Diagnosis	Graft versus host disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of acute GVHD
- Disease is steroid refractory

OR

2 - BOTH of the following:

- Diagnosis of chronic GVHD
- Failure of one or two lines of systemic therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Jakafi [a]

Diagnosis	Graft versus host disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of symptom improvement while on Jakafi

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Jakafi [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - Patient has a JAK2 rearrangement

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Jakafi [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Jakafi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Jakafi [a]	
Diagnosis	Myelodysplastic Syndromes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of chronic myelomonocytic leukemia (CMML)-2
- Use in combination with a hypomethylating agent (e.g., azacitidine, decitabine)

OR

2 - BOTH of the following:

- Diagnosis of myelodysplastic/myeloproliferative neoplasm (MDS/MPN) with neutrophilia
- Disease is positive for CSF3R or JAK2 mutation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Jakafi [a]	
Diagnosis	Myelodysplastic Syndromes
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Jakafi therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Jakafi [a]	
Diagnosis	Myeloproliferative Neoplasms
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of accelerated/blast phase myeloproliferative neoplasm **AND** **2** - Used for splenomegaly or other disease-related symptoms	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

	NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name:Jakafi [a]	
Diagnosis	Myeloproliferative Neoplasms
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name:Jakafi [a]	
Diagnosis	Pediatric Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pediatric acute lymphoblastic leukemia	

AND **2** - Used as a component of consolidation therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Jakafi [a]	
Diagnosis	Pediatric Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Jakafi therapy.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Jakafi [a]	
Diagnosis	Immunotherapy-Related Toxicities
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of CAR-T induced G4 cytokine release syndrome

- Disease is refractory to high-dose corticosteroids and anti-IL-6 therapy [e.g., Actemra (tocilizumab)]

OR

2 - BOTH of the following:

2.1 Diagnosis of immunotherapy related toxicities

AND

2.2 ONE of the following:

- Used in combination with Orencia (abatacept) for the management of concomitant myositis and myocarditis
- Used as additional therapy for hemophagocytic lymphohistiocytosis-like syndrome if no response to corticosteroids after 5 days

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Jakafi [a]	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of peripheral T-cell lymphoma
- Used as initial palliative intent therapy or second-line and subsequent therapy for relapsed/refractory disease

OR

2 - BOTH of the following:

2.1 ONE of the following diagnoses:

- T-cell large granular lymphocytic leukemia
- T-cell prolymphocytic leukemia
- Breast implant-associated anaplastic large cell lymphoma (ALCL)

AND

2.2 Used as second-line or subsequent therapy

OR

3 - BOTH of the following:

- Diagnosis of hepatosplenic T-cell lymphoma
- Used for refractory disease after two first-line therapy regimens

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Jakafi [a]	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Jakafi therapy.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Jakafi [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Jakafi will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Jakafi [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Jakafi therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Benefit/Coverage/Program Information Jakafi (ruxolitinib) is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults. It is also indicated in adult patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea. It is also indicated for the treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older and chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. The National Cancer Comprehensive Network (NCCN) also recommends Jakafi for the treatment of polycythemia vera, essential thrombocythemia, accelerated/blast phase myeloproliferative neoplasm, lymphoid, myeloid/lymphoid neoplasms with eosinophilia and JAK2 rearrangement, myelodysplastic syndromes, pediatric acute lymphoblastic leukemia, T-Cell Lymphomas, and management of CAR-T-cell and immunotherapy-related toxicities. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Jakafi [package insert]. Wilmington, DE: Incyte Corporation; January 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed September 29, 2025.

5 . Revision History

Date	Notes
10/29/2025	Removed reference to footnote from essential thrombocytopenia section. Updated coverage criteria for myelofibrosis, polycythemia vera, immunotherapy-related toxicities, and T-cell lymphoma based on NCCN recommendations. Updated references.

Jesduvroq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164993
Guideline Name	Jesduvroq
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	1/17/2024
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Jesduvroq (daprodustat)
Anemia due to chronic kidney disease (CKD) Indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months.

2 . Criteria

Product Name:Jesduvroq [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of anemia due to chronic kidney disease (CKD)

AND

2 - Patient has been receiving dialysis for at least four months

AND

3 - BOTH of the following:

- Ferritin greater than 100 mcg/L
- Transferrin saturation (TSAT) greater than 20%

AND

4 - Hemoglobin level less than 11 g/dL

AND

5 - Trial and failure, contraindication or intolerance to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

AND

6 - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Nephrologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Jesduvroq [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Jesduvroq therapy (e.g., clinically meaningful increase in hemoglobin level)

AND

2 - Adequate iron stores confirmed by BOTH of the following:

- Ferritin greater than 100 mcg/L
- Transferrin saturation (TSAT) greater than 20%

AND

3 - Hemoglobin level does not exceed 12 g/dL

AND

4 - Patient is not on concurrent treatment with an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

AND

5 - Prescribed by or in consultation with ONE of the following:

• Hematologist • Nephrologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Jesduvroq (daprodustat) is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months. The treatment of anemia includes intravenous (IV) iron and/or treatment with either an erythropoiesis-stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] or a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF PHI) [e.g., Jesduvroq (daprodustat)]. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limit may be in place.

4 . References

1. Jesduvroq [package insert]. Durham, NC: GlaxoSmithKline; August 2023.
2. Akizawa T, Nangaku M, Yonekawa T, et al. Efficacy and Safety of Daprodustat Compared with Darbepoetin Alfa in Japanese Hemodialysis Patients with Anemia: A Randomized, Double-Blind, Phase 3 Trial. Clin J Am Soc Nephrol. 2020;15(8):1155-1165. doi:10.2215/CJN.16011219

3. Ketteler M, Block GA, Evenepoel P, Fukagawa M, Herzog CA, McCann L, Moe SM, Shroff R, Tonelli MA, Toussaint ND, Vervloet MG, Leonard MB. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD). Ann Intern Med. 2018 Mar 20;168(6):422-430.

5 . Revision History

Date	Notes
2/11/2025	Annual review, no updates.

Joenja

Prior Authorization Guideline

Guideline ID	GL-267194
Guideline Name	Joenja
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	5/25/2023
P&T Revision Date:	05/17/2024 ; 5/16/2025

1 . Indications

Drug Name: Joenja (leniolisib)
Activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) Indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older.

2 . Criteria

Product Name:Joenja [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS)

AND

2 - Diagnosis has been confirmed by the presence of an APDS-associated genetic variant in either PIK3CD or PIK3R1.

AND

3 - Documentation of other clinical findings and manifestations consistent with APDS (e.g., recurrent respiratory tract infections, recurrent herpesvirus infections, lymphadenopathy, hepatosplenomegaly, autoimmune cytopenia)

AND

4 - Patient has a history of trial and failure, intolerance or contraindication to current standard of care for APDS (e.g., antimicrobial prophylaxis, immunoglobulin replacement therapy, immunosuppressive therapy)

AND

5 - Prescribed by ONE of the following:

- Hematologist
- Immunologist

AND

6 - BOTH of the following:

- Patient is 12 years of age or older

• Patient weighs greater than or equal to 45 kg	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Joenja [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Joenja therapy (e.g., reduced lymph node size, increased naïve B-cell percentage, decreased frequency or severity of infections, decreased frequency of hospitalizations)

AND

2 - Prescribed by ONE of the following:

- Hematologist
- Immunologist

AND

3 - Patient weighs greater than or equal to 45 kg

Notes	a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Joenja (leniolisib) is a kinase inhibitor indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older.[1] APDS is a rare primary immunodeficiency caused by variations in the genes encoding subunits of the PI3Kδ enzyme complex and PI3Kδ hyperactivity. PI3Kδ hyperactivity results in altered development of B and T-cell which can lead to severe lymphoproliferation, recurrent infections, autoimmune disorders, and malignancies. APDS can be characterized by a variety of symptoms, including recurrent respiratory tract infections (e.g., pneumonia, otitis media, rhinosinusitis), recurrent herpesvirus infections (e.g., Epstein Barr virus, cytomegalovirus, herpes simplex virus), lymphoproliferation (e.g., lymphadenopathy, hepatosplenomegaly), autoimmune cytopenia and glomerulonephritis, and neurodevelopmental delay. A definitive diagnosis can be made through genetic testing. Current standard of care includes antimicrobial prophylaxis (e.g., trimethoprim/ sulfamethoxazole, azithromycin), immunoglobulin replacement therapy (IRT), immunosuppressive therapy (e.g., glucocorticoids, rituximab), and hematopoietic stem cell transplant (HSCT).[4] **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits may be in place.

4 . References

1. Joenja [package insert]. Foster City, CA: Pharming Technologies, Inc.; March 2023.
2. Rao VK, Webster S, Šedivá A, et al. A randomized, placebo-controlled phase 3 trial of the PI3Kδ inhibitor leniolisib for activated PI3Kδ syndrome. Blood. 2023;141(9):971-983.
3. Singh A, Joshi V, Jindal AK, Mathew B, Rawat A. An updated review on activated PI3 kinase delta syndrome (APDS). Genes Dis. 2019 Oct 14;7(1):67-74.
4. Vanselow S, Wahn V, Schuetz C. Activated PI3Kδ syndrome - reviewing challenges in diagnosis and treatment. Front Immunol. 2023 Jul 20;14:1208567.

5 . Revision History

Date	Notes
5/14/2025	Annual review with no changes to coverage criteria. Updated references.

Juxtapid

Prior Authorization Guideline

Guideline ID	GL-523264
Guideline Name	Juxtapid
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	7/20/2022
P&T Revision Date:	07/19/2023 ; 10/18/2023 ; 02/16/2024 ; 02/20/2025 ; 2/20/2026

1 . Indications

Drug Name: Juxtapid (lomitapide)
Homozygous familial hypercholesterolemia (HoFH) Indicated as an adjunct to a low-fat diet and other lipid lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

2 . Criteria

Product Name:Juxtapid [a]

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) confirming genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) genes or ≥ 2 such variants at different loci

OR

1.2 BOTH of the following:

1.2.1 Untreated low-density lipoprotein cholesterol LDL-C greater than 400 mg/dL

AND

1.2.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of familial hypercholesterolemia in at least one parent

AND

2 - Patient is on a low-fat diet

AND

3 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - History of intolerance, failure or contraindication to Repatha (evolocumab) (document date of trial and list reason for therapeutic failure, contraindication, or intolerance)

AND

6 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab), Repatha (evolocumab)]

AND

7 - Not used in combination with Evkeeza (evinacumab-dgnb)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Juxtapid [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Patient is on a low-fat diet

AND

2 - Patient continues to receive other lipid-lowering therapy (e.g., statin, LDL apheresis)

AND

3 - Documentation of a positive clinical response to therapy from pre-treatment baseline

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab), Repatha (evolocumab)]

AND

6 - Not used in combination with Evkeeza (evinacumab-dgnb)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Juxtapid (lomitapide) is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). The safety and efficacy of Juxtapid have not been established in patients with hypercholesterolemia who do not have HoFH including those with heterozygous familial hypercholesterolemia (HeFH). The effect of Juxtapid on cardiovascular morbidity and mortality has not been determined.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Juxtapid [package insert]. Parma, Italy: Chiesi Farmaceutici S.p.A; January 2024.
2. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014; 35:2146-57.
3. Writing Committee, Lloyd-Jones DM, Morris PB, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2022;80(14):1366-1418. doi:10.1016/j.jacc.2022.07.006
4. Cuchel M, Raal FJ, Hegele RA, et al. 2023 Update on European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolaemia: new treatments and clinical guidance. Eur Heart J. 2023;44(25):2277-2291. doi:10.1093/eurheartj/ehad197

5 . Revision History

Date	Notes
2/20/2026	Annual review with no changes to coverage criteria. Updated references.

Kerendia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-345292
Guideline Name	Kerendia
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	10/1/2025
P&T Approval Date:	9/21/2022
P&T Revision Date:	12/14/2022 ; 09/20/2023 ; 10/16/2024 ; 8/22/2025

1 . Indications

Drug Name: Kerendia (finerenone)
Chronic Kidney Disease associated with type 2 diabetes Indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). **Heart Failure** Indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%.

2 . Criteria

Product Name:Kerendia [a]	
Diagnosis	Chronic Kidney Disease associated with type 2 diabetes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

AND

2 - BOTH of the following:

- Urinary albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g
- An eGFR greater than or equal to 25 mL/min/1.73 m2

AND

3 - Used to reduce the risk of ANY of the following:

- Sustained eGFR decline
- End-stage kidney disease
- Cardiovascular death
- Non-fatal myocardial infarction
- Hospitalization for heart failure

AND

4 - Serum potassium level is less than or equal to 5 mEQ/L prior to initiating treatment

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

5.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs

AND

6 - Prescriber attests the patient's diabetes is being managed with a diabetes medication with proven CKD benefit [e.g., SGLT2 inhibitor (e.g., Jardiance), GLP1 receptor agonist (e.g., Ozempic)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kerendia [a]	
Diagnosis	Chronic Kidney Disease associated with type 2 diabetes
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kerendia [a]	
Diagnosis	Heart Failure with preserved ejection fraction (HFpEF)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of heart failure with preserved ejection fraction (HFpEF)

AND

2 - Ejection fraction is greater than or equal to 50%

AND

3 - An eGFR of greater than or equal to 25 mL/min/1.73 m2

AND

4 - Serum potassium level is less than or equal to 5 mEQ/L prior to initiating treatment

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following:

- maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)
- maximally tolerated angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., sacubitril/valsartan)

OR

5.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors, ARB, and ARNI

AND

6 - ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with a SGLT-2 inhibitor (e.g., Jardiance)
- Patient has an allergy, contraindication, or intolerance to a SGLT-2 inhibitor (e.g., Jardiance)

AND

7 - Trial and failure, contraindication or intolerance to a mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kerendia [a]	
Diagnosis	Heart Failure with preserved ejection fraction (HFpEF)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kerendia [a]	
Diagnosis	Heart Failure with mildly reduced ejection fraction (HFmrEF)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of heart failure with mildly reduced ejection fraction (HFmrEF)

AND

2 - Ejection fraction 40% to less than 50%

AND

3 - An eGFR of greater than or equal to 25 mL/min/1.73 m2

AND

4 - Serum potassium level is less than or equal to 5 mEQ/L prior to initiating treatment

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following:

- maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)
- maximally tolerated angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., candesartan, valsartan)

OR

5.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors, ARB, and ARNI

AND

6 - ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with a SGLT-2 inhibitor (e.g., Jardiance)
- Patient has an allergy, contraindication, or intolerance to a SGLT-2 inhibitor (e.g., Jardiance)

AND

7 - ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
- Patient has an allergy, contraindication, or intolerance to a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)

AND

8 - Trial and failure, contraindication or intolerance to a mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kerendia [a]	
Diagnosis	Heart Failure with mildly reduced ejection fraction (HFmrEF)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Kerendia (finerenone) is indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). Kerendia is also indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Kerendia [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc. July 2025.
2. Bakris, GL, Agarwal R, Anker SD, Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes. NEJM. 2020; 383:2219-29.
3. American Diabetes Association. Standards of Medical Care in Diabetes—2025. Diabetes Care. 2025;48(Suppl 1):S1-S200

4. de Boer, IH, Khunti, K, Sadusky, T, et al. Diabetes Management in Chronic Kidney Disease: A Consensus Report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO). Diabetes Care 2022.
5. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney Int. 2024;105 (4S): S117–S314
6. Heidenreich, P. A., Bozkurt, B., Aguilar, D., et. al. (2022). 2022 AHA/ACC/HFSA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation, 145(18), e895–e1032.

5 . Revision History

Date	Notes
7/29/2025	Annual review. Modified SGLT2 requirement to provider attestation st atement. Added new heart failure indication. Updated background an d references.

Kisqali

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-276243
Guideline Name	Kisqali
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	5/16/2025
P&T Revision Date:	6/18/2025

1 . Indications

Drug Name: Kisqali (ribociclib)
Advanced or Metastatic Breast Cancer Inhibitor indicated for the treatment of adult patients with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic cancer in combination with an aromatase inhibitor as initial endocrine-based therapy or fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy. **Early Breast Cancer** Indicated for use in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence.

2 . Criteria

Product Name:Kisqali [a]	
Diagnosis	Early-Stage (II or III) Breast Cancer at High Risk of Recurrence
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of early-stage (II or III) breast cancer at high risk of recurrence

AND

2 - ONE of the following:

2.1 Disease is node-positive

OR

2.2 BOTH of the following:

2.2.1 Disease is node-negative

AND

2.2.2 ONE of the following:

2.2.2.1 Tumor size > 5 cm

OR

2.2.2.2 BOTH of the following:

2.2.2.2.1 Tumor size is 2-5 cm

AND

2.2.2.2.2 ONE of the following:

- Grade 2 and high genomic risk or Ki-67 ≥ 20%
- Grade 3

AND

3 - Disease is hormone receptor (HR)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kisqali [a]	
Diagnosis	Early-Stage (II or III) Breast Cancer at High Risk of Recurrence
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Kisqali therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kisqali [a]	
Diagnosis	Advanced, Recurrent, or Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, recurrent, or metastatic breast cancer

AND

2 - Disease is hormone receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

- Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)
- Used in combination with Faslodex (fulvestrant)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kisqali [a]	
Diagnosis	Advanced, Recurrent, or Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Kisqali therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kisqali [a]	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of recurrent or metastatic endometrial cancer **AND** **2** - Tumor is estrogen receptor (ER)-positive **AND** **3** - Used in combination with letrozole	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Kisqali [a]	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Kisqali therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Kisqali [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Kisqali will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Kisqali [a]	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Kisqali therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Kisqali (ribociclib) is a kinase inhibitor indicated for the treatment of adult patients with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic cancer in combination with an aromatase inhibitor as initial endocrine-based therapy or fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy. Kisqali is also indicated for use in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence.

The National Comprehensive Cancer Network (NCCN) recommends the use of Kisqali similarly for men and premenopausal women receiving ovarian ablation/suppression with recurrent unresectable (local or regional) or metastatic HR-positive HER2-negative breast cancer disease, in combination with an aromatase inhibitor or Faslodex®(fulvestrant). The use of an aromatase inhibitor in men with breast cancer is ineffective without concomitant suppression of testicular steroidogenesis. The NCCN also recommends Kisqali for estrogen receptor (ER)-positive recurrent or metastatic endometrial carcinoma in combination with letrozole.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Kisqali® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. September 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed May 2, 2025.

5 . Revision History

Date	Notes
5/28/2025	Updated breast cancer criteria based on NCCN recommendations. S eparated breast cancer into two separate sections.

Kisqali Femara Co-Pack

Prior Authorization Guideline

Guideline ID	GL-276242
Guideline Name	Kisqali Femara Co-Pack
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	02/18/2022 ; 08/19/2022 ; 02/17/2023 ; 02/16/2024 ; 11/22/2024 ; 6/18/2025

1 . Indications

Drug Name: Kisqali Femara Co-Pack (ribociclib/letrozole)
Advanced or Metastatic Breast Cancer Indicated as initial endocrine-based therapy for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. **Early Breast Cancer** Indicated for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence.

2 . Criteria

Product Name:Kisqali Femara Co-Pack [a]	
Diagnosis	Early-Stage (II or III) Breast Cancer at High Risk of Recurrence
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of early-stage (II or III) breast cancer at high risk of recurrence

AND

2 - ONE of the following:

2.1 Disease is node-positive

OR

2.2 BOTH of the following:

2.2.1 Disease is node-negative

AND

2.2.2 ONE of the following:

2.2.2.1 Tumor size > 5 cm

OR

2.2.2.2 BOTH of the following:

2.2.2.2.1 Tumor size is 2-5 cm

AND

2.2.2.2.2 ONE of the following:

- Grade 2 and high genomic risk or Ki-67 ≥ 20%
- Grade 3

AND

3 - Disease is hormone receptor (HR)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kisqali Femara Co-Pack [a]	
Diagnosis	Early-Stage (II or III) Breast Cancer at High Risk of Recurrence
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Kisqali Femara Co-Pack therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kisqali Femara Co-Pack [a]	
Diagnosis	Advanced, Recurrent, or Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, recurrent, or metastatic breast cancer

AND

2 - Disease is hormone receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kisqali Femara Co-Pack [a]	
Diagnosis	Advanced, Recurrent, or Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Kisqali Femara Co-Pack therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kisqali Femara Co-Pack [a]	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or metastatic endometrial cancer

AND

2 - Tumor is estrogen receptor (ER)-positive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kisqali Femara Co-Pack [a]	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Kisqali Femara Co-Pack therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kisqali Femara Co-Pack [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Kisqali Femara Co-Pack will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Kisqali Femara Co-Pack [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Kisqali Femara Co-Pack therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Kisqali Femara Co-Pack is a co-packaged product containing ribociclib, a kinase inhibitor, and letrozole, an aromatase inhibitor, and is indicated as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. Kisqali is also indicated for use in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence. The National Comprehensive Cancer Network (NCCN) recommends the use of Kisqali similarly for men and premenopausal women receiving ovarian ablation/suppression with recurrent unresectable (local or regional) or metastatic HR-positive HER2-negative breast cancer disease in combination with an aromatase inhibitor or fulvestrant. The use of an aromatase inhibitor in men with breast cancer is ineffective without concomitant suppression of testicular steroidogenesis. The NCCN also recommends Kisqali for estrogen receptor (ER)-positive recurrent or metastatic endometrial carcinoma in combination with letrozole. **Additional Clinical Programs:** • Supply limits may be in place. • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Kisqali Femara Co-Pack [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. September 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 15, 2025.

5 . Revision History

Date	Notes
5/28/2025	Updated breast cancer criteria based on NCCN recommendations. S eparated breast cancer into two separate sections.

Lenvima

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523192
Guideline Name	Lenvima
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 11/19/2021 ; 02/18/2022 ; 08/19/2022 ; 02/17/2023 ; 08/18/2023 ; 02/16/2024 ; 02/20/2025 ; 09/17/2025 ; 2/20/2026

1 . Indications

Drug Name: Lenvima (lenvatinib)
Thyroid Carcinoma Indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer. **Renal Cell Cancer** Indicated in combination with everolimus for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy. Indicated in combination with pembrolizumab for the first-line treatment of adult patients with advanced RCC. **Hepatocellular Carcinoma** Indicated for the first-line treatment of patients with unresectable hepatocellular carcinoma. **Endometrial Carcinoma** Indicated in combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (pMMR), who have disease progression following prior

systemic therapy and are not candidates for curative surgery or radiation.

Other Uses: The National Cancer Comprehensive Network (NCCN) also recommends Lenvima for the treatment of medullary thyroid carcinoma in patients who have experienced disease progression while on Caprelsa (vandetanib) or Cometriq (cabozantinib), as a systemic therapy for recurrent adenoid cystic carcinoma, and for the treatment of metastatic hepatocellular carcinoma, thymic carcinoma, and cutaneous melanoma.

2 . Criteria

Product Name:Lenvima [a]	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC)

AND

2 - Disease is locally recurrent, metastatic, progressive, or symptomatic

AND

3 - Disease is radioactive iodine-refractory or ineligible

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]

Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]	
Diagnosis	Renal Cell Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 History of failure, contraindication, or intolerance to prior anti-angiogenic therapy [e.g., Avastin (bevacizumab), Votrient (pazopanib), Sutent (sunitinib), Nexavar (sorafenib)]^

AND

2.1.2 Used in combination with everolimus (generic Afinitor)

OR

2.2 Used in combination with Keytruda (pembrolizumab)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines.

Product Name:Lenvima [a]	
Diagnosis	Renal Cell Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

AND

2 - Used in combination with everolimus (generic Afinitor) or Keytruda (pembrolizumab)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]	
Diagnosis	Hepatocellular Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hepatocellular carcinoma	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]	
Diagnosis	Hepatocellular Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Lenvima therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of endometrial carcinoma	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Lenvima therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]	
Diagnosis	Adenoid Cystic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of recurrent adenoid cystic carcinoma	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]

Diagnosis	Adenoid Cystic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Lenvima therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of thymic carcinoma	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]	
Diagnosis	Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous melanoma

AND

2 - ONE of the following:

- Disease is unresectable
- Disease is metastatic

AND

3 - Used in combination with Keytruda (pembrolizumab)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]	
Diagnosis	Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Lenvima therapy **AND** **2** - Used in combination with Keytruda (pembrolizumab)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Lenvima will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lenvima [a]

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Lenvima therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Lenvima (lenvatinib) is a kinase inhibitor indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer in combination with Afinitor (everolimus), for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy, in combination with Keytruda (pembrolizumab), for the first-line treatment of patients with advanced RCC, for the first-line treatment of patients with unresectable hepatocellular carcinoma, and in combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (pMMR), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

In addition, the National Cancer Comprehensive Network (NCCN) also recommends Lenvima for the treatment of medullary thyroid carcinoma in patients who have experienced disease progression while on Caprelsa (vandetanib) or Cometriq (cabozantinib), as a systemic therapy for recurrent adenoid cystic carcinoma, and for the treatment of metastatic hepatocellular carcinoma, thymic carcinoma, and cutaneous melanoma.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Lenvima [package insert]. Woodcliff Lake, NJ: Eisai Inc.; January 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at NCCN Drugs and Biologics Compendium®. Accessed January 9, 2026.

5 . Revision History

Date	Notes
2/12/2026	Updated criteria based on current NCCN recommendations. Updated references.

Leqembi IQLIK

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-458247
Guideline Name	Leqembi IQLIK
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	9/25/2025
P&T Revision Date:	12/17/2025

1 . Indications

Drug Name: Leqembi (lecanemab-irmb)
Alzheimer's disease Indicated for the treatment of Alzheimer's disease.

2 . Criteria

Product Name:Leqembi IQLIK [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Alzheimer's disease

AND

2 - Presence of amyloid beta pathology has been confirmed

AND

3 - Patient has been established on intravenous Leqembi therapy under an active UnitedHealthcare medical benefit prior authorization

AND

4 - BOTH of the following:

4.1 Submission of medical records (e.g., chart notes) confirming follow-up brain magnetic resonance imaging (MRI) has been completed after the initiation of intravenous Leqembi therapy

AND

4.2 ONE of the following:

4.2.1 Amyloid-related imaging abnormalities (ARIA) have not been observed on MRI

OR

4.2.2 ALL of the following:

4.2.2.1 ARIA has been observed on MRI

AND

4.2.2.2 Prescriber attests that continuation of therapy with Leqembi IQLIK is appropriate based on the severity of the patient's clinical symptoms

AND

4.2.2.3 ONE of the following:

- Follow-up MRI demonstrates radiographic resolution and/or stabilization
- Prescriber attests that continuation of therapy with Leqembi IQLIK is appropriate based on the radiographic severity of ARIA

AND

5 - Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Kisunla)

AND

6 - Prescribed by a neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Leqembi IQLIK [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Kisunla)

AND **2** - Prescribed by a neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Leqembi is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Leqembi [Package insert]. Eisai, Inc. Nutley, NJ. August 2025.
2. Cummings J, Apostolova L, Rabinovici GD, et al. Lecanemab: Appropriate Use Recommendations. J Prev Alzheimers Dis. 2023;10(3):362-377. doi:10.14283/jpad.2023.30
3. Jack CR Jr, Andrews JS, Beach TG, Buracchio T, Dunn B, Graf A, Hansson O, Ho C, Jagust W, McDade E, Molinuevo JL, Okonkwo OC, Pani L, Rafii MS, Scheltens P, Siemers E, Snyder HM, Sperling R, Teunissen CE, Carrillo MC. Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup. Alzheimers Dement. 2024 Jun 27. doi: 10.1002/alz.13859. Epub ahead of print. PMID: 38934362.

5 . Revision History

Date	Notes
12/1/2025	Removed criteria for staging of dementia due to Alzheimer's disease.

Leqselvi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-328201
Guideline Name	Leqselvi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	9/1/2025
P&T Approval Date:	7/16/2025
P&T Revision Date:	

1 . Indications

Drug Name: Leqselvi (deuruxolitinib)
Alopecia Areata Indicated for the treatment of adults with severe alopecia areata.

2 . Criteria

Product Name:Leqselvi [a]	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of severe alopecia areata

AND

2 - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecia, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania)

AND

3 - Patient has a current episode of alopecia areata lasting more than 6 months with at least 50% scalp hair loss

AND

4 - History of failure, contraindication or intolerance to Olumiant

AND

5 - Patient is not receiving Leqselvi in combination with EITHER of the following for treatment of the same indication:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecitinib), Olumiant (baricitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

6 - Prescribed by or in consultation with a dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Leqselvi [a]	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Leqselvi therapy

AND

2 - Patient is not receiving Leqselvi in combination with EITHER of the following for treatment of the same indication:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecitinib), Olumiant (baricitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Leqselvi (deuruxolitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with severe alopecia areata. Use of Leqselvi in combination with other JAK

inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Additional Clinical Rules:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Leqselvi [package insert]. Whippany, NJ.: Sun Pharmaceutical Industries, Inc.; July 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2021;73(7):924-939.
3. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Arlington, VA: American Psychiatric Publishing. 2013.
4. Messenger AG, McKillop J, Farrant P, et al. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. Br J Dermatol. 2012;166(5):916-926.
5. King B, Ohyama M, Kwon O, et al. BRAVE-AA Investigators. Two Phase 3 Trials of Baricitinib for Alopecia Areata. N Engl J Med. 2022 May 5;386(18):1687-1699.
6. King BA, Mesinkovska NA, Craiglow B, et al. Development of the alopecia areata scale for clinical use: results of an academic-industry collaborative effort. J Am Acad Dermatol. 2022;86(2):359-364.
7. Meah N, Wall D, York K, et al. The Alopecia Areata Consensus of Experts (ACE) study: Results of an international expert opinion on treatments for alopecia areata. J Am Acad Dermatol. 2020;83(1):123-130.

5 . Revision History

Date	Notes
7/14/2025	New program.

Leuprolide

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-424259
Guideline Name	Leuprolide
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 10/20/2021 ; 10/20/2021 ; 10/19/2022 ; 12/14/2022 ; 08/18/2023 ; 04/17/2024 ; 06/17/2024 ; 10/01/2024 ; 05/16/2025 ; 10/15/2025

1 . Indications

Drug Name: Subcutaneously (SC) administered leuprolide acetate (Camcevi, Eligard, Lutrate Depot)
Advanced prostate cancer Indicated for the palliative treatment of advanced prostate cancer. **Central precocious puberty (CPP)** While a depot formulation of leuprolide (Lupron Depot-Ped) is FDA labeled for the treatment of central precocious puberty (CPP), clinical evidence supports the use of daily SC administered leuprolide acetate for the same indication. CPP is defined as early onset of secondary sexual characteristics, generally earlier than 8 years of age in girls and 9 years of age in boys, associated with pubertal pituitary gonadotropin activation. Leuprolide prescribing information states that prior to initiation of treatment, a clinical diagnosis of CPP should be confirmed by blood concentration of luteinizing hormone (LH) (basal or stimulated with a GnRH analog) and assessment of bone age versus chronological age. Once therapy is initiated, CPP patients should be evaluated every 3 to 6

months for pubertal development and growth, and bone age should be measured radiographically every 6 to 12 months. **Gender dysphoria** Clinical evidence supporting the use of GnRH analogs for the treatment of gender dysphoria is limited and lacks long-term safety data. Statistically robust randomized controlled trials are needed to address the issue of whether the benefits outweigh the clinical risk in its use. **Salivary gland tumors and uterine sarcoma** The National Cancer Comprehensive Network (NCCN) recommends leuprolide acetate for the treatment of salivary gland tumors and uterine sarcoma
Drug Name: Intramuscular (IM) administered leuprolide acetate 22.5 mg injection
Advanced prostate cancer Indicated for the treatment of advanced prostate cancer.

2 . Criteria

Product Name:Camcevi, Eligard, leuprolide inj kit 1 mg/0.2 mL, leuprolide acetate 22.5 mg injection, Lutrate Depot [a]	
Diagnosis	Treatment of Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - Disease is ONE of the following:

- Advanced
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Camcevi, Eligard, leuprolide inj kit 1 mg/0.2 mL, leuprolide acetate 22.5 mg injection, Lutrate Depot [a]	
Diagnosis	Treatment of Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:leuprolide acetate inj kit 1 mg/0.2 mL [a]	
Diagnosis	Treatment of Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of central precocious puberty (idiopathic or neurogenic) **AND** **2** - Onset of secondary sexual characteristics in ONE of the following:	

- Females at birth less than or equal to 8 years of age
- Males at birth less than or equal to 9 years of age

AND

3 - Confirmation of diagnosis as defined by ONE of the following:

- A pubertal luteinizing hormone response to a GnRH stimulation test
- Bone age advanced one year beyond the chronological age

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:leuprolide acetate inj kit 1 mg/0.2 mL [a]	
Diagnosis	Treatment of Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response (e.g., decrease in height velocity, cessation of menses, arrest pubertal progression, reduction in bone age advancement)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:leuprolide acetate inj kit 1 mg/0.2 mL [a]	
Diagnosis	Infertility**
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND

2 - Used as part of an assisted reproductive technology (ART) protocol

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. **NOTE: Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas, and Texas should be denied as a benefit exclusion.

Product Name:Eligard, leuprolide acetate inj kit 1 mg/0.2 mL, Lutrate Depot [a]	
Diagnosis	Salivary Gland Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of salivary gland tumor

AND

2 - Disease is ONE of the following:

- Recurrent
- Unresectable
- Metastatic

AND **3** - Disease is androgen receptor positive (AR+)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Eligard, leuprolide acetate inj kit 1 mg/0.2 mL, Lutrate Depot [a]	
Diagnosis	Salivary Gland Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Camcevi, Eligard, leuprolide inj kit 1 mg/0.2 mL, leuprolide acetate 22.5 mg injection, Lutrate Depot [a]	
Diagnosis	Gender dysphoria [b][c]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Using hormones to change physical characteristics

AND **2** - The covered person must be diagnosed with gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] Gender Dysphoria/Gender affirming treatment is not a coverable benefit in the following markets: AL, AZ, FL, GA, IN, IA, KS, LA, MS, MO, NE, NC, NM, OH, OK, SC, TN, TX, WY [c] In Texas, if an enrollee has ever been provided coverage for a gender transition procedure or treatment then coverage shall be provided for all possible adverse consequences or side effects related to that treatment or procedure and for any procedure, treatment, or therapy necessary to manage, reverse, reconstruct from, or recover from the procedure or treatment.

Product Name:Camcevi, Eligard, leuprolide inj kit 1 mg/0.2 mL, leuprolide acetate 22.5 mg injection, Lutrate Depot [a]	
Diagnosis	Gender dysphoria [b][c]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient continues to use hormone therapy to change physical characteristics **AND** **2** - Documentation of positive clinical response to therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] Gender Dysphoria/Gender affirming treatment is not a coverable b

	enefit in the following markets: AL, AZ, FL, GA, IN, IA, KS, LA, MS, M O, NE, NC, NM, OH, OK, SC, TN, TX, WY [c] In Texas, if an enrollee has ever been provided coverage for a gen der transition procedure or treatment then coverage shall be provided for all possible adverse consequences or side effects related to that tr eatment or procedure and for any procedure, treatment, or therapy ne cessary to manage, reverse, reconstruct from, or recover from the pro cedure or treatment.

Product Name:Camcevi, Eligard, leuprolide inj kit 1 mg/0.2 mL, leuprolide acetate 22.5 mg injection, Lutrate Depot [a]	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of ONE of the following: • Low-grade endometrial stromal sarcoma (ESS) • Adenosarcoma without sarcomatous overgrowth • Estrogen receptor/progesterone receptor positive (ER/PR+) uterine sarcoma	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Camcevi, Eligard, leuprolide inj kit 1 mg/0.2 mL, leuprolide acetate 22.5 mg injection, Lutrate Depot [a]	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Coverage Criteria:

These criteria provides parameters for coverage of oncology indications based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium. The Compendium lists the appropriate drugs and biologics for specific cancers using US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

UnitedHealthcare recognizes indications and uses of leuprolide acetate listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven.

Clinical evidence supporting the use of GnRH analogs for the treatment of gender dysphoria is limited and lacks long-term safety data. Statistically robust randomized controlled trials are needed to address the issue of whether the benefits outweigh the clinical risk in its use.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limitations may be in place.

Background:

Leuprolide acetate is a synthetic nonapeptide analog of naturally occurring gonadotropin releasing hormone (GnRH) or luteinizing hormone-releasing hormone (LH-RH) which acts as a potent inhibitor of gonadotropin secretion when given continuously in therapeutic doses. Leuprolide aetate is indicated in the palliative treatment of advanced prostatic cancer

Subcutaneously (SC) administered leuprolide acetate (Eligard, Lutrate Depot) is FDA-labeled for the palliative treatment of advanced prostate cancer.[1,2]

Intramuscular (IM) administered leuprolide acetate 22.5 mg injection is FDA-labeled for the treatment of advanced prostate cancer.[18]

In addition to prostate cancer, the National Cancer Comprehensive Network (NCCN) recommends leuprolide acetate for the treatment of salivary gland tumors and uterine sarcoma. [2]

While a depot formulation of leuprolide (Lupron Depot-Ped) is FDA labeled for the treatment of central precocious puberty (CPP),[4] clinical evidence supports the use of daily SC administered leuprolide acetate for the same indication.[5] CPP is defined as early onset of secondary sexual characteristics, generally earlier than 8 years of age in girls and 9 years of age in boys, associated with pubertal pituitary gonadotropin activation. Leuprolide prescribing information states that prior to initiation of treatment, a clinical diagnosis of CPP should be confirmed by blood concentration of luteinizing hormone (LH) (basal or stimulated with a GnRH analog) and assessment of bone age versus chronological age. [4] Once therapy is initiated, CPP patients should be evaluated every 3 to 6 months for pubertal development and growth, and bone age should be measured radiographically every 6 to 12 months.[5]

4 . References

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2. Leuprolide acetate [package insert]. Princeton, NJ: Sandoz Inc; June 2020.
3. Camcevi [package insert]. Durham, NC: Accord BioPharma Inc.; November 2022.
4. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/ Accessed May 1, 2024.
5. Lupron Depot-Ped [package insert]. North Chicago, IL: AbbVie Inc.; August 2022.

6. Carel JC, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. Pediatrics. 2009 Apr;123(4):e752-62. Epub 2009 Mar 30.
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10. Albuquerque LE1, Tso LO, Saconato H, Albuquerque MC, Macedo CR. Depot versus daily administration of gonadotrophin-releasing hormone agonist protocols for pituitary down regulation in assisted reproduction cycles. Cochrane Database Syst Rev. 2013 Jan 31;1:CD002808.
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13. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. 2013. Washington, DC. Pages 451-459.
14. Costa R, Dunsford M, Skagerberg E, et al. Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria. J Sex Med 2015;12:2206–2214
15. de Vries AL, McGuire JK, Steensma TD, et al. Young adult psychological outcome after puberty suppression and gender reassignment. Pediatrics. 2014 Oct;134(4):696-704.
16. Leuprolide acetate depot [package insert]. Warren, NJ: Cipla USA, Inc. November 2023.
17. Lutrate Depot [package insert]. Parsippany, NJ: Avyxa Pharma, LLC.; November 2024.

5 . Revision History

Date	Notes
10/20/2025	Added New York to ovulation induction operation note for 2026 imple mentation. Added operational note to identify states which do not cov er Gender Dysphoria and exception for Texas.

Lidocaine Patch

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-533196
Guideline Name	Lidocaine Patch
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	3/15/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	06/16/2021 ; 10/20/2021 ; 09/21/2022 ; 08/18/2023 ; 11/17/2023 ; 02/16/2024 ; 10/01/2024 ; 11/22/2024 ; 12/17/2025

1 . Indications

Drug Name: Lidoderm (lidocaine patch), ZTlido (lidocaine patch), Lidocan (lidocaine patch), Tridacaine (lidocaine patch)
Pain associated with post-herpetic neuralgia (PHN) Indicated for the relief of pain associated with post-herpetic neuralgia (PHN). The American Academy of Neurology recommends the use of lidocaine patch as an option for the management of PHN. Evidence also exists in support of using lidocaine patch for non-PHN neuropathies.

2 . Criteria

Product Name:Brand Lidoderm patch, generic lidocaine patch, ZTLido patch, Brand Lidocan patch, Brand Tridacaine [a]

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Diagnosis of post-herpetic neuralgia
- Diagnosis of neuropathic pain

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Lidoderm is indicated for the relief of pain associated with post-herpetic neuralgia (PHN). The American Academy of Neurology recommends the use of lidocaine patch as an option for the management of PHN. Evidence also exists in support of using lidocaine patch for non-PHN neuropathies.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Baron, R., Allegri, M., Correa-Illanes, G., et al. The 5% Lidocaine-Medicated Plaster: Its Inclusion in International Treatment Guidelines for Treating Localized Neuropathic Pain, and Clinical Evidence Supporting its Use. Pain Ther. 2016; 5: 149.
2. Derry S, Wiffen PJ, Moore RA, et al. Topical Lidocaine for Neuropathic Pain in Adults (Review). Cochrane Database of Systemic Reviews 2014; 7: 1-41.
3. Finnerup NB, Attal N, Haroutounian S, et al. Pharmacotherapy for Neuropathic Pain in Adults: Systematic Review, Meta-analysis and Updated NeuPSIG Recommendations. The Lancet Neurology. 2015; 14(2):162-173.
4. Gilron, Ian et al. Neuropathic Pain: Principles of Diagnosis and Treatment. Mayo Clinic Proceedings, Volume 90, Issue 4, 532 - 545.
5. Lidoderm [package insert]. San Jose, CA: TPU Pharma; December 2022.
6. Soliman N, Abuukar Abdullahi R et al. Pharmacotherapy and non-invasive neuromodulation for neuropathic pain: a systematic review and meta-analysis.The Lancet Neurology, Volume 24, Issue 5, 413 - 428
7. ZTlido [package insert]. Palo Alto, CA: Scilex Pharmaceuticals Inc; April 2021.

5 . Revision History

Date	Notes
2/26/2026	Added Tridacaine patch

Linzess, Symproic

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-458248
Guideline Name	Linzess, Symproic
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 03/17/2021 ; 06/16/2021 ; 09/15/2021 ; 11/18/2022 ; 03/15/2023 ; 04/19/2023 ; 07/19/2023 ; 10/16/2024 ; 12/17/2025

1 . Indications

Drug Name: Linzess (linaclotide)
Chronic idiopathic constipation Indicated in adults for the treatment of chronic idiopathic constipation. **Irritable bowel syndrome** Indicated for the treatment of irritable bowel syndrome with constipation in adults and pediatric patients 7 years of age and older. **Functional constipation (FC)** Indicated for treatment of functional constipation (FC) in pediatric patients 6 to 17 years of age.
Drug Name: Symproic (naldemedine)
Opioid-induced constipation Indicated for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

2 . Criteria

Product Name:Linzess [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic idiopathic constipation **OR** **2** - Diagnosis of irritable bowel syndrome with constipation **OR** **3** - Diagnosis of functional constipation	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Symproic [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of opioid-induced constipation in patients being treated for chronic, non-cancer pain **OR** **2** - Diagnosis of opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Symproic [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: Linzess will continue to go through initial authorization for a diagnosis check only.

3 . Background

Benefit/Coverage/Program Information
Background

Linzess (linaclotide) is indicated for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation in adults aged 18 years and older and for the treatment of functional constipation (FC) in pediatric patients 6 to 17 years of age. Symproic (naldemedine) is an opioid antagonist indicated for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Physicians and patients should periodically assess the need for continued treatment with these agents.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Linzess [package insert]. North Chicago, IL: AbbVie; November 2025.
2. Symproic [package insert]. Raleigh, NC: BioDelivery Services International, Inc.; July 2021.

5 . Revision History

Date	Notes
12/1/2025	Annual review with no changes to coverage criteria. Updated backgr ound and references.

Litfulo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-461339
Guideline Name	Litfulo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	9/20/2023
P&T Revision Date:	09/20/2023 ; 12/13/2023 ; 12/18/2024 ; 07/16/2025 ; 12/17/2025

1 . Indications

Drug Name: Litfulo (ritlecitinib)
Alopecia Areata Indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.

2 . Criteria

Product Name:Litfulo [a]	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of severe alopecia areata

AND

2 - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecia, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania)

AND

3 - Patient has a current episode of alopecia areata lasting more than 6 months with at least 50% scalp hair loss

AND

4 - History of failure, contraindication or intolerance to Olumiant

AND

5 - Patient is not receiving Litfulo in combination with EITHER of the following:

- Biologic immunomodulator or JAK inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Leqselvi (deuruxolitinib), Nemluvio (nemolizumab-ilto), Olumiant (baricitinib), Rinvoq (upadacitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine) [1]

AND

6 - Prescribed by or in consultation with a dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Litfulo [a]	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Litfulo therapy

AND

2 - Patient is not receiving Litfulo in combination with EITHER of the following:

- Biologic immunomodulator or JAK inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Leqselvi (deuruxolitinib), Nemluvio (nemolizumab-ilto), Olumiant (baricitinib), Rinvoq (upadacitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine) [1]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background

Litfulo® (ritlecitinib) is an oral kinase inhibitor indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older. Use of Litfulo in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Litfulo [package insert]. New York, NY: Pfizer Inc; June 2023.
2. Messenger AG, McKillop J, Farrant P, et al. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. Br J Dermatol. 2012;166(5):916-926.
3. King BA, Mesinkovska NA, Craiglow B, et al. Development of the alopecia areata scale for clinical use: results of an academic-industry collaborative effort. J Am Acad Dermatol. 2022;86(2):359-364.
4. Meah N, Wall D, York K, et al. The Alopecia Areata Consensus of Experts (ACE) study: Results of an international expert opinion on treatments for alopecia areata. J Am Acad Dermatol. 2020;83(1):123-130.
5. King BA, Senna MM, Ohyama M, et al. Defining Severity in Alopecia Areata: Current Perspectives and a Multidimensional Framework. Dermatol Ther (Heidelb). 2022 Apr;12(4):825-834.

5 . Revision History

Date	Notes
12/8/2025	Updated combination examples and language.

Livdelzi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-461341
Guideline Name	Livdelzi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	12/18/2024
P&T Revision Date:	12/17/2025

1 . Indications

Drug Name: Livdelzi (seladelpar)
Primary biliary cholangitis (PBC) Indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.

2 . Criteria

Product Name:Livdelzi [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of primary biliary cholangitis

AND

2 - Patient does not have decompensated cirrhosis

AND

3 - ONE of the following:

3.1 BOTH of the following^:

- Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)
- Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)

OR

3.2 History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol)

AND

4 - Patient is not receiving Livdelzi in combination with Iqirvo (elafibranor) or Ocaliva (obeticholic acid)

AND

5 - Prescribed by ONE of the following:

- Hepatologist

• Gastroenterologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling and/or treatment guidelines.

Product Name:Livdelzi [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in ALP level from pre-treatment baseline (i.e., prior to Livdelzi therapy)

AND

2 - Patient does not have decompensated cirrhosis

AND

3 - Patient is not receiving Livdelzi in combination with Iqirvo (elafibranor) or Ocaliva (obeticholic acid)

AND

4 - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Livdelzi (seladelpar) is a peroxisome proliferator-activated receptor (PPAR)-delta agonist indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. This indication is approved under accelerated approval based on a reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).[1] **Additional Clinical Rules:** • Supply limits may be in place. • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Livdelzi [package insert]. Foster City, CA: Gilead Sciences, Inc.; October 2025.

5 . Revision History

Date	Notes

12/8/2025	Annual review without changes to coverage criteria. Updated referen ce.

Livmarli

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-374429
Guideline Name	Livmarli
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	11/19/2021
P&T Revision Date:	01/19/2022 ; 08/19/2022 ; 01/18/2023 ; 05/25/2023 ; 05/17/2024 ; 09/18/2024 ; 9/25/2025

1 . Indications

Drug Name: Livmarli (maralixibat)
Alagille Syndrome Indicated for the treatment of cholestatic pruritis in patients 3 months of age and older with Alagille syndrome (ALGS). **Progressive Familial Intrahepatic Cholestasis** Indicated for the treatment of cholestatic pruritis in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC).

2 . Criteria

Product Name:Livmarli [a]	
Diagnosis	Progressive Familial Intrahepatic Cholestasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of progressive familial intrahepatic cholestasis (PFIC)

AND

2 - Patient does not have a ABCB11 variant resulting in non-functional or complete absence of bile salt export pump (BSEP) protein

AND

3 - Patient is experiencing cholestatic pruritus associated with PFIC.

AND

4 - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory.

AND

5 - Patient has had an inadequate response to at least TWO conventional treatments for the symptomatic relief of pruritus (e.g., ursodeoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, and sertraline).

AND

6 - Prescribed by a gastroenterologist or hepatologist.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Livmarli [a]	
Diagnosis	Progressive Familial Intrahepatic Cholestasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to Livmarli therapy (e.g., reduced serum bile acids, improved pruritis and less sleep disturbance) **AND** **2** - Prescribed by a gastroenterologist or hepatologist.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Livmarli [a]	
Diagnosis	Alagille Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
Approval Criteria **1** - Diagnosis of Alagille syndrome (ALGS)	

AND

2 - Confirmation of diagnosis by presence of the JAG1 or Notch2 gene mutation

AND

3 - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory.

AND

4 - Patient is experiencing cholestatic pruritis associated with ALGS

AND

5 - Patient has had an inadequate response to at least TWO conventional treatments for the symptomatic relief of pruritus (e.g., ursodeoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, and sertraline).

AND

6 - Prescribed by a gastroenterologist or hepatologist.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Livmarli [a]	
Diagnosis	Alagille Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Livmarli therapy (e.g., reduced serum bile acids, improved pruritis)

AND

2 - Prescribed by a gastroenterologist or hepatologist.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Livmarli (maralixibat) is an ileal bile acid transporter inhibitor indicated for the treatment of cholestatic pruritis in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Livmarli is also indicated for the treatment of cholestatic pruritis in patients 3 months of age and older with Alagille syndrome (ALGS).

Conventional treatments for pruritis associated with PFIC or Alagille syndrome include ursodeoxycholic acid (UCDA), antihistamines (e,g., diphenhydramine), bile acid sequestrants (e.g., cholestyramine), rifampin, naltrexone and sertraline.

Limitation of Use:

Livmarli is not recommended in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in non-functional or complete absence of bile salt export pump (BSEP) protein.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.

4 . References

1. Livmarli [package insert]. Foster City, CA: Mirum Pharmaceuticals, Inc.; April 2025.
2. Gonzales E, Hardikar W, Stormon M, et al. Efficacy and safety of maralixibat treatment in patients with Alagille syndrome and cholestatic pruritus (ICONIC): a randomised phase 2 study. Lancet. 2021;398(10311):1581-1592.
3. Miethke AG, Moukarzel A, Porta G, et al. Maralixibat in progressive familial intrahepatic cholestasis (MARCH-PFIC): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial [published correction appears in Lancet Gastroenterol Hepatol. 2024 Jul;9(7):e10.
4. Chowdhury JR, Chowdhury NR. Inherited disorders associated with conjugated hyperbilirubinemia in adults. In: Post TW, ed. UpToDate. UpToDate, 2024. Accessed July 9, 2024. Inherited disorders associated with conjugated hyperbilirubinemia in adults - UpToDate
5. Kohut TJ, Loomes KM. Alagille syndrome. In: Post TW, ed. UpToDate. UpToDate, 2024. Accessed July 9, 2024. Alagille syndrome - UpToDate

5 . Revision History

Date	Notes
9/3/2025	Annual review. Removed definitions of PFIC and ALGS from the bac kground. Removed the pruritis severity requirement from the initial au thorization and updated the type of pruritis in coverage criteria for PF IC and ALGS.

Lokelma, Veltassa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-355231
Guideline Name	Lokelma, Veltassa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	10/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	06/16/2021 ; 06/15/2022 ; 06/21/2023 ; 06/17/2024 ; 07/17/2024 ; 8/22/2025

1 . Indications

Drug Name: Lokelma (sodium zirconium cyclosilicate), Veltassa (patiromer)
Hyperkalemia Indicated for the treatment of hyperkalemia.

2 . Criteria

Product Name:Lokelma, Veltassa [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-life threatening hyperkalemia

AND

2 - Where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed

AND

3 - Patient follows a low potassium diet (less than or equal to 3 grams per day)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Lokelma, Veltassa [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a positive clinical response to Lokelma or Veltassa therapy and continues to require treatment for hyperkalemia

AND

2 - Patient follows a low potassium diet (less than or equal to 3 grams per day)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply

3 . Background

Benefit/Coverage/Program Information
Additional Clinical Rules: • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits may be in place **Background:** Lokelma and Veltassa are indicated for the treatment of hyperkalemia. Lokelma and Veltassa should not be used as an emergency treatment for life threatening hyperkalemia because of its delayed onset of action. Non-emergent hyperkalemia is generally treated by addressing the reversible causes, such as removing drugs that may be causing impaired renal function, removing or adjusting medications that directly cause hyperkalemia, and initiating therapies for potassium removal.

4 . References

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5 . Revision History

Date	Notes
8/5/2025	Annual review. Updated references.

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-419218
Guideline Name	Long-Acting Opioids
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	12/16/2020
P&T Revision Date:	05/21/2021 ; 09/15/2021 ; 05/20/2022 ; 10/19/2022 ; 12/14/2022 ; 03/15/2023 ; 04/19/2023 ; 08/18/2023 ; 03/20/2024 ; 10/01/2024 ; 12/18/2024 ; 9/17/2025

1 . Indications

Drug Name: Fentanyl patches, hydrocodone ER caps, Hysingla ER (hydrocodone ER tabs), hydromorphone ER, generic levorphanol, methadone tabs/soln, Methadose conc (methadone conc), MS Contin (morphine sulfate ER tabs), morphine sulfate ER caps, Xtampza ER, Oxycodone ER, Oxycontin, oxymorphone ER, Nucynta ER, Conzip, Tramadol ER caps/tabs
Management of moderate to severe pain Indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid is needed for an extended period of time and for which alternative treatment options are not appropriate. They are not intended for use as an as needed analgesic.

2 . Criteria

Product Name:generic fentanyl patches, generic hydrocodone ER caps/tabs, Brand Hysingla ER, generic hydromorphone ER, generic levorphanol, generic methadone tabs/soln/conc, Brand Methadose conc, Brand MS Contin, generic morphine sulfate ER caps/tabs, Xtampza ER, Oxycodone ER, Oxycontin, generic oxymorphone ER, Nucynta ER, Conzip, Tramadol ER, generic tramadol ER [a]	
Diagnosis	Cancer, Sickle Cell, Hospice, or End of Life Related Pain [a]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)

OR

1.2 Patient is in hospice or is receiving end of life care

OR

1.3 Patient is being treated for pain related to Sickle Cell Disease

AND

2 - If the request is for fentanyl transdermal, hydrocodone extended- release capsules, hydromorphone extended-release tablets, oxymorphone extended-release tablets, morphine sulfate extended-release capsules, Nucynta ER (tapentadol extended-release tablets), methadone tablets, levorphanol tablets, methadone 5mg/5ml and 10mg/5ml solution, Methadose (methadone concentrate), one of the following:

2.1 The patient has a history of failure, contraindication, or intolerance to a trial of morphine sulfate ER tablets (generic MS Contin)*

OR **2.2** Patient is established on pain therapy with the requested medication for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), Sickle Cell Disease related pain, hospice related pain, or end of life care related pain, and the medication is not a new regimen for treatment of cancer-related pain, hospice, or end of life care pain. (Document date regimen was started) **AND** **3** - If the request is for Hysingla ER (hydrocodone extended-release tablets), OxyContin (oxycodone extended-release tablets), oxycodone ER tablets (Oxycontin authorized generic), Xtampza ER (oxycodone extended-release capsules), one of the following: **3.1** The patient has a history of failure, contraindication, or intolerance to a trial of morphine sulfate ER tablets (generic MS Contin)* **OR** **3.2** The physician attests the patient has risk factors for substance abuse **OR** **3.3** Patient is established on pain therapy with the requested medication for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), Sickle Cell Disease related pain, hospice related pain, or end of life care related pain, and the medication is not a new regimen for treatment of cancer-related pain, hospice, or end of life care pain. (Document date regimen was started)	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply. If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization c riteria requirements for long-acting opioids, a denial should be issued and a maximum 60-day authorization may be authorized one time for t he requested drug/strength combination up to the requested quantity f

	or transition to an alternative treatment. *morphine sulfate ER tablets (generic MS Contin) may require prior au thorization.

Product Name:generic fentanyl patches, generic hydrocodone ER caps/tabs, Brand Hysingla ER, generic hydromorphone ER, generic levorphanol, generic methadone tabs/soln/conc, Brand Methadose conc, Brand MS Contin, generic morphine sulfate ER caps/tabs, Xtampza ER, Oxycodone ER, Oxycontin, generic oxymorphone ER, Nucynta ER, Conzip, Tramadol ER, generic tramadol ER [a]	
Diagnosis	Non-Cancer, Non-sickle cell, Non-Hospice, or Non-End of Life pain [a]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The prescriber attests to BOTH of the following:

- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

AND

2 - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

AND

3 - Patient has been screened for underlying depression and/or anxiety. If applicable, any underlying conditions have been or will be addressed

AND

4 - ONE of the following:

4.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days (document drug(s), and date of trial), unless the patient is already receiving chronic opioid therapy prior to surgery for postoperative pain, or in the postoperative pain is expected to be moderate to severe and persist for an extended period of time

OR

4.2 Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

AND

5 - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias and neuropathies), ONE of the following:

5.1 BOTH of the following:

5.1.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (document date of trial)

AND

5.1.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and duration of trial)

OR

5.2 The patient is new to the plan and is currently established on the requested long-acting opioid therapy for at least the past 30 days

AND

6 - If the request is for fentanyl transdermal, hydrocodone extended- release capsules, hydromorphone extended-release tablets, oxymorphone extended-release tablets, morphine sulfate extended-release capsules, Nucynta ER (tapentadol extended-release tablets), methadone tablets, levorphanol tablets, methadone 5mg/5ml and 10mg/5ml solution,

Methadose (methadone concentrate), the patient has a history of failure, contraindication or intolerance to a trial of morphine sulfate ER tablets (generic MS Contin)* **AND** **7** - If the request is for Hysingla ER (hydrocodone extended-release tablets), OxyContin (oxycodone extended-release tablets)oxycodone ER tablets (Oxycontin authorized generic) , Xtampza ER (oxycodone extended-release capsules), one of the following: **7.1** The patient has a history of failure, contraindication, or intolerance to a trial of morphine sulfate ER tablets (generic MS Contin)* **OR** **7.2** The physician attests the patient has risk factors for substance abuse

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for long-acting opioids, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *morphine sulfate ER tablets (generic MS Contin) may require prior authorization.

Product Name:generic fentanyl patches, generic hydrocodone ER caps/tabs, Brand Hysingla ER, generic hydromorphone ER, generic levorphanol, generic methadone tabs/soln/conc, Brand Methadose conc, Brand MS Contin, generic morphine sulfate ER caps/tabs, Xtampza ER, Oxycodone ER, Oxycontin, generic oxymorphone ER, Nucynta ER, Conzip, Tramadol ER, generic tramadol ER [a]	
Diagnosis	Non-Cancer, Non-sickle cell, Non-Hospice or Non-End of Life pain [a]
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement)

AND

2 - Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

AND

3 - Prescriber attests to BOTH of the following:

- Patient has been screened for substance abuse/opioid dependence
- Pain is moderate to severe and expected to persist for an extended period of time (chronic)

AND

4 - If the request is for fentanyl transdermal, hydrocodone extended- release capsules, hydromorphone extended-release tablets, oxymorphone extended-release tablets, morphine sulfate extended-release capsules, Nucynta ER (tapentadol extended-release tablets), methadone, levorphanol tablets, methadone 5mg/5ml and 10mg/5ml solution, Methadose (methadone concentrate), the patient has a history of failure, contraindication or intolerance to a trial of morphine sulfate ER tablets (generic MS Contin)*

AND

5 - If the request is for Hysingla ER (hydrocodone extended-release tablets), OxyContin (oxycodone extended-release tablets), oxycodone ER tablets (Oxycontin authorized generic) , Xtampza ER (oxycodone extended-release capsules), one of the following:

5.1 The patient has a history of failure, contraindication, or intolerance to a trial of morphine sulfate ER tablets (generic MS Contin)*

OR **5.2** The physician attests the patient has risk factors for substance abuse	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for long-acting opioids, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *morphine sulfate ER tablets (generic MS Contin) may require prior authorization.

3 . Background

Benefit/Coverage/Program Information
Background: Long-acting opioid analgesics are indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid is needed for an extended period of time and for which alternative treatment options are not appropriate. They are not intended for use as an as needed analgesic Long-acting opioids are not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time. They are only indicated for postoperative use if the patient is already receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate. Long-acting opioids should not be used in treatment naïve patients. Physicians should individualize treatment in every case, initiating therapy at the appropriate point along a

progression from non-opioid analgesics, such as non-steroidal anti-inflammatory drugs and acetaminophen to opioids in a plan of pain management.

UnitedHealthcare employs opioid safety edits at point-of-sale (POS) to prompt prescribers and pharmacists to conduct additional safety reviews to determine if the member's opioid use is appropriate and medically necessary. Development of opioid safety edit specifications, to include cumulative MME thresholds, are determined by the plan taking into consideration clinical guidelines, regulatory/state requirements, utilization and P&T Committee feedback.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on prevoius claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

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2. Hydromorphone extended release [package insert]. Webster Grover, MO: Mallinckrodt, Inc.; January 2021.
3. Hysingla ER [package insert]. Stanford, CT: Purdue Pharma; December 2023.
4. Morphine Sulfate extended-release capsules [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; March 2021.
5. MS Contin [package insert]. Stanford, CT. Purdue Pharma; December 2023.
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7. Oxymorphone Extended Release [package insert]. Brookhaven, NY. Amneal Pharmaceuticals of NY; August 2022.
8. OxyContin [package insert]. Stanford, CT: Purdue Pharma; December 2023.
9. Xtampza ER [package insert]. Cincinnati, OH: Patheon Pharmaceuticals; December 2023.
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5 . Revision History

Date	Notes
10/14/2025	Added oxymorphone ER tablets to non-abuse deterrent product list. Removed references to Exalgo as brand is obsolete. Added dosage f orms where missing.

Lonsurf

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-237193
Guideline Name	Lonsurf
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	6/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	04/20/2022 ; 08/19/2022 ; 04/19/2023 ; 04/17/2024 ; 4/16/2025

1 . Indications

Drug Name: Lonsurf (trifluridine/tipiracil)
Colorectal cancer Indicated for the treatment of patients with metastatic colorectal cancer as a single agent or in combination with bevacizumab who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. **Gastric cancer** Indicated for the treatment of patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

2 . Criteria

Product Name:Lonsurf [a]	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic colorectal cancer (mCRC)

AND

2 - History of failure, contraindication, or intolerance to treatment with ALL of the following^:

- Fluoropyrimidine-based chemotherapy
- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy
- Anti-VEGF biological therapy

AND

3 - ONE of the following:

3.1 Tumor is RAS mutant-type

OR

3.2 BOTH of the following:

- Tumor is RAS wild-type
- History of failure, contraindication, or intolerance to anti-EGFR therapy^

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may ap

	ply. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Lonsurf [a]	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Lonsurf therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lonsurf [a]	
Diagnosis	Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Unresectable locally advanced, recurrent, or metastatic gastric cancer
- Unresectable locally advanced, recurrent, or metastatic gastroesophageal junction adenocarcinoma

AND

2 - History of failure, contraindication, or intolerance to treatment with at least TWO prior lines of chemotherapy that consisted of the following agents^:

- Fluoropyrimidine (e.g, fluorouracil)
- Platnium (e.g., carboplatin, cisplatin, oxaliplatin)
- Taxane (e.g, docetaxel, paclitaxel) or irinotecan
- HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Lonsurf [a]	
Diagnosis	Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lonsurf therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lonsurf [a]	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Lonsurf will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lonsurf [a]	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Lonsurf therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Lonsurf (trifluridine/tipiracil) is a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, indicated for the treatment of adult patients with: • Metastatic colorectal cancer as a single agent or in combination with bevacizumab who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. • Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a

platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

In addition, the National Cancer Comprehensive Network (NCCN) also recommends the use of colon, appendiceal, or rectal cancer as second-line and subsequent therapy as a single agent, or in combination with bevacizumab (preferred), for advanced or metastatic disease (proficient mismatch repair/microsatellite-stable [pMMR/MSS], or ineligible for, or progressed on, checkpoint inhibitor immunotherapy for deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation not previously treated with Lonsurf in patients who have progressed through all available regimens besides Fruzaqla, Stivarga, or Lonsurf with or without bevacizumab.

Additional Clinical Programs:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Lonsurf [package insert]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; August 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed March 6, 2025.

5 . Revision History

Date	Notes
4/7/2025	Annual review. No changes to clinical criteria. Updated references.

Lorbrena

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523201
Guideline Name	Lorbrena
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 02/18/2022 ; 08/19/2022 ; 02/17/2023 ; 02/16/2024 ; 02/20/2025 ; 2/20/2026

1 . Indications

Drug Name: Lorbrena (lorlatinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC).

2 . Criteria

Product Name:Lorbrena [a]	
Diagnosis	Non-small cell lung cancer (NSCLC)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of NSCLC

AND

2 - ONE of the following:

2.1 Disease is BOTH of the following:

- Advanced, metastatic, or recurrent
- Anaplastic lymphoma kinase (ALK) - positive

OR

2.2 BOTH of the following:

2.2.1 Disease is BOTH of the following:

- Recurrent, advanced, or metastatic
- ROS proto-oncogene 1 (ROS1) - positive

AND

2.2.2 Disease has progressed on at least ONE of the following therapies^:

- Augtyro (repotrectinib)
- Rozlytrek (entrectinib)
- Xalkori (crizotinib)
- Zykadia (ceritinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

	^Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines

Product Name:Lorbrena [a]	
Diagnosis	Non-small cell lung cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Lorbrena therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lorbrena [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Erdheim-Chester Disease (ECD) **AND** **2** - Disease is BOTH of the following: • Symptomatic, relapsed, or refractory • ALK-positive	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lorbrena [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Lorbrena therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lorbrena [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of inflammatory myofibroblastic tumor (IMT) **AND** **2** - Disease is ALK-positive	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Lorbrena [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Lorbrena therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Lorbrena [a]	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - Disease is ONE of the following:

- Advanced
- Recurrent/metastatic

• Inoperable **AND** **3** - Disease is ALK-positive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lorbrena [a]	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Lorbrena therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lorbrena [a]	
Diagnosis	Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following diagnoses:	

- Anaplastic large cell lymphoma (ALCL)
- Large B-Cell lymphoma

AND

2 - Disease is relapsed or refractory

AND

3 - Disease is ALK-positive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lorbrena [a]	
Diagnosis	Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lorbrena therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lorbrena [a]	
Diagnosis	Glioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pediatric diffuse high-grade glioma **AND** **2** - Disease is ALK-positive	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lorbrena [a]	
Diagnosis	Glioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Lorbrena therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lorbrena [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Lorbrena will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lorbrena [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Lorbrena therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Lorbrena (lorlatinib) is a kinase inhibitor indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC).

In addition, the National Cancer Comprehensive Network (NCCN) recommends Lorbrena for the treatment of patients with ALK-positive recurrent and advanced NSCLC and in patients with ROS1 rearrangement positive recurrent, advanced, or metastatic NSCLC.

The use of Lorbrena is also recommended by the NCCN for the treatment of relapsed or refractory ALK-positive large B-Cell lymphoma, inflammatory myofibroblastic tumor (IMT) with ALK translocation, ALK positive advanced, recurrent/metastatic, or inoperable uterine sarcoma, Erdheim-Chester Disease (ECD) with symptomatic or relapsed/refractory disease, ALK-positive pediatric diffuse high-grade glioma, limited and extensive brain metastases in patients with ALK rearrangement-positive NSCLC, and relapsed/refractory or progressive ALK-positive peripheral T-Cell lymphoma.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Lorbrena [package insert]. New York, NY: Pfizer Labs, August 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed December 17, 2025.

5 . Revision History

Date	Notes
2/13/2026	Annual review. Added criteria for pediatric diffuse high-grade glioma. Updated background and references.

Lotronex



Prior Authorization Guideline

Guideline ID	GL-500238
Guideline Name	Lotronex
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 06/15/2022 ; 01/15/2025 ; 1/21/2026

1 . Indications

Drug Name: Lotronex (alosetron)
Severe diarrhea-predominant irritable bowel syndrome (IBS) Indicated only for use in women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have chronic IBS, had anatomical or biochemical abnormalities of the gastrointestinal tract excluded and have not responded to conventional therapy.

2 . Criteria

Product Name:Brand Lotronex, generic alosetron [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) with symptoms for at least six months

AND

2 - Patient was female at birth

AND

3 - Has not responded adequately to conventional therapy (e.g., loperamide, antispasmodics)

AND

4 - Anatomic or biochemical abnormalities of the GI tract have been excluded

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Lotronex, generic alosetron [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Lotronex will be approved based on documentation of positive clinical response to therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background Lotronex (alosteron) is indicated only for use in women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have chronic IBS, had anatomical or biochemical abnormalities of the gastrointestinal tract excluded and have not responded to conventional therapy. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limits may be in place.

4 . References

1. Lotronex [package insert]. Roswell, Georgia: Sebela Pharmaceuticals; April 2019.

5 . Revision History

Date	Notes
1/20/2026	Annual review with no changes to coverage criteria. Updated referen ces.

Lovaza, Vascepa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-540192
Guideline Name	Lovaza, Vascepa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/14/2021
P&T Revision Date:	03/17/2021 ; 09/15/2021 ; 03/16/2022 ; 03/15/2023 ; 01/17/2024 ; 03/20/2024 ; 10/01/2024 ; 09/25/2025 ; 3/18/2026

1 . Indications

Drug Name: Lovaza (omega-3-acid ethyl esters)
Severe Hypertriglyceridemia Indicated as adjunctive therapy to diet and exercise to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.
Drug Name: Vascepa (icosapent ethyl)
Cardiovascular Risk Reduction Indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and either established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease. **Severe Hypertriglyceridemia** Indicated as adjunctive therapy to diet and exercise to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

2 . Criteria

Product Name:Brand Vascepa, generic icosapent ethyl, Brand Lovaza, generic omega-3-acid ethyl esters [a]	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe hypertriglyceridemia (pre-treatment triglyceride level of greater than or equal to 500 mg/dL) **AND** **2** - Patient is on an appropriate lipid-lowering diet and exercise regimen	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Brand Vascepa, generic icosapent ethyl, Brand Lovaza, generic omega-3-acid ethyl esters [a]	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is on an appropriate lipid-lowering diet and exercise regimen

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Brand Vascepa, generic icosapent ethyl [a]	
Diagnosis	Cardiovascular Risk Reduction
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypertriglyceridemia (pre-treatment triglyceride level of greater than or equal to 150 mg/dL)

AND

2 - Patient currently has or is considered high or very high risk for cardiovascular disease (CVD) as evidenced by ONE of the following:

2.1 BOTH of the following:

2.1.1 Age ≥ 45

AND

2.1.2 Established CVD confirmed by ONE of the following:

- Acute coronary syndrome

- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease

OR

2.2 ALL of the following:

2.2.1 Diagnosis of Type 2 diabetes

AND

2.2.2 TWO of the following risk factors for developing cardiovascular disease:

- Family history of premature CVD (Men < 55 years or women < 65 years)
- Primary hypercholesterolemia (e.g., LDL cholesterol, 160 to 189 mg/dL; non-HDL cholesterol 190 to 219 mg/dL
- Metabolic syndrome [e.g., increased waist circumference, elevated triglycerides (>150 mg/dL, nonfasting), elevated blood pressure, elevated glucose, and low HDL cholesterol (<40 mg/dL in males; <50 mg/dL in females)]
- Chronic kidney disease (eGFR 15 to 59 mL/min/1.73 m2 with or without albuminuria; not treated with dialysis or kidney transplantation)
- Chronic inflammatory conditions (e.g., psoriasis, rheumatoid arthritis, lupus, HIV/AIDS)
- History of premature menopause (before age 40 years) and/or history of pregnancy-associated conditions that increase later CVD risk (e.g., preeclampsia)
- Biomarkers associated with increased CVD risk [e.g., elevated high-sensitivity C-reactive protein (≥ 2 mg/L), elevated Lp(a), elevated apoB (≥130 mg/dL)
- Abnormal ankle-brachial index [ABI (< 0.9)]
- Cigarette smoker or stopped smoking within the past 3 months

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

3.1 Patient has been receiving at least 12 consecutive weeks of high- intensity statin therapy (i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive a high-intensity statin at maximally tolerated dose

OR

3.2 BOTH of the following:

3.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

3.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin ≥ 10 mg, pravastatin ≥ 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin) ≥ 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

AND

4 - Submission of medical record (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

- Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia®) therapy as adjunct to maximally tolerated statin therapy
- Patient has a history of contraindication or intolerance to ezetimibe
- Patient has a LDL-C less than 100 mg/dL while on maximally tolerated statin therapy

AND

5 - Used as an adjunct to a low-fat diet and exercise

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Brand Vascepa, generic icosapent ethyl [a]	
Diagnosis	Cardiovascular Risk Reduction
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for cardiovascular risk reduction

AND

2 - Documentation of positive clinical response to therapy

AND

3 - Patient is on an appropriate low-fat diet and exercise regimen

AND

4 - Patient is receiving maximally tolerated statin therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3 . Background

Benefit/Coverage/Program Information
Background:

Lovaza (omega-3-acid ethyl esters) and Vascepa are indicated as adjunctive therapy to diet and exercise to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg/dL) hypertriglyceridemia. Vascepa is also indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (greater than or equal to 150 mg/dL) and either established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Vascepa [package insert]. Bridgewater, NJ : Amarin Pharma Inc.; September 2025.
2. Lovaza [package insert]. Wixom, MI: Woodward Pharma Services LLC; November 2024.
3. Orringer, CE, Jacobson, TA, Maki, KC. National Lipid Association Scientific Statement on the use of icosapent ethyl in statin-treated patients with elevated triglycerides and high or very-high ASCVD risk. J Clin Lipidol. 2019;13(6):860-72.
4. Grundy, S. M., Stone, N. J., Bailey, A. L., et. al, (2019). 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation:139, e1082–e1143.
5. Rosenson RS, Lopez-Sendon J. Atherosclerotic cardiovascular disease risk assessment for primary prevention in adults. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed January 28, 2026.

5 . Revision History

Date	Notes
3/4/2026	Updated risk factors to mirror cardiovascular disease risk assessmen t in adults. Updated references.

Lynkuet, Veozah



Prior Authorization Guideline

Guideline ID	GL-458249
Guideline Name	Lynkuet, Veozah
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	8/18/2023
P&T Revision Date:	08/16/2024 ; 11/22/2024 ; 11/21/2025 ; 12/17/2025

1 . Indications

Drug Name: Lynkuet (elinzanetant), Veozah (fezolinetant)
Moderate to severe vasomotor symptoms due to menopause Indicated for the treatment of moderate to severe vasomotor symptoms due to menopause

2 . Criteria

Product Name:Lynkuet, Veozah [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderate to severe vasomotor symptoms due to menopause

AND

2 - History of failure (after a 30-day trial), contraindication or intolerance to one of the following:

- Hormonal therapy (e.g., estradiol, Premarin, Prempro)
- Non-hormonal therapy [e.g., clonidine, gabapentin, selective serotonin inhibitors (e.g., paroxetine), serotonin and norepinephrine reuptake inhibitors (e.g., venlafaxine)]

AND

3 - Patient has received baseline hepatic laboratory tests to rule out the presence of underlying liver disease

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lynkuet, Veozah [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decrease in frequency and severity of vasomotor symptoms from baseline)

AND

2 - Patient has received periodic evaluation of hepatic laboratory tests to rule out liver injury associated with Lynkuet or Veozah use	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Lynkuet (elinzanetant) and Veozah (fezolinetant) are indicated for the treatment of moderate to severe vasomotor symptoms due to menopause. Veozah use has been associated with reports of hepatotoxicity in post marketing studies that gradually resolve after discontinuation of Veozah. Baseline hepatic laboratory tests should be evaluated prior to initiation of Lynkuet or Veozah. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Lynkuet [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; October 2025.
2. Veozah [package insert]. Northbrook, IL: Astellas US LLC. December 2024.
3. Khan, SJ, Kapoor, E, Faubion, SS, Kling, JM. Vasomotor Symptoms During Menopause: A Practical Guide on Current Treatments and Future Perspectives. Int J Womens Health.2023: 15: 273-87.

5 . Revision History

Date	Notes
12/1/2025	Added Lynkuet and updated references.

Lynparza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-334204
Guideline Name	Lynparza
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	9/1/2025
P&T Approval Date:	5/16/2025
P&T Revision Date:	7/16/2025

1 . Indications

Drug Name: Lynparza (olaparib)
Adjuvant Treatment of Germline BRCA-mutated HER2-negative High Risk Early Breast Cancer Indicated for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. **Germline BRCA-mutated HER2-negative Metastatic Breast Cancer** Indicated for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer, who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. **First-Line Maintenance Treatment of BRCA-mutated Advanced Ovarian Cancer** Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or

primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy.

First-line Maintenance Treatment of HRD-positive Advanced Ovarian Cancer in Combination with Bevacizumab Indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: • a deleterious or suspected deleterious BRCA mutation, and/or • genomic instability.

Maintenance Treatment of BRCA-mutated Recurrent Ovarian Cancer Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm or sBRCAm recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.

HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone.

Treatment of BRCA-mutated Metastatic Castration-Resistant Prostate Cancer in Combination with Abiraterone and Prednisone or Prednisolone Indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC).

2 . Criteria

Product Name:Lynparza [a]	
Diagnosis	Breast Cancer (High Risk Early Breast Cancer)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of high risk early breast cancer

AND

2 - Presence of deleterious or suspected deleterious germline BRCA-mutations (gBRCAm)

AND

3 - Disease is human growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

4.1 Patient is hormone receptor (HR) negative

OR

4.2 BOTH of the following:

- Patient is hormone receptor (HR) positive
- Patient is continuing concurrent treatment with endocrine therapy

AND

5 - Patient has been treated with neoadjuvant or adjuvant chemotherapy

AND

6 - Treatment duration has not exceeded 12 months of therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lynparza [a]

Diagnosis	Breast Cancer (Metastatic or Recurrent Breast Cancer)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Metastatic breast cancer
- Recurrent breast cancer

AND

2 - Presence of deleterious or suspected deleterious germline BRCA-mutations (gBRCAm)

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

3.1.2 ONE of the following:

3.1.2.1 Disease is hormone receptor (HR) negative

OR

3.1.2.2 BOTH of the following:

3.1.2.2.1 Disease is hormone receptor (HR) positive

AND

3.1.2.2.2 ONE of the following:

- Disease has progressed on previous endocrine therapy
- Provider attestation that treatment with endocrine therapy is inappropriate

OR

3.2 Disease is human epidermal growth factor receptor 2 (HER2)-positive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lynparza [a]	
Diagnosis	Breast Cancer (Metastatic or Recurrent Breast Cancer)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lynparza therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lynparza [a]	
Diagnosis	Ovarian Cancer (Maintenance Therapy)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - Disease is ONE of the following:

- Advanced
- Recurrent

AND

3 - ONE of the following:

3.1 Presence of deleterious or suspected deleterious germline or somatic BRCA-mutations

OR

3.2 BOTH of the following:

- Cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation or genomic instability
- Used in combination with bevacizumab (e.g., Avastin, Mvasi)

AND

4 - Patient has had a complete or partial response to platinum-based chemotherapy

AND **5** - Request is for maintenance therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lynparza [a]	
Diagnosis	Ovarian Cancer (Maintenance Therapy)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lynparza therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lynparza [a]	
Diagnosis	Ovarian Cancer (Treatment)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - Disease is ONE of the following:

- Advanced
- Persistent
- Recurrent

AND

3 - Presence of deleterious or suspected deleterious germline BRCA-mutation

AND

4 - Patient has been treated with two or more prior lines of chemotherapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lynparza [a]	
Diagnosis	Ovarian Cancer (Treatment)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lynparza therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Lynparza [a]	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic adenocarcinoma

AND

2 - Disease is metastatic

AND

3 - Presence of deleterious or suspected deleterious germline BRCA1/2-mutation

AND

4 - Disease has NOT progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Lynparza [a]	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lynparza therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lynparza [a]	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Presence of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations

AND

2.1.2 Disease has progressed following prior treatment with ONE of the following^:

- Enzalutamide (Xtandi)

- Abiraterone (e.g., Zytiga, Yonsa)

OR

2.2 ALL of the following:

- Presence of deleterious or suspected deleterious BRCA-mutation
- Used in combination with abiraterone (e.g., Zytiga, Yonsa)
- Used in combination with steroids (e.g., methylprednisolone, prednisolone, prednisone)

AND

3 - ONE of the following:

3.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

3.2 Patient has had bilateral orchiectomy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines

Product Name:Lynparza [a]	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lynparza therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines

Product Name:Lynparza [a]	
Diagnosis	Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - NOT used as first-line therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lynparza [a]	
Diagnosis	Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lynparza therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lynparza [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Lynparza will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Lynparza [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lynparza therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Lynparza (olaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated (g*BRCA*m or s*BRCA*m) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Lynparza is also indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious g*BRCA*m or s*BRCA*m recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy. Lynparza is also indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: a deleterious or suspected deleterious *BRCA* mutation or genomic instability. Lynparza is also indicated in patients with deleterious or suspected deleterious g*BRCA*m, human epidermal growth factor receptor 2 (HER2)-negative high risk early, or metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or, in the setting of metastatic breast cancer, the metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment. The National Comprehensive Cancer Network (NCCN) also recommends Lynparza therapy in patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-positive recurrent unresectable or metastatic breast cancer. Patients with high risk early breast cancer should continue treatment for a total of 1 year, or until disease recurrence, or unacceptable toxicity, whichever occurs first. Lynparza is indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Lynparza is also indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) mCRPC.

Patients receiving Lynparza for mCRPC should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy.

Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious g*BRCA*m metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

The NCCN also recommends Lynparza therapy in patients with uterine sarcoma as single-agent second-line therapy.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Lynparza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, Inc, November 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed June 16, 2025.

5 . Revision History

Date	Notes
7/17/2025	Annual review. Updated language for use with concurrent steroids for prostate cancer to reflect NCCN recommendations. Updated background and references.



Prior Authorization Guideline

Guideline ID	GL-399291
Guideline Name	Medical Foods, Nutritional Supplements, Enteral Nutrition
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	05/21/2021 ; 09/15/2021 ; 04/19/2023 ; 08/18/2023 ; 09/18/2024 ; 09/25/2025 ; 9/25/2025

1 . Criteria

Product Name:RCF, Calcilo XD, Phenex Chews, Cyclinex-1, Cyclinex-2, Elecare, Elecare DHA/ARA Infant, Elecare JR, Elecare/DHA/ARA, Glutarex-1, Glutarex-2, Hominex-1, Hominex-2, I-Valex-1, I-Valex-2, Ketonex-1, Ketonex-2, Phenex-1, Phenex-2, Propimex-1, Propimex-2, Provimin, Tyrex-1, Tyrex-2, Puramino DHA/ARA, Alfamino Infant, Neocate Syneo Infant, Neocate Nutra, Neocate Infant DHA/ARA [a]	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Being used as part of disease or disorder specific treatment

AND

2 - Requested product has been proven effective for the patient's specific disease or disorder. This includes, but is not limited to:

2.1 Inherited diseases of amino acid and/or organic acid metabolism (e.g. glutaric aciduria type I, vitamin B6-nonresponsive homocystinuria or hypermethioninemia, hyperlycinemia, histidinemia, disorder of leucine catabolism, PKU, maternal PKU, branched chain ketonuria/MSUD, propionic or methylmalonic acidemia, tyrosinemia types I, II or III)

OR

2.2 Patients who require a formula modified in carbohydrate, fat, and/or increased protein (e.g. abetalipoproteinemia; cholestasis; chylothorax; fatty acid oxidation defects; galactosemia, glutaric acidemias; hyperlipoproteinemia type I (fasting chylomicronemia); hypobetalipoproteinemia; lymphangiectasis, intestinal malabsorption of carbohydrate and/or fat; supplement for any patient who requires increased protein, minerals, and vitamins; X-linked adrenoleukodystrophy)

OR

2.3 Hypercalcemia, as may occur in infants with Williams syndrome, osteopetrosis, and primary neonatal hyperparathyroidism

OR

2.4 Urea cycle disorder, gyrate atrophy of the choroid and retina, or HHH syndrome

OR

2.5 Infants or children who cannot tolerate intact or hydrolyzed protein, or unable to tolerate the type or amount of carbohydrate in milk or infant formulas

OR

2.6 Infants or children with severe food or protein allergies

OR

2.7 Immunoglobulin E and non-immunoglobulin E-mediated allergies to multiple food proteins

OR

2.8 Severe food protein induced enterocolitis syndrome

OR

2.9 Eosinophilic disorders

OR

2.10 Chronic intestinal pseudo-obstruction

OR

2.11 Impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract (e.g., Crohn's disease, ulcerative colitis, gastroesophageal reflux)

OR

2.12 BOTH of the following:

- Multiple food protein intolerance
- The child has not been responsive to trials of standard non-cow milk-based formulas, including soybean and goat milk.

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

2 . Background

Benefit/Coverage/Program Information
Background: The intent of this program is to provide coverage for specialized foods (including nutritional supplements), for specific medical conditions, including, but not limited to, inherited enzymatic disorders, inherited metabolic diseases, severe protein allergic conditions, severe protein induced enterocolitis, eosinophilic disorders, impaired absorption disorders, conditions requiring amino acid-based modified elemental formulas, and formulas necessary for phenylketonuria. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

3 . References

1. Abbott Nutrition [package inserts]. 100 Abbott Park Road, Abbott Park, Ill. 60064; August 2020

4 . Revision History

Date	Notes
10/7/2025	Updated program type to Prior Authorization.

Mekinist

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-264232
Guideline Name	Mekinist
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	03/16/2022 ; 08/19/2022 ; 05/25/2023 ; 06/21/2023 ; 05/17/2024 ; 12/18/2024 ; 5/16/2025

1 . Indications

Drug Name: Mekinist (trametinib)
Melanoma Indicated, as a single agent in BRAF-inhibitor treatment-naïve patients or in combination with dabrafenib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Mekinist is also indicated, in combination with dabrafenib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations and involvement of lymph node(s) following complete resection. **Non-small cell lung cancer** Indicated, in combination with dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation. **Anaplastic thyroid cancer** Indicated, in combination with dabrafenib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. **Solid Tumors** Indicated for the treatment of adult and pediatric patients 1 year of age and

older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.

BRAF V600E Mutation-Positive Low-Grade Glioma Indicated, in combination with Tafinlar, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy

Other Uses: The National Comprehensive Cancer Network (NCCN) also recommends use of Mekinist in combination with Tafinlar for the adjuvant treatment of anaplastic thyroid cancer with BRAF V600E mutations following resection; for the treatment of follicular, oncocytic, and papillary thyroid carcinomas with a BRAF mutation; for the treatment of central nervous system (CNS) cancer in patients with melanoma or infiltrative supratentorial astrocytoma/oligodendroglioma; distant metastatic uveal melanoma; epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer with persistent disease, recurrence in BRAF V600E positive tumors, or recurrence of low-grade serous carcinoma; pancreatic and ampullary adenocarcinomas if BRAF V600E mutation positive; and BRAF V600E mutation positive histiocytic neoplasms and hepatobiliary cancers.

2 . Criteria

Product Name:Mekinist [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 Unresectable melanoma

OR

1.1.2 Metastatic melanoma

OR

1.1.3 BOTH of the following:

- Prescribed as adjuvant therapy for melanoma involving the lymph node(s)
- Used in combination with Tafinlar (dabrafenib)

AND

1.2 Cancer is positive for BRAF V600 mutation

OR

2 - Distant metastatic uveal melanoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Tafinlar (dabrafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of anaplastic thyroid cancer (ATC)

AND

1.2 Cancer is positive for BRAF V600E mutation

AND

1.3 Used in combination with Tafinlar (dabrafenib)

AND

1.4 ONE of the following:

1.4.1 Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

OR

1.4.2 Prescribed as adjuvant therapy following resection

OR

2 - ALL of the following:

2.1 ONE of the following diagnoses:

- Follicular Carcinoma
- Oncocytic Carcinoma
- Papillary Carcinoma

AND

2.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

2.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

2.4 Disease is refractory to radioactive iodine treatment

AND **2.5** Cancer is positive for BRAF V600 mutation **AND** **2.6** Used in combination with Tafinlar (dabrafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

- Patient has metastatic brain lesions
- Mekinist is active against primary tumor (melanoma)

OR

1.2 Patient has a glioma

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - Used in combination with Tafinlar (dabrafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial Ovarian Cancer
- Fallopian Tube Cancer
- Primary Peritoneal Cancer

AND

2 - ONE of the following:

- Persistent disease
- Recurrence in BRAF V600E positive tumors
- Recurrence of low-grade serous carcinoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic Cholangiocarcinoma
- Intrahepatic Cholangiocarcinoma

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND **4** - Cancer is positive for BRAF V600E mutation **AND** **5** - Used in combination with Tafinlar (dabrafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease
- Rosai-Dorfman Disease

AND

2 - Mitogen-activated protein (MAP) kinase pathway mutation, no detectable mutation, or testing not available

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Solid Tumors
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of solid tumor

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E mutation

AND

5 - Used in combination with Tafinlar (dabrafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Pancreatic Cancer / Ampullary Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Pancreatic adenocarcinoma
- Ampullary adenocarcinoma

AND

2 - Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

AND

3 - Cancer is positive for BRAF V600E mutation

AND **4** - Used in combination with Tafinlar (dabrafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Pancreatic Cancer / Ampullary Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

• Diagnosis of hairy cell leukemia • Used in combination with Tafinlar (dabrafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Mekinist therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of salivary gland tumor	

AND

2 - Disease is ONE of the following:

- Recurrent and unresectable
- Metastatic

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Tafinlar (dabrafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRAF V600E-mutated GIST

AND

2 - Disease is ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Progressive
- Recurrent
- Metastatic

AND

3 - Used in combination with Tafinlar (dabrafenib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Mekinist will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Mekinist [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mekinist therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Mekinist (trametinib) is a kinase inhibitor indicated as a single agent or in combination with Tafinlar (dabrafenib) for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutations as detected by an FDA-approved test. It is also indicated in combination with Tafinlar for the treatment of metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA approved test, for the adjuvant treatment of melanoma with BRAF V600E or BRAF V600K mutations, as detected by an FDA-approved test, involving the lymph nodes following resection, and for the treatment of locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options, and for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. The latter indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). [1] Mekinist, in combination with Tafinlar, is also indicated for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy. The National Comprehensive Cancer Network (NCCN) also recommends use of Mekinist in combination with Tafinlar for the adjuvant treatment of anaplastic thyroid cancer with BRAF V600E mutations following resection; for the treatment of follicular, oncocytic, and papillary thyroid carcinomas with a BRAF mutation; for the treatment of central nervous system (CNS) cancer in patients with melanoma or infiltrative supratentorial astrocytoma/oligodendroglioma; distant metastatic uveal melanoma; epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer with persistent disease, recurrence in BRAF V600E positive tumors, or recurrence of low-grade serous carcinoma; pancreatic and

ampullary adenocarcinomas if BRAF V600E mutation positive; and BRAF V600E mutation positive histiocytic neoplasms and hepatobiliary cancers. [2]

Information on FDA-approved tests for the detection of BRAFV600 mutations in melanoma may be found at: http://www.fda.gov/CompanionDiagnostics

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Mekinist [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 8, 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available atwww.nccn.org. Accessed April 8, 2025.

5 . Revision History

Date	Notes
5/16/2025	Annual review. Updated background and references.

Menopur

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412241
Guideline Name	Menopur
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	10/20/2021
P&T Revision Date:	06/15/2022 ; 09/21/2022 ; 12/14/2022 ; 06/21/2023 ; 08/18/2023 ; 04/17/2024 ; 06/17/2024 ; 10/01/2024 ; 06/18/2025 ; 9/17/2025

1 . Indications

Drug Name: Menopur (menotropins)
Development of Multiple Follicles and Pregnancy in Ovulatory Women as Part of an Assisted Reproductive Technology (ART) Cycle Indicated for the development of multiple follicles and pregnancy in ovulatory women participating in an assisted reproductive technology (ART) program.

2 . Criteria

Product Name:Menopur [a]

Diagnosis	Ovulation Induction
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ovulatory dysfunction

AND

2 - ONE of the following exists:

- Anovulation
- Oligo-ovulation
- Amenorrhea

AND

3 - Other specific causative factors (e.g., thyroid disease, hyperprolactinemia) have been excluded or treated

AND

4 - Infertility is not due to primary ovarian failure

AND

5 - For induction of ovulation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Menopur [a]	
Diagnosis	Controlled Ovarian Stimulation**

Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (controlled ovarian stimulation)

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 ONE of the following exists:

- Diminished ovarian reserve
- Endometriosis
- Male factor infertility
- Tubal factor infertility
- Unexplained infertility
- Uterine factor infertility
- Ovulatory dysfunction
- Recurrent pregnancy loss
- Failure to achieve conception with other treatment modalities

AND

3.1.2 Documentation of an approved assisted reproductive technology (ART) protocol

OR

3.2 BOTH of the following:

3.2.1 ONE of the following exists:

- Diminished ovarian reserve
- Mild to moderate male factor infertility
- Minimal to mild endometriosis
- Unilateral tubal factor infertility
- Unexplained infertility

AND

3.2.2 Will be used in conjunction with intrauterine insemination (IUI)

Notes	**NOTE: Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas, and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Menopur [a]	
Diagnosis	Male Hypogonadotropic Hypogonadism**
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Diagnosis of male primary hypogonadotropic hypogonadism
- Diagnosis of male secondary hypogonadotropic hypogonadism

AND

2 - For induction of spermatogenesis

AND

3 - Infertility is not due to primary testicular failure

Notes	**NOTE: Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas, and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

The body produces two types of gonadotropins, follicle-stimulating hormone (FSH) and luteinizing hormone (LH), both of which play a role in fertility and human reproduction. After they are produced by the pituitary gland, gonadotropins trigger production of other sex hormones which then promote production of egg and sperm. Gonadotropins include hMG (human menopausal gonadotropin –Menopur) and follicle stimulating hormone. Gonadotropins are used in the treatment of infertility, a disease of the reproductive system defined as one of the following:

- inability to achieve a successful pregnancy due to an individual's medical, sexual, or reproductive history;
- failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse when the female partner is less than 35 years;
- failure to achieve a pregnancy after 6 months or more of regular unprotected sexual intercourse when the female partner is 35 years or older

Menopur (menotropins) is indicated for the development of multiple follicles and pregnancy in ovulatory women participating in an assisted reproductive technology (ART) program. hMG is used for the treatment of ovulation induction in women with ovulatory dysfunction including polycystic ovary syndrome (PCOS) who failed on clomiphene as well as for ovulation induction in the setting of hypogonadotropic hypogonadism. hMG is also used for induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.

The clinically appropriate dosing for hMG agents when used in an ART cycle without an FSH product is 450 IU/day or less for not more than 14 days of treatment. When used as part of a mixed stimulation protocol (hMG + FSH) or when used alone for ovulation induction or controlled ovarian stimulation the clinically appropriate maximum dosing for hMG agents is

225 IU/day and 150 IU/day respectively. Exceeding this daily dose and duration of treatment has not been proven to be efficacious in terms of pregnancy outcome.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. World Health Organization web site. https://www.who.int/health-topics/infertility#tab=tab. Accessed May 3, 2024.
2. American Society for Reproductive Medicine. Definitions of infertility and recurrent pregnancy loss: a committee opinion. Fertil Steril 2013; Jan 99(1):63.
3. Menopur [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; May 2018.
4. Platteau P, Andersen AN, Balen A, et al. Similar ovulation rates, but different follicular development with highly purified menotrophin compared with recombinant FSH in WHO Group II anovulatory infertility: a randomized controlled study. Hum. Reprod. 2006;21:1798-1804.
5. Kelly AC, Jewlewicz R. Alternate regimens for ovulation induction in polycystic ovarian disease. Fertil Steril. 1990;54;195-202.
6. Muasher SJ. Use of gonadotrophin-releasing hormone agonists in controlled ovarian hyperstimulation for in vitro fertilization. Clin Ther 1992;14(Suppl A):74-86.
7. Ferraretti A, Marca A, Fauser B, et al. ESHRE consensus on the definition of 'poor response' to ovarian stimulation for in vitro fertilization: the Bologna criteria. Human Reprod 2011; 26: 1616-24.
8. Andoh K, Mizunuma H, Liu X, et al. A comparative study of fixed-dose, stepdown, and low-dose step-up regimens of human menopausal gonadotropin for patients with polycystic ovary syndrome. Fertil Steril m1998: 70; 840-846.
9. Pal L, Jindal S, Witt B, Santoro N. Less is more: increased gonadotropin use for ovarian stimulation adversely influences clinical pregnancy and live birth after in vitro fertilization. Fertil Steril 2008;89:1694-701.
10. Fauser B, Nargund G, Anderson A, et al. Mild ovarian stimulation for IVF: 10 years later. Human Reprod 2010; 25: 2678-84.
11. Baart E, Martini E, Eijkemans M, et al. Milder ovarian stimulation for in-vitro fertilization reduces aneuploidy in the human preimplantation embryo: a randomized controlled trial. Human Reprod 2007; 22: 980-8.
12. Sunkara S, Rittenberg V, Raine-Fenning N, et al. Association between the number of eggs and live birth in IVF treatment: an analysis of 400,135 treatment cycles. Human Reprod 2011; 26: 1768-74.
13. The Practice Committee of the American Society for Reproductive Medicine. Use of exogenous gonadotropins in anovulatory women: a technical bulletin. Fertil Steril 2008;90:S7–12.

14. Practice Committees of the American Society for Reproductive Medicine and Society for Reproductive Endocrinology and Infertility. Electronic address: asrm@asrm.org. Use of exogenous gonadotropins for ovulation induction in anovulatory women: a committee opinion. Fertil Steril. 2020;113(1):66-70. doi:10.1016/j.fertnstert.2019.09.020
15. Practice Committee of the American Society for Reproductive Medicine, American Society for Reproductive Medicine. Definition of infertility: a committee opinion (2023). Available at: https://www.asrm.org/practiceguidance/practice-committee-documents/denitions-of-infertility/
16. Gerber R, Fazzari M, Kappy M, et al. Differential impact of controlled ovarian hyperstimula-tion on live birth rate in fresh versus frozen embryo transfer cycles: a Society for Assisted Re-productive Technology Clinic Outcome System study. Fertil Steril 2020; 114: 1225-1231.
17. Youseff M A-F; van Wiley M, Mochtar M, et al: Low dosing of gonadotropins in in vitro ferti-lization cycles for women with poor ovarian reserve: systematic review and meta-analysis. Fertil Steril 2018; 109: 289-301.

5 . Revision History

Date	Notes
10/7/2025	Added New York to ovulation induction operation note for 2026 imple mentation.

Mifeprex (Benefit Determination)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-232245
Guideline Name	Mifeprex (Benefit Determination)
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	6/1/2025
P&T Approval Date:	11/18/2022
P&T Revision Date:	11/18/2022 ; 02/17/2023 ; 4/16/2025

1 . Criteria

Product Name:Brand Mifeprex 200mg, mifepristone (generic Mifeprex) 200 mg	
Approval Length	1 month(s)
Guideline Type	Administrative
Approval Criteria **1** - Provider attests patient requires treatment for purposes identified in the Hyde amendment and any applicable state laws and regulations	

2 . Background

Benefit/Coverage/Program Information
Background: Effective January 3, 2023, the Risk Evaluation and Mitigation Strategy (REMS) program for Mifeprex (mifepristone) was revised to allow the product to be dispensed by certified retail and mail order pharmacies. Previously, this product was only available when ordered, prescribed, and dispensed by or under the supervision of a healthcare provider. These products are standardly covered without prior authorization. The purpose of this program is to determine coverage of Mifeprex 200mg and mifepristone (generic Mifeprex) 200mg when variations to our standard are present in plan benefit documents (e.g., required by state mandate, etc.). The Hyde amendment prohibits federal funding for most abortions with the exception of abortion of pregnancies that are the result of rape, incest, or where the life of the mother is at risk. [1] **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3 . References

1. "S.142 - 113th Congress (2013-2014): Hyde Amendment Codification Act." Congress.gov, Library of Congress, 24 January 2013, https://www.congress.gov/bill/113th-congress/senate-bill/142.

4 . Revision History

Date	Notes
4/4/2025	Updated background of policy to clarify the intent of the Hyde Amend ment.

Miplyffa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-500239
Guideline Name	Miplyffa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	11/22/2024
P&T Revision Date:	01/15/2025 ; 1/21/2026

1 . Indications

Drug Name: Miplyffa (arimoclomol)
Niemann-Pick disease type C (NPC) Indicated for use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older.

2 . Criteria

Product Name:Miplyffa [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - BOTH of the following:

- Diagnosis of Niemann-Pick disease type C (NPC)
- Diagnosis has been genetically confirmed by mutation analysis of NPC1 and NPC2 genes

AND

2 - Miplyffa is being used to treat neurological manifestations of NPC

AND

3 - Miplyffa is prescribed in combination with miglustat

AND

4 - Patient is not receiving Miplyffa in combination with Aqneursa (levacetylleucine)

AND

5 - Miplyffa is prescribed by or in consultation with a provider with expertise in the treatment of NPC

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Miplyffa [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Miplyffa therapy (e.g., slowed disease progression from baseline based on assessment with NPC–specific scales)

AND

2 - Miplyffa continues to be prescribed in combination with miglustat

AND

3 - Patient is not receiving Miplyffa in combination with Aqneursa (levacetylleucine)

AND

4 - Miplyffa is prescribed by or in consultation with a provider with expertise in the treatment of NPC

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Miplyffa (arimoclomol) is indicated for use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Miplyffa® [package insert], Celebration, FL: Zevra Therapeutics, Inc.; September 2024.
2. Geberhiwot T, Moro A, Dardis A, et al. Consensus clinical management guidelines for Niemann-Pick disease type C. Orphanet J Rare Dis. 2018;13(1):50. Published 2018 Apr 6. doi:10.1186/s13023-018-0785-7

5 . Revision History

Date	Notes
1/20/2026	Annual review with no changes to coverage criteria. Updated references.

Motofen

Prior Authorization Guideline

Guideline ID	GL-412197
Guideline Name	Motofen
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	09/21/2022 ; 09/18/2024 ; 10/15/2025

1 . Indications

Drug Name: Motofen (difenoxin/atropine)
Diarrhea Indicated as adjunctive therapy in management of acute nonspecific diarrhea and acute exacerbations of chronic functional diarrhea.

2 . Criteria

Product Name:Motofen [a]	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used as adjunctive therapy

AND

2 - Used for the management of acute nonspecific diarrhea or acute exacerbations of chronic functional diarrhea

AND

3 - History of failure, contraindication, or intolerance to BOTH of the following:

- diphenoxylate/atropine (generic Lomotil)
- loperamide

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Motofen is indicated as adjunctive therapy in management of acute nonspecific diarrhea and acute exacerbations of chronic functional diarrhea.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Motofen [package insert]. Roswell, GA: Sebela Pharmaceuticals Inc; January 2025.

5 . Revision History

Date	Notes
10/6/2025	Annual review, updated reference.

MS Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-458256
Guideline Name	MS Agents
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/15/2025
P&T Approval Date:	12/16/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 05/20/2022 ; 09/21/2022 ; 12/14/2022 ; 02/17/2023 ; 02/17/2023 ; 01/17/2024 ; 05/17/2024 ; 12/18/2024 ; 05/16/2025 ; 09/25/2025

1 . Indications

Drug Name: Avonex and Rebif(interferon β-1a), Betaseron and Extavia(interferon β-1b), Plegridy(peginterferon β-1a), Copaxone and Glatopa(glatiramer acetate), Aubagio(teriflunomide)
Relasping forms of multiple sclerosis Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Mayzent (siponimod), Tecfidera (dimethyl fumarate), Bafiertam (monomethyl fumarate), Kesimpta (ofatumumab), Ponvory (Ponesimod), Vumerity (diroximel fumarate)

Relasping Forms of Multiple Sclerosis Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Gilenya (fingolimod)
Relapsing forms of multiple sclerosis Indicated for the treatment of patients 10 years of age and older with relapsing forms of multiple sclerosis.
Drug Name: Mavenclad (cladribine)
Relapsing forms of multiple sclerosis Indicated for the treatment of relapsing forms of multiple sclerosis, including relapsing-remitting (RRMS) and active secondary progressive disease in adults who have had inadequate response or are intolerant to other therapies for multiple sclerosis.
Drug Name: Tascenso ODT (fingolimod)
Relapsing forms of multiple sclerosis Indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in pediatric patients 10 years of age and older.

2 . Criteria

Product Name:Brand Aubagio, generic teriflunomide, Avonex, Bafiertam, Betaseron, Brand Copaxone, generic glatiramer, Extavia, Brand Gilenya, generic fingolimod, Glatopa, Kesimpta, Brand Mavenclad, generic cladribine, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Brand Tecfidera, generic dimethyl fumerate, Vumerity [a]	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple sclerosis (MS)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Aubagio (teriflunomide), Avonex (interferon β-1a), Bafiertam (monomethyl fumarate), Betaseron (interferon β-1b), Copaxone (glatiramer acetate), Extavia (interferon β-1b), Glatopa (glatiramer acetate), Kesimpta (ofatumamab), Mayzent (siponimod), Plegridy (Peginterferon Beta-1a), Ponvory (ponesimod), Rebif (interferon β-1a), Tecfidera (dimethyl fumarate), and Vumerity (diroximel fumarate) are indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. [1-3, 5, 6]

Mavenclad (cladribine) is indicated for the treatment of relapsing forms of multiple sclerosis, including relapsing-remitting (RRMS) and active secondary progressive disease in adults who have had inadequate response or are intolerant to other therapies for multiple sclerosis. Mavenclad is also indicated for the treatment of active hairy cell leukemia as defined by clinically significant anemia, neutropenia, thrombocytopenia, or disease-related symptoms.

Gilenya (fingolimod) is indicated for the treatment of patients with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older. [4] Tascenso ODT™ (fingolimod) is indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in pediatric patients 10 years of age and older. [16] Due to the risk of a decrease in heart rate and/or atrioventricular conduction after the first dose of Gilenya, all patients should be observed for signs and symptoms of bradycardia for at least 6 hours after their first dose. First-dose monitoring should also be performed when restarting Gilenya after discontinuation for more than 14 days and with dose increases. Novartis, the manufacturer of Gilenya, provides a First-Dose Observation program at no cost to the patient through the GILENYA Go Program. To find a first-dose observation center, visit http://www.gilenya.com/c/ms-pill/first-day

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Avonex [package insert]. Cambridge, MA: Biogen Inc.; July 2023.
2. Rebif [package insert]. Rockland, MA: EMD Serono Inc; July 2023.
3. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2023.
4. Copaxone [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; January 2025.
5. Extavia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2023.
6. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; June 2024.
7. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; December 2022.
8. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; March 2024.
9. Plegridy [package insert]. Cambridge, MA: Biogen Inc; July 2023.
10. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; February 2025.
11. Mayzent [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.
12. Mavenclad [package insert]. Rockland, MA: EMD Serono Inc; May 2024.
13. Vumerity [package insert]. Cambridge, MA: Biogen Inc.; September 2024.
14. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LLC; September 2023.
15. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.
16. Ponvory [package insert]. Titusville, NJ: Janssen Pharmaceuticals Inc; August 2023.
17. Tascenso ODT [package insert]. San Jose, CA: Handa Neuroscience, LLC; August 2023.

5 . Revision History

Date	Notes
12/1/2025	added generic Mavenclad

Mulpleta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412198
Guideline Name	Mulpleta
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 10/01/2024 ; 10/15/2025

1 . Indications

Drug Name: Mulpleta (lusutrombopag)
Thrombocytopenia Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

2 . Criteria

Product Name:Mulpleta [a]	
Diagnosis	Thrombocytopenia
Approval Length	1 month(s)

Guideline Type	Non Formulary
Approval Criteria **1** - Diagnosis of thrombocytopenia **AND** **2** - Patient has chronic liver disease **AND** **3** - Patient is scheduled to undergo a procedure	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Mulpleta (lusutrombopag) is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Mulpleta [Package Insert]. Florham Park, NJ: Shionogi, Inc.; April 2019.

5 . Revision History

Date	Notes
10/6/2025	Annual review with no changes to coverage criteria.

Multaq



Prior Authorization Guideline

Guideline ID	GL-399225
Guideline Name	Multaq
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	07/21/2021 ; 09/21/2022 ; 10/16/2024 ; 9/25/2025

1 . Indications

Drug Name: Multaq (dronedarone)
Atrial fibrillation Indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

2 . Criteria

Product Name:Multaq [a]	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following criteria:

1.1 Diagnosis of a history of ONE of the following:

- Paroxysmal atrial fibrillation (AF)
- Persistent AF defined as AF less than 6 months duration

AND

1.2 ONE of the following:

- Patient is in sinus rhythm
- Patient is planned to undergo cardioversion to sinus rhythm

AND

1.3 Patient has NONE of the following:

- NYHA Class IV heart failure
- Symptomatic heart failure with recent decompensation requiring hospitalization

OR

2 - For continuation of current therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3 . Background

Benefit/Coverage/Program Information

Background:

Multaq is an antiarrhythmic drug indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

Multaq carries a black box warning for increased risk of death, stroke, and heart failure in patients with decompensated heart failure or permanent atrial fibrillation. It is contraindicated in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure, as Multaq doubles the risk of death in these patients. Multaq is also contraindicated in patients in atrial fibrillation who will not or cannot be cardioverted into normal sinus rhythm. In patients with permanent atrial fibrillation, Multaq doubles the risk of death, stroke and hospitalization for heart failure.

Patients currently on Multaq therapy will be allowed to remain on therapy.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Multaq [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S LLC; October 2023.
2. American College of Cardiology. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and the Heart Rhythm Society. Circulation 2014; 130:e199.
3. American College of Cardiology. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am CollCardiol. 2019 Jul 9;74(1):104-132.
4. American College of Cardiology. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Volume 149, Issue 1, 2 January 2024; e1-e156.

5 . Revision History

Date	Notes
9/17/2025	Added state mandate language.

Myalept

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-276245
Guideline Name	Myalept
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	05/21/2021 ; 05/20/2022 ; 06/21/2023 ; 06/17/2024 ; 6/18/2025

1 . Indications

Drug Name: Myalept (metreleptin)
Generalized lipodystrophy Indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.

2 . Criteria

Product Name:Myalept [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital or acquired generalized lipodystrophy associated with leptin deficiency

AND

2 - Myalept is being used as an adjunct to diet modification

AND

3 - Prescribed by an endocrinologist

AND

4 - Patient has at least ONE of the following:

4.1 Diabetes mellitus or insulin resistance with persistent hyperglycemia (HgbA1C greater than 7.0) despite BOTH of the following:

- Dietary intervention
- Optimized insulin therapy at maximum tolerated doses

OR

4.2 Persistent hypertriglyceridemia (TG greater than 200) despite BOTH of the following:

- Dietary intervention
- Optimized therapy with at least TWO triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Myalept [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Myalept therapy

AND

2 - Myalept is being used as an adjunct to diet modification

AND

3 - Prescribed by an endocrinologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

Background:

Myalept (metreleptin) is a leptin analog indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.

Limitations of Use:

- The safety and effectiveness of Myalept for the treatment of complications of partial lipodystrophy have not been established.
- The safety and effectiveness of Myalept for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH), have not been established.
- Myalept is not indicated for use in patients with HIV-related lipodystrophy.
- Myalept is not indicated for use in patients with metabolic disease, without concurrent evidence of generalized lipodystrophy.

Myalept is available only through a restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS), called the Myalept REMS program, because of the risks associated with the development of anti-metreleptin antibodies that neutralize endogenous leptin and the risk of lymphoma.

4 . References

1. Myalept [package insert]. Amryt Pharmaceuticals, Inc. Cambridge, MA. February 2022.
2. Brown RJ, Araujo-Vilar D, Cheung PT, et al. The Diagnosis and Management of Lipodystrophy Syndromes: A Multi-Society Practice Guideline. J Clin Endocrinol Metab. 2016;101(12):4500-4511.
3. Brush M, Auh S, Cochran E, et al. Effects of Metreleptin in Patients With Generalized Lipodystrophy Before vs After the Onset of Severe Metabolic Disease. J Clin Endocrinol Metab. 2025;110(4):e1051-e1061.

5 . Revision History

Date	Notes
5/28/2025	Annual review. Updated reference value for triglycerides. Updated references.

Myqorzo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-552194
Guideline Name	Myqorzo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	2/20/2026
P&T Revision Date:	

1 . Indications

Drug Name: Myqorzo (aficamten)
Obstructive hypertrophic cardiomyopathy (HCM) Indicated for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms.

2 . Criteria

Product Name:Myqorzo [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of obstructive hypertrophic cardiomyopathy (HCM)

AND

2 - Heart failure is classified as ONE of the following:

- New York Heart Association (NYHA) class II heart failure
- New York Heart Association (NYHA) class III heart failure

AND

3 - BOTH of the following were measured prior to Myqorzo therapy:

- Patient had a left ventricular ejection fraction of greater than or equal to 55%
- Patient had a Valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation

AND

4 - History of inadequate response, intolerance, failure, or contraindication to one of the following at a maximally tolerated dose:

- Non-vasodilating beta blocker (e.g., atenolol, bisoprolol, metoprolol, nadolol, propranolol)
- Nondihydropyridine calcium channel blocker (i.e., diltiazem, verapamil)

AND

5 - Not used in combination with another cardiac myosin inhibitor [i.e., Camzyos (mavacamten)]

AND

6 - Prescribed by or in consultation with a cardiologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Myqorzo [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in NYHA class, no worsening in NYHA class)

AND

2 - Patient has a left ventricular ejection fraction of greater than or equal to 50%

AND

3 - Not used in combination with another cardiac myosin inhibitor [i.e., Camzyos (mavacamten)]

AND

4 - Prescribed by or in consultation with a cardiologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Myqorzo (aficamten) is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Myqorzo™ [package insert]. South San Francisco, CA: Cytokinetics Incorporated; December 2025.
2. Maron MS, Masri A, Nassif ME, et al. Aficamten for Symptomatic Obstructive Hypertrophic Cardiomyopathy. N Engl J Med. 2024;390(20):1849-1861. doi:10.1056/NEJMoa2401424
3. Ommen SR, Ho CY, Asif IM, et al. 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR Guideline for the Management of Hypertrophic Cardiomyopathy: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines [published correction appears in Circulation. 2024 Aug 20;150(8):e198. doi: 10.1161/CIR.0000000000001277.]. Circulation. 2024;149(23):e1239-e1311. doi:10.1161/CIR.0000000000001250

5 . Revision History

Date	Notes
3/16/2026	New program.

Nemluvio

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-402253
Guideline Name	Nemluvio
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	3/19/2025
P&T Revision Date:	06/18/2025 ; 10/15/2025

1 . Indications

Drug Name: Nemluvio (nemolizumab-ilto)
Atopic Dermatitis Indicated for the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies. **Prurigo nodularis** Indicated for the treatment of adults with prurigo nodularis

2 . Criteria

Product Name:Nemluvio [a]

Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderate-to-severe chronic atopic dermatitis

AND

2 - ONE of the following:

2.1 History of inadequate response, contraindication or intolerance to BOTH of the following therapeutic classes of topical therapies^ (document drug, date of trial, and/or contraindication to medication):

- One medium, high or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]

OR

2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of atopic dermatitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Opzelura (ruxolitinib), Rinvoq (upadacitinib)].

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to Dupixent (dupilumab) (document date and duration of trial)

OR

3.2 Patient is currently on Nemluvio therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

AND

4 - Nemluvio will be used in combination with a topical corticosteroid and/or topical calcineurin inhibitor

AND

5 - Patient is NOT receiving Nemluvio in combination with either of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupxient (dupilumab), Ebglyss (lebrikizumab-lbkz)]
- Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]

AND

6 - Prescribed by, or in consultation with, ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Nemluvio [a]	
Diagnosis	Atopic Dermatitis
Approval Length	Patient has achieved clear or almost clear skin: Authorization of Nemluvio 30mg given every 8 weeks for 12 months; Patient has not

	yet achieved clear or almost clear skin: Authorization of Nemluvio 30mg given every 4 weeks for 6 months
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Nemluvio therapy

AND

2 - Patient is NOT receiving Nemluvio in combination with either of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupxient (dupilumab), Ebglyss (lebrikizumab-lbkz)]
- Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Dermatologist
- Allergist
- Immunologist

AND

4 - ONE of the following:

- Patient has achieved clear or almost clear skin (Authorization of Nemluvio 30mg given every 8 weeks for 12 months)
- Patient has not yet achieved clear or almost clear skin (Authorization of Nemluvio 30mg given every 4 weeks for 6 months)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nemluvio [a]	
Diagnosis	Prurigo Nodularis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of prurigo nodularis

AND

2 - Patient has greater than or equal to 20 nodular lesions

AND

3 - History of failure, contraindication or intolerance to at least one previous prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin)

AND

4 - ONE of the following:

- History of failure, contraindication, or intolerance to Dupixent (dupilumab) (document drug, date, and duration of trial)
- Patient is currently on Nemluvio therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

AND

5 - Patient is NOT receiving Nemluvio in combination with Dupixent for treatment of the same indication

AND

6 - Prescribed by, or in consultation with, ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nemluvio [a]	
Diagnosis	Prurigo Nodularis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Nemluvio therapy

AND

2 - Patient is NOT receiving Nemluvio in combination with Dupixent for treatment of the same indication

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Dermatologist
- Allergist

• Immunologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Clinical Practice Guidelines

Table 1: Relative potencies of topical corticosteroids [3]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	tridifloronide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05

	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Table 2: Low, medium and high daily doses of inhaled corticosteroids [6]

Adults and adolescents (12 years of age and older)			
Drug	Daily dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (CFC)	200-500	>500-1000	>1000
Beclometasone dipropionate (HFA)	100-200	>200-400	>400
Budesonide DPI	200-400	>400-800	>800
Ciclesonide (HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	N/A	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (HFA)	100-250	>250-500	>500
Mometasone furoate	110-220	>220-440	>440
Triamcinolone acetonide	400-1000	>1000-2000	>2000

Benefit/Coverage/Program Information

Background:

Nemluvio is an interleukin-31 receptor alpha antagonist indicated for the treatment of adults with prurigo nodularis and for the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limitations may be in place

4 . References

1. Nemluvio [package insert]. Dallas, TX: Galderma Laboratories, L.P.; December 2024.
2. Simpson EL, Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. N Engl J Med. 2016 Sep 30.
3. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014; 70(1):338-51.
4. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
5. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.

5 . Revision History

Date	Notes
9/30/2025	Removed step through Rinvoq for atopic dermatitis.



Prior Authorization Guideline

Guideline ID	GL-412251
Guideline Name	New to Therapy (NTT) and Morphine Milligram Equivalents (MME)
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	9/15/2021
P&T Revision Date:	09/21/2022 ; 10/18/2023 ; 11/22/2024 ; 12/18/2024 ; 03/19/2025 ; 9/17/2025

1 . Criteria

Product Name:Requested opioid pain medication (Formulary and non-formulary)	
Diagnosis	New to Therapy: Criteria for Opioid Naïve Members. An opioid-naïve member is defined as not having filled an opioid in the past 60 days. Patients will be limited to a 7 day supply for their initial opioid fill
Approval Length	Authorization for cancer-related pain, end of life, palliative care, or sickle cell pain will be issued for 12 months. All other approvals will be issued for the requested duration, not to exceed one month.
Guideline Type	Administrative

Approval Criteria

1 - Opioid naïve members (defined as not having filled an opioid in the past 60 days) may receive greater than the supply limit based on the following:

1.1 If the request is for greater than the supply limit ONE of the following:

- Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)
- End of life care, including hospice care
- Palliative care
- Sickle cell anemia
- Long term care
- A written or verbal statement is received from the requesting prescriber saying that it is medically necessary for the patient to take the opioid drug for more than 7 days

Notes	NOTE: This section applies to all formulary and non-formulary medications

Product Name:Morphine Milligram Equivalents (MME) Reviews: For Requests Exceeding the 90MME Cumulative Threshold^ (Formulary and non-formulary)	
Diagnosis	Cancer-related pain /Hospice/End of Life/Long-Term Care/Palliative Care/Sickle Cell Related Pain
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Doses exceeding the cumulative morphine mg equivalent (MME) of 90 mg will be approved up to the requested amount for all opioid products if one of the following conditions is met:

- Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)
- End of life diagnosis, including hospice
- Sickle cell anemia diagnosis
- Long-term care

• Palliative care	
Notes	^The authorization should be entered for an MME of 99999.99 so as t o prevent future disruptions in therapy if the patient's dose is increase d. NOTE: This section applies to all formulary and non-formulary medica tions

Product Name:Morphine Milligram Equivalents (MME) Reviews: For Requests Exceeding the 90MME Cumulative Threshold^ (Formulary and non-formulary)	
Diagnosis	Non-cancer related pain, non-hospice, non-end of life, non-long-term care, non-palliative care, non-sickle cell related pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Administrative

Approval Criteria

1 - If the dose exceeds the maximum cumulative MME of 90mg, must meet ALL of the following:

1.1 Prescriber attest the patient has been screened for substance abuse/opioid dependence

AND

1.2 Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

AND

1.3 Patient has been screened for underlying depression and/or anxiety. If applicable, any underlying conditions have been or will be addressed

AND

1.4 ONE of the following:

- Opioid medication doses of less than 90MME have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)
- Patient is new to plan and currently established on the requested MME for at least the past 30 days

Notes	^Authorization will be issued for 6 months for non-cancer related pain/ non-hospice/non-end of life/non-long-term care/non-palliative care/no n-sickle cell related pain up to the current requested MME plus 90 MM E. NOTE: If the member has been established on the requested MME do se for at least 30 days and does not meet the medical necessity autho rization criteria requirements, a denial should be issued and a maximu m 60-day authorization may be authorized one time for the requested MME dose. NOTE: This section applies to all formulary and non-formulary medica tions.

Product Name:Morphine Milligram Equivalents (MME) Reviews: For Requests Exceeding the 90MME Cumulative Threshold^ (Formulary and non-formulary)	
Diagnosis	Non-cancer related pain, non-hospice, non-end of life, non-long-term care, non-palliative care, non-sickle cell related pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Administrative

Approval Criteria

1 - If the dose exceeds the maximum cumulative MME of 90mg, must meet ALL of the following:

1.1 Prescriber attest the patient has been screened for substance abuse/opioid dependence

AND

1.2 Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

AND **1.3** Documented meaningful improvement in pain and function when assessed against treatment goals (Document improvement in function or pain score improvement)	
Notes	^Authorization will be issued for 6 months for non-cancer related pain/ non-hospice/non-end of life/non-long-term care/non-palliative care/no n-sickle cell related pain up to the current requested MME plus 90 MM E. NOTE: If the member has been established on the requested MME do se for at least 30 days and does not meet the medical necessity autho rization criteria requirements, a denial should be issued and a maximu m 60-day authorization may be authorized one time for the requested MME dose. NOTE: This section applies to all formulary and non-formulary medica tions.

2 . Background

Benefit/Coverage/Program Information
Background: UnitedHealthcare employs opioid safety edits at point-of-sale (POS) to prompt prescribers and pharmacists to conduct additional safety reviews to determine if the member's opioid use is appropriate and medically necessary. Development of opioid safety edit specifications, to include cumulative MME thresholds, are determined by the plan taking into consideration clinical guidelines, regulatory/state requirements, utilization and P&T Committee feedback. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

3 . References

1. Franklin GM. Opioids for chronic noncancer pain. A position paper of the American Academy of Neurology. Neurology. 2014;83:1277-1284.
2. Rosenquist, R. Use of opioids in the management of chronic pain in adults. UptoDate, Waltham, MA, 2024.
3. Argoff CE, Silvershein DI. A Comparison of Long- and Short-Acting Opioids for the Treatment of Chronic Noncancer Pain: Tailoring Therapy to Meet Patient Needs. Mayo Clin Proc. 2009;84(7):602-612.
4. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. Published online March 15, 2016.
5. Spatar, SB. Standardizing the use of mental health screening instruments in patients with pain. Fed Pract. 2019 Oct; 36 (Suppl 6): S28-S30
6. Sullivan MD. Depression effects on long-term prescription opioid use, abuse, and addiction. Clin J Pain. 2018 Sep;34(9):878-884.

4 . Revision History

Date	Notes
10/8/2025	Updated products to align with Long Acting Opioid Products policy.

Nexavar

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-374431
Guideline Name	Nexavar
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 09/21/2022 ; 09/20/2023 ; 09/18/2024 ; 9/25/2025

1 . Indications

Drug Name: Nexavar (sorafenib tosylate)
Renal cell carcinoma Indicated for the treatment of advanced renal cell carcinoma. **Hepatocellular carcinoma** Indicated for the treatment of unresectable hepatocellular carcinoma. **Thyroid carcinoma** Indicated for the treatment of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

2 . Criteria

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of advanced renal cell carcinoma (RCC)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Nexavar therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - ONE of the following:

- Disease is unresectable
- Used as subsequent-line therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nexavar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Papillary carcinoma

AND

1.2 Disease is ONE of the following:

- Unresectable locoregional recurrent or persistent
- Metastatic

AND

1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.4 Disease is refractory to radioactive iodine treatment

OR

2 - BOTH of the following:

2.1 Diagnosis of medullary thyroid carcinoma

AND

2.2 Disease is ONE of the following:

- Recurrent
- Metastatic

OR

3 - ALL of the following:

3.1 Diagnosis of oncocytic thyroid carcinoma

AND

3.2 Disease is ONE of the following:

- Unresectable locoregional recurrent or persistent
- Metastatic

AND

3.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Nexavar therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of ONE of the following: • Angiosarcoma • Desmoid tumors / aggressive fibromatosis • Solitary fibrous tumor / hemangiopericytoma	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nexavar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of chordoma
- Disease is recurrent

OR

2 - BOTH of the following:

2.1 ONE of the following:

- Diagnosis of osteosarcoma
- Diagnosis of dedifferentiated chondrosarcoma
- Diagnosis of high-grade undifferentiated pleomorphic sarcoma (UPS)

AND

2.2 NOT used as first-line therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Nexavar therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of acute myeloid leukemia (AML) **AND** **2** - Patient has FLT3-ITD mutation-positive disease	

AND

3 - ONE of the following:

3.1 Used for those who are post-allogeneic stem cell transplantation, in remission

OR

3.2 BOTH of the following:

- Patient has relapsed/refractory disease
- Used in combination with azacitidine or decitabine

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nexavar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Ovarian Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - ONE of the following:

- Patient has persistent disease
- Patient has recurrent disease

AND

3 - Disease is platinum-resistant

AND

4 - Used in combination with topotecan

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nexavar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of salivary gland tumor

AND

2 - Disease is ONE of the following:

- Recurrent
- Unresectable
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Salivary Gland Tumor

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nexavar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid/lymphoid neoplasm with eosinophilia

AND

2 - Presence of FLT3 gene rearrangement

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nexavar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Disease is ONE of the following:

- Unresectable
- Progressive
- Metastatic

AND

3 - History of failure, contraindication, or intolerance to ALL of the following^:

- Imatinib
- Qinlock (ripretinib)

• Stivarga (regorafenib) • Sutent (sunitinib)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Nexavar therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Nexavar or sorafenib will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Nexavar, generic sorafenib [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Nexavar therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limit may be in place.

Background

Nexavar® (sorafenib tosylate) is a kinase inhibitor indicated for the treatment of unresectable hepatocellular carcinoma, advanced renal cell carcinoma and locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

The National Comprehensive Cancer Network also recommends the use of Nexavar for the treatment of gastrointestinal stromal tumor (GIST), chordoma, osteosarcoma, acute myeloid leukemia (AML), soft tissue sarcoma, salivary gland tumors, ovarian/fallopian tube cancer/primary peritoneal cancer, and myeloid/lymphoid neoplasms with tyrosine kinase gene fusions.

4 . References

1. Nexavar [package insert]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed July 29, 2025.

5 . Revision History

Date	Notes
9/4/2025	Annual review. Updated criteria for renal cell carcinoma per FDA label. Updated hepatocellular carcinoma, thyroid cancer, soft tissue sarcoma, acute myeloid leukemia, salivary gland tumor, and myeloid/lymphoid neoplasms based on NCCN recommendations. Moved gastrointestinal stromal tumors out of soft tissue sarcoma into its own section and updated per NCCN guidance.

Nocdurna

Prior Authorization Guideline

Guideline ID	GL-164994
Guideline Name	Nocdurna
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 02/18/2022 ; 02/17/2023 ; 02/16/2024 ; 10/01/2024 ; 2/20/2025

1 . Indications

Drug Name: Nocdurna (desmopressin acetate)
nocturia due to nocturnal polyuria Indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

2 . Criteria

Product Name:Nocdurna [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of nocturia due to nocturnal polyuria (as defined by nighttime urine production that exceeds one-third of the 24-hour urine production)

AND

2 - Patient wakes at least twice per night on a reoccurring basis to void

AND

3 - Documented serum sodium level is currently within normal limits of the normal laboratory reference range and has been within normal limits over the previous six months.

AND

4 - The patient has been evaluated for other medical causes and has either not responded to, tolerated, or has a contraindication to treatments for identifiable medical causes (e.g., overactive bladder, benign prostatic hyperplasia/lower urinary tract symptoms (BPH/LUTS), elevated post-void residual urine, and heart failure)

AND

5 - Prescriber attests that the risks have been assessed and benefits outweigh the risks

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nocdurna [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Nocdurna therapy

AND

2 - Patient has routine monitoring for serum sodium levels

AND

3 - Prescriber attests that the risks of hyponatremia have been assessed and benefits outweigh the risks

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background

Nocdurna (desmopressin acetate) sublingual tablets are indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void. In clinical trials, nocturnal polyuria was defined as nighttime urine production exceeding one-third of the 24-hour urine production. Prior to initiating treatment with Nocdurna, patients should be evaluated for possible causes of nocturia and to optimize the treatment of underlying conditions that may be contributing to the nocturia.

Desmopressin should be avoided in older adults (those 65 or older) due to the risk of hyponatremia. This medication is included in the American Geriatrics Society Beers Criteria. Nocdurna have a Black Box Warning for hyponatremia listed in the FDA prescribing information. Nocdurna use is contraindicated in patients with hyponatremia or a history of hyponatremia, SIADH, eGFR <50 mL/min/1.7m^2, uncontrolled hypertension, and New York

Heart Association Class II – IV congestive heart failure. See package insert for full listing of contraindications and safety warnings.

This prior authorization program is intended to ensure appropriate prescribing of Nocdurna prior to initiating therapy.

Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Johnson, TM. Nocturia: Clinical presentation, evaluation and management in adults. O'Leary, MP, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on December 23, 2019.)
2. Nocdurna (desmopressin) sublingual tablets [package insert]. Parsippany, NJ: Ewing, NJ: Antares Pharma, Inc; November 2020.
3. American Geriatrics Society 2023 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults J Am Geriatr Soc. 942023; 71: 2052-81

5 . Revision History

Date	Notes
2/11/2025	Annual review. Updated background in alignment with commercial. N o changes to coverage criteria.

Non-Formulary Administrative

Prior Authorization Guideline

Guideline ID	GL-424272
Guideline Name	Non-Formulary Administrative
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	10/20/2021
P&T Revision Date:	10/20/2021 ; 06/17/2024

Note:

Termination date of non-formulary exception authorizations approved pursuant to this guideline is 12 months from date of approval.

1 . Criteria

Product Name:Non-Formulary Medications (other than contraceptive products) [a]	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - In the absence of a drug-specific non-formulary guideline that has been approved by the P&T Committee to guide the non-formulary exceptions process, the following guideline will be used to establish medical necessity:

1.1 One of the following:

1.1.1 Both of the following:

1.1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g.: first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.1.2 Meets Off-Label Administrative guideline criteria

AND

1.2 One of the following:

1.2.1 If the target drug is NOT listed on the Non-Formulary Alternatives table, then the patient must try and fail, or have specific medical reason(s) why a maximum of five (5) equivalent formulary drugs, as determined by the PA pharmacist are not appropriate

OR

1.2.2 If the target drug is listed on the Non-Formulary Alternatives table, then the patient must try and fail, or have specific medical reason(s) why the number of alternatives* specified by the Non-Formulary Alternatives Table is not appropriate (see technician note for NF Alts Table URL)

OR

1.2.3 No formulary drug is appropriate to treat the patient's condition**

AND

1.3 The use is not excluded as documented in the limitations and exclusions section of the certificate of coverage (see technician note for the Exclusions and Limitations Grid URL)

Notes	[a] Formulary: 2026 UnitedHealthcare Government Programs Exchange Formulary. If approved, the non-formulary drug will be covered at tier 5 for 6-tiered formularies, at tier 4 for 5-tiered formularies, or tier 3 for 4-tiered formularies. *If an alternative is the generic equivalent of the non-formulary target drug, then it must be one of the required alternatives the patient must try and fail or have a specific medical reason why the alternative is not appropriate. ** For Virginia and Illinois, if the provider indicates that changing drug therapy presents a significant health risk (e.g., provider states the patient is stable on the requested medication, transition to another medication may result in destabilization) and there is a paid claim for the requested drug in the prior plan year, the member does not have to T/F the alternatives, unless the alternative is the generic of the requested brand drug.

Product Name:Non-Formulary Contraceptive Medications	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - In the absence of a drug-specific non-formulary guideline that has been approved by the P&T Committee to guide the non-formulary exceptions process, the following guideline will be used to establish medical necessity:

1.1 One of the following:

1.1.1 Both of the following [a]:

1.1.1.1 Diagnosis of contraception

AND

1.1.1.2 One of the following:

- If the contraceptive drug is NOT listed on the Non-Formulary Alternatives table, then the patient must try and fail, or have specific medical reason(s) why a maximum of two (2) equivalent formulary drugs, as determined by the PA pharmacist are not appropriate
- If the contraceptive drug is listed on the Non-Formulary Alternatives table, then the patient must try and fail, or have specific medical reason(s) why two (2) alternatives* specified by the Non-Formulary Alternatives Table is not appropriate (see technician note for NF Alts Table URL)
- Provider attests the non-formulary contraceptive drug is the preferred product for this patient (e.g., provider attestation that the non-formulary contraceptive is medically necessary, patient is stable on the requested non-formulary contraceptive, patient requires continuation of therapy to complete the course of treatment, transition to another agent could result in destabilization)

OR

1.1.2 All of the following [b]:

1.1.2.1 Drug is requested for a non-contraception use

AND

1.1.2.2 One of the following:

- Requested drug is FDA-approved for the condition being treated
- Meets Off-Label Administrative guideline criteria

AND

1.1.2.3 One of the following**:

- If the target drug is NOT listed on the Non-Formulary Alternatives table, then the patient must try and fail, or have specific medical reason(s) why a maximum of five (5) equivalent formulary drugs, as determined by the PA pharmacist are not appropriate
- If the target drug is listed on the Non-Formulary Alternatives table, then the patient must try and fail, or have specific medical reason(s) why the number of alternatives* specified by the Non-Formulary Alternatives Table is not appropriate (see technician note for NF Alts Table URL)
- No formulary drug is appropriate to treat the patient's condition

AND **1.1.2.4** The use is not excluded as documented in the limitations and exclusions section of the certificate of coverage (see technician note for the Exclusions and Limitations Grid URL)	
Notes	[a] If used for contraceptive purpose and approved, authorizations should have overrides to allow for $0 cost share for non-formulary drugs. [b] Formulary: 2026 UnitedHealthcare Government Programs Exchange Formulary. If used for non-contraceptive purpose and approved, the non-formulary drug will be covered at tier 5 for 6-tiered formularies, at tier 4 for 5-tiered formularies, or tier 3 for 4-tiered formularies. *If an alternative is the generic equivalent of the non-formulary target drug, then it must be one of the required alternatives the patient must try and fail or have a specific medical reason why the alternative is not appropriate. **For Illinois, if the provider indicates that changing drug therapy presents a significant health risk (e.g., provider states the patient is stable on the requested medication, transition to another medication may result in destabilization), and there is a paid claim for the requested drug in the prior plan year, the member does not have to T/F the alternatives, unless the alternative is the generic of the requested brand drug.

2 . Background

Benefit/Coverage/Program Information
Technician Note: Non-Formulary Alternatives Table link: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x01200027C80175A8369D44AC45A99A99328B80&View=%7B4B6D25AD%2D6A95%2D496D%2D9937%2D65CECD43AFE7%7D&viewid=c2ad0afa%2D814c%2D499e%2Dbf25%2D3411fac9171f&id=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FUHCGP%20Exchange%2FNF%20Alt%20Tables **Background:** Non-formulary medications will have a Tier 8/non-formulary status on the RxWeb Formulary Lookup tool. This guideline applies to these Tier 8 medications. If a medication has a non-formulary status and a PA flag of yes, apply the criteria within the drug-specific guideline as well as the non-formulary alternatives grid in the link in the technician note.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

3 . Revision History

Date	Notes
10/22/2025	Annual review. Administrative changes to notes only.

Non-Solid Oral Dosage Forms

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399292
Guideline Name	Non-Solid Oral Dosage Forms
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	03/17/2021 ; 08/20/2021 ; 09/15/2021 ; 09/15/2021 ; 10/19/2022 ; 08/18/2023 ; 10/01/2024 ; 9/25/2026

1 . Criteria

Product Name:Sotylize, generic naproxen susp, generic nitrofurantoin suspension 25mg/5mL, Tirosint-Sol, Thyquidity, generic sucralfate susp [a]	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following:	

• Age • oral/motor difficulties • dysphagia **OR** **2** - Patient utilizes a feeding tube for medication administration
Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background: Coverage criteria outlined below are for patients unable to ingest a solid oral dosage form. Claims for patients under the age of 6 will process automatically for Naproxen (generic for Naprosyn) suspension, nitrofurantoin suspension 25mg/5mL, Sotylize, sucralfate suspension, Thyquidity, and Tirosint-Sol. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

3 . References

1. Naprosyn [package insert]. Atlanta, GA: Athena Bioscience LLC.; July 2021.
2. Sotylize [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; January 2024.
3. Thyquidity [package insert]. New Providence, NJ: VistaPharm, Inc.; September 2022.
4. Tirosint-Sol [package insert]. Pambio-Noranco, Switzerland: IBSA Institute Biochimique SA; November 2023.

5. Sucralfate suspension [package insert]. Chestnut Ridge, NY. Par Pharmaceutical; June 2018.
6. Nitrofurantoin suspension [package insert]. East Brunswick, NJ. Rising Pharma Holdings, Inc.; February 2024.

4 . Revision History

Date	Notes
9/23/2025	Added nitrofurantoin suspension 25mg/5mL.

Nubeqa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-328224
Guideline Name	Nubeqa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	9/1/2025
P&T Approval Date:	8/18/2023
P&T Revision Date:	09/18/2024 ; 05/16/2025 ; 7/16/2025

1 . Indications

Drug Name: Nubeqa (darolutamide)
Prostate cancer Indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer and metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently while taking Nubeqa or should have had bilateral orchiectomy.

2 . Criteria

Product Name:Nubeqa [a]	
Diagnosis	Prostate Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Disease is non-metastatic
- Disease is castration-resistant

OR

2.2 BOTH of the following:

- Disease is metastatic
- Disease is castration-sensitive

AND

3 - ONE of the following:

3.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

3.2 Patient has had a bilateral orchiectomy

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Nubeqa [a]	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Nubeqa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Nubeqa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Nubeqa will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Nubeqa [a]	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Nubeqa® (darolutamide) is an androgen receptor inhibitor indicated for the treatment of adult patients with non-metastatic castration-resistant prostate cancer (nmCRPC), metastatic castration-sensitive prostate cancer (mCSPC), and metastatic castration-sensitive prostate cancer (mCSPC) in combination with docetaxel. Patients should also receive a gonadotropin-releasing hormone (GnRH) agonist or antagonist concurrently or have had bilateral orchiectomy. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Nubeqa [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; June 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed June 6, 2025.

5 . Revision History

Date	Notes
7/15/2025	Annual review. Expanded coverage criteria to include mCSPC. Updated references.

Nucala

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-458250
Guideline Name	Nucala
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	7/21/2021
P&T Revision Date:	09/15/2021 ; 11/19/2021 ; 12/15/2021 ; 01/19/2022 ; 02/18/2022 ; 06/21/2023 ; 07/19/2023 ; 07/17/2024 ; 07/16/2025 ; 10/15/2025 ; 12/17/2025

Note:

This program applies to the prefilled autoinjector and prefilled syringe formulations.

1 . Indications

Drug Name: Nucala (mepolizumab) prefilled autoinjector and prefilled syringe
Severe Asthma Indicated for the add-on maintenance treatment of patients with severe asthma 6 years and older, and with an eosinophilic phenotype. **Eosinophilic Granulomatosis with Polyangiitis** Indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). **Hypereosinophilic Syndrome** Indicated for the treatment of adult and pediatric patients

aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause.

Maintenance Treatment of Chronic Rhinosinusitis with Nasal Polyps Indicated for add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP)

Maintenance Treatment of Chronic Obstructive Pulmonary Disease Indicated for add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype

2 . Criteria

Product Name:Nucala prefilled autoinjector and prefilled syringe [a]	
Diagnosis	Eosinophilic granulomatosis with polyangiitis (EGPA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - ALL of the following:

1.1 Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of EGPA

AND

1.2 Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency and/or severity of relapses
- Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant
- Disease remission
- Reduction in severity or frequency of EGPA-related symptoms

AND

1.3 Patient is not receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

1.4 Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist
- Rheumatologist

OR

2 - ALL of the following:

2.1 Diagnosis of relapsing or refractory EGPA as defined by ALL of the following:

2.1.1 Diagnosis of EGPA

AND

2.1.2 Past medical history or presence of asthma

AND

2.1.3 Presence of at least TWO of the following characteristics typical of EGPA:

- Histopathological evidence of: Eosinophilic vasculitis, Perivascular eosinophilic infiltration, Eosinophil-rich granulomatous inflammation
- Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
- Pulmonary infiltrates, non-fixed

- Sino-nasal abnormality
- Cardiomyopathy (established by echocardiography or MRI)
- Glomerulonephritis (hematuria, red cell casts, proteinuria)
- Alveolar hemorrhage
- Palpable purpura
- Anti-neutrophil cytoplasmic antibody (ANCA) positive

AND

2.1.4 History of relapsing or refractory disease defined as ONE of the following:

- Relapsing disease as defined as a past history (within the past 2 years) of at least one EGPA relapse (requiring additional or dose escalation of corticosteroids or immunosuppressant, or hospitalization)
- Refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens

AND

2.2 Patient is currently taking standard therapy [i.e., systemic glucocorticoids (e.g., prednisone, methylprednisolone)] with or without immunosuppressive therapy (e.g., cyclophosphamide, rituximab)]

AND

2.3 Patient is not receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

2.4 Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

• Rheumatologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nucala prefilled autoinjector and prefilled syringe [a]	
Diagnosis	Eosinophilic granulomatosis with polyangiitis (EGPA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency and/or severity of relapses
- Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant
- Disease remission
- Reduction in severity or frequency of EGPA-related symptoms

AND

2 - Patient is not receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nucala prefilled autoinjector and prefilled syringe [a]	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - ALL of the following:

1.1 Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

AND

1.2 Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

1.3 Nucala is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

1.4 Patient is not receiving Nucala in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]

- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

1.5 Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

OR

2 - ALL of the following:

2.1 Diagnosis of severe asthma

AND

2.2 Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:

- Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
- Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
- Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
- Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
- Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

2.3 Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level ≥ 150 cells/μL

AND

2.4 Nucala will be used in combination with ONE of the following:

2.4.1 ONE maximally dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

2.4.2 Combination therapy including BOTH of the following:

- ONE maximally dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]
- ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

2.5 History of failure, contraindication, or intolerance to BOTH of the following products (document date and duration of trial):

- Dupixent (dupilumab)
- Xolair (omalizumab)

AND

2.5 Patient is not receiving Nucala in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

2.7 Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nucala prefilled autoinjector and prefilled syringe [a]	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Nucala is being used in combination with an ICS-containing controller maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

3 - Patient is not receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nucala prefilled autoinjector and prefilled syringe [a]	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - ALL of the following:

1.1 Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of HES

AND

1.2 Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

- Reduction in frequency of HES flares
- Maintenance or reduction in background HES therapy requirements

AND

1.3 Patient is not receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

1.4 Prescribed by ONE of the following:

- Allergist
- Cardiologist
- Hematologist
- Immunologist
- Pulmonologist

OR

2 - ALL of the following:

2.1 Diagnosis of HES greater than or equal to 6 months ago

AND

2.2 BOTH of the following:

- There is no identifiable non-hematologic secondary cause of the patient's HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)
- HES is not FIP1L1-PDGFRα kinase-positive

AND

2.3 Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting BOTH of the following:

- Baseline (pre-mepolizumab treatment) blood eosinophil level greater than or equal to 1000 cells/μL within the past 4 weeks

- Patient is currently receiving a stable dose of background HES therapy (e.g., oral corticosteroid, immunosuppressor, or cytotoxic therapy)

AND

2.4 Patient is not receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

2.5 Prescribed by ONE of the following:

- Allergist
- Cardiologist
- Hematologist
- Immunologist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nucala prefilled autoinjector and prefilled syringe [a]	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

- Reduction in frequency of HES flares
- Maintenance or reduction in background HES therapy requirements

AND

2 - Patient is not receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nucala prefilled autoinjector and prefilled syringe [a]	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - ALL of the following:

1.1 Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of CRSwNP

AND

1.2 Documentation of positive clinical response to Nucala therapy

AND

1.3 Patient will continue to receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

1.4 Patient is NOT receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

1.5 Prescribed by ONE of the following:

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

OR

2 - ALL of the following:

2.1 Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) defined by ALL of the following:

2.1.1 TWO OR MORE of the following symptoms for longer than 12 weeks duration:

- Nasal mucopurulent discharge
- Nasal obstruction, blockage, or congestion
- Facial pain, pressure, and/or fullness
- Reduction or loss of sense of smell

AND

2.1.2 ONE of the following findings using nasal endoscopy and/or sinus computed tomography (CT):

- Purulent mucus or edema in the middle meatus or ethmoid regions
- Polyps in the nasal cavity or the middle meatus
- Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

AND

2.1.3 ONE of the following:

- Presence of bilateral nasal polyposis
- Patient has previously required surgical removal of bilateral nasal polyps

AND

2.1.4 ONE of the following:

2.1.4.1 Patient has required prior sinus surgery

OR

2.1.4.2 Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for CRSwNP in the previous 2 years

OR

2.1.4.3 Patient has been unable to obtain symptom relief after trial of two of the following classes of agents:

- Nasal saline irrigations
- Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)
- Antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)

AND

2.2 Patient will receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

2.3 History of failure, contraindication, or intolerance to BOTH of the following products (document date and duration of trial):

- Dupixent (dupilumab)
- Xolair (omalizumab)

AND

2.4 Patient is NOT receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

2.5 Prescribed by ONE of the following:

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nucala prefilled autoinjector and prefilled syringe [a]

Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Nucala therapy

AND

2 - Patient will continue to receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

3 - Patient is NOT receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nucala prefilled autoinjector and prefilled syringe [a]	
Diagnosis	Chronic Obstructive Pulmonary Disease (COPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - ALL of the following:

1.1 Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of COPD

AND

1.2 Documentation of positive clinical response to Nucala therapy

AND

1.3 Patient will continue to receive Nucala as add-on maintenance therapy

AND

1.4 Patient is not receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

OR

2 - ALL of the following:

2.1 Diagnosis of COPD

AND

2.2 Submission of medical records (e.g., chart notes) documenting ALL of the following:

- Post-bronchodilator forced expiratory volume (FEV1) / forced vital capacity (FVC) ratio less than 0.7
- Post-bronchodilator FEV1 % predicted greater than or equal to 20% and less than or equal to 80%
- Patient has an eosinophilic phenotype defined by a baseline (pre-mepolizumab treatment) peripheral blood eosinophil level ≥ 300 cells/µL

AND

2.3 Uncontrolled or inadequately controlled COPD demonstrated by BOTH of the following:

2.3.1 ONE of the following:

- Two or more COPD exacerbations in the previous year requiring treatment with systemic corticosteroids and/or antibiotics
- One or more COPD exacerbation(s) that resulted in hospitalization or observation for over 24 hours in an emergency department or urgent care facility in the past year

AND

2.3.2 COPD exacerbation(s) occurred while receiving maintenance therapy with ONE of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

AND

2.4 Nucala will be used as add-on maintenance therapy in combination with ONE of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

AND

2.5 History of failure, contraindication, or intolerance to Dupixent (dupilumab) (document date and duration of trial).

AND

2.6 Patient is not receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

2.7 Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nucala prefilled autoinjector and prefilled syringe [a]	
Diagnosis	Chronic Obstructive Pulmonary Disease (COPD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of a positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of COPD exacerbations
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of COPD-related symptoms (e.g., dyspnea, wheezing, cough, sputum volume, decrease in sputum purulence)
- Reduction in oral corticosteroid requirements

AND

2 - Nucala is being used as add-on maintenance therapy in combination with ONE of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a long-acting muscarinic antagonist (LAMA) and long-acting beta agonist (LABA) (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

AND

3 - Patient is not receiving Nucala in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Nucala (mepolizumab) is an interleukin-5 receptor antagonist indicated for add-on maintenance treatment of patients aged 6 years and older with severe asthma and with an eosinophilic phenotype, for add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP), the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA), for add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype, and the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause[1]. Limitations of use: Nucala is not for relief of acute bronchospasm of status asthmaticus. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place. • The single-dose vial is typically covered under the medical benefit. Please refer to the United Healthcare Medical Benefit Drug Policy: “Respiratory Interleukins (Cinqair®, Fasenra®, and Nucala®)”.

4 . References

1. Nucala® [package insert]. Philadelphia, PA; GlaxoSmithKline, LLC; May 2025.
2. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014 Feb:43(2):343-73.
3. Institute for Clinical and Economic Review (ICER). Mepolizumab (Nucala®, GlaxoSmithKline plc.) for the Treatment of Severe Asthma with Eosinophilia:

Effectiveness, Value, and Value-Based Price Benchmarks. March 14, 2016. Available at http://icer-review.org/material/asthma-final-report/. Accessed May 2024.
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5 . Revision History

Date	Notes
12/1/2025	Updated criteria for COPD section by removing criteria requiring sym ptoms of a chronic productive cough and updating post-bronchodilato r FEV1 % predicted values. Updated references.

Nuedexta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-334208
Guideline Name	Nuedexta
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	9/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	07/21/2021 ; 09/15/2021 ; 07/20/2022 ; 07/17/2024 ; 7/16/2025

1 . Indications

Drug Name: Nuedexta (dextromethorphan/quinidine)
Pseudobulbar affect (PBA) Indicated for the treatment of pseudobulbar affect (PBA). PBA occurs secondary to a variety of neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying.

2 . Criteria

Product Name:Nuedexta [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pseudobulbar affect

AND

2 - ONE of the following

- Amyotrophic lateral sclerosis (ALS)
- Alzheimer's disease
- Multiple sclerosis (MS)
- Parkinson's disease
- Stroke
- Traumatic brain injury

AND

3 - Documented absence of cardiac rhythm disorders

AND

4 - Prescribed by or in consultation with a neurologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nuedexta [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Nuedexta, a combination product containing dextromethorphan hydrobromide and quinidine sulfate, is indicated for the treatment of pseudobulbar affect (PBA). PBA occurs secondary to a variety of neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or are inappropriate to the underlying emotional state. PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurological disease or injury. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Nuedexta [package insert]. Rockville MD: Otsuka America Pharmaceutical, Inc.; December 2022.

5 . Revision History

Date	Notes
7/17/2025	Annual review. Updated references.

Nurtec, Qulipta, Ubrelvy, Zavzpret

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-540193
Guideline Name	Nurtec, Qulipta, Ubrelvy, Zavzpret
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	4/17/2024
P&T Revision Date:	08/16/2024 ; 09/25/2025 ; 3/18/2026

1 . Indications

Drug Name: Nurtec ODT (rimegepant)
Migraine Indicated for the acute treatment of migraine with or without aura in adults **Episodic Migraine** Indicated for the preventive treatment of episodic migraine in adults.
Drug Name: Ubrelvy (ubrogepant), Zavzpret (zavegepant)
Migraine Indicated for the acute treatment of migraine with or without aura in adults
Drug Name: Qulipta (atogepant)
Episodic Migraine Indicated for the preventive treatment of migraine in adults

2 . Criteria

Product Name:Ubrelvy [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for acute treatment of migraine

AND

2 - History of therapeutic failure (after at least 3 migraine episodes and a minimum of a 30-day trial), contraindication or intolerance to TWO of the following (document name and date tried):

- naratriptan (Amerge)
- rizatriptan (Maxalt/Maxalt MLT)
- sumatriptan (Imitrex)

AND

3 - ONE of the following:

3.1 Patient is currently treated with one of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- Monoclonal antibodies or small-molecules targeting calcitonin gene-related peptide (CGRP) or its receptor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab), Nurtec ODT, Qulipta, Vyepti (eptinezumab-jjmr)]
- Divalproex sodium (Depakote/Depakote ER)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

3.2 Patient has < 4 migraine days per month

OR

3.3 Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to ONE of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- Monoclonal antibodies or small-molecules targeting calcitonin gene-related peptide (CGRP) or its receptor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab), Nurtec ODT, Qulipta, Vyepti (eptinezumab-jjmr)]
- Divalproex sodium (Depakote/Depakote ER)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - Medication will not be used in combination with another small-molecule targeting the CGRP receptor (“gepants”) (e.g., Nurtec ODT, Qulipta, Zavzpret)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zavzpret [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for acute treatment of migraine

AND

2 - History of therapeutic failure (after at least 3 migraine episodes and a minimum of a 30-day trial), contraindication or intolerance to BOTH of the following (document name and date tried):

- TWO formulary 5-HT1 receptor agonist (triptan) alternatives (e.g., sumatriptan, rizatriptan, or naratriptan with step therapy), one of which must be sumatriptan nasal spray
- Ubrelvy

AND

3 - ONE of the following:

3.1 Patient is currently treated with one of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- Monoclonal antibodies or small-molecules targeting calcitonin gene-related peptide (CGRP) or its receptor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab), Nurtec ODT, Qulipta, Vyepti (eptinezumab-jjmr)]
- Divalproex sodium (Depakote/Depakote ER)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

3.2 Patient has less than 4 migraine days per month

OR

3.3 Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to ONE of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- Monoclonal antibodies or small-molecules targeting calcitonin gene-related peptide (CGRP) or its receptor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab), Nurtec ODT, Qulipta, Vyepti (eptinezumab-jjmr)]
- Divalproex sodium (Depakote/Depakote ER)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - Medication will not be used in combination with another small-molecule targeting the CGRP receptor (“gepants”) (e.g., Nurtec ODT, Qulipta, Ubrelvy)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ubrelvy or Zavzpret [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Medication will not be used in combination with another small-molecule targeting the CGRP receptor (“gepants”) (e.g., Nurtec ODT, Qulipta)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Nurtec ODT [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Used for acute treatment of migraine

AND

1.2 History of a therapeutic failure (after at least 3 migraine episodes and a minimum of a 30-day trial) contraindication or intolerance to TWO of the following (document name and date tried):

- naratriptan (Amerge)
- rizatriptan (Maxalt/Maxalt MLT)
- sumatriptan (Imitrex)

AND

1.3 History of failure (after at least 3 migraine episodes and a minimum of a 30-day trial), contraindication, or intolerance to Ubrelvy (document date tried).

AND

1.4 ONE of the following:

1.4.1 Patient is currently treated with one of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)

- Monoclonal antibodies or small-molecules targeting calcitonin gene-related peptide (CGRP) or its receptor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab), Qulipta, Vyepti (eptinezumab-jjmr)]
- Divalproex sodium (Depakote/Depakote ER)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

1.4.2 Patient has less than 4 migraine days per month

OR

1.4.3 Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to one of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- Monoclonal antibodies or small-molecules targeting calcitonin gene-related peptide (CGRP) or its receptor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab), Qulipta, Vyepti (eptinezumab-jjmr)]
- Divalproex sodium (Depakote/Depakote ER)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

1.5 Medication will not be used in combination with another small-molecule targeting the CGRP receptor (“gepants”) (e.g., Ubrelvy, Qulipta, Zavzpret)

OR

2 - ALL of the following:

2.1 Diagnosis of episodic migraines with greater than or equal to 4 migraine days per month

AND

2.2 Used for preventive treatment of migraines

AND

2.3 Failure (after a trial of at least three months), contraindication or intolerance to Aimovig (document name and date tried)

AND

2.4 History of failure (after a trial of at least two months), contraindication or intolerance to TWO of the following prophylactic therapies (document name and date tried):

- One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
- Divalproex sodium (Depakote/Depakote ER)
- Topiramate (Topamax)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

2.5 BOTH of the following:

- Medication will not be used in combination with a monoclonal antibody targeting CGRP or its receptor (e.g., Aimovig, Ajovy, Emgality, Vyepti)
- Medication will not be used in combination with another small-molecule targeting the CGRP receptor (“gepants”) (e.g., Qulipta, Ubrelvy, Zavzpret)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Nurtec ODT [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Use is for the acute treatment of migraine
- Medication will not be used in combination with another small-molecule targeting the CGRP receptor (“gepants”) (e.g., Qulipta, Ubrelvy, Zavzpret)

OR

2.2 BOTH of the following:

2.2.1 Use is for the preventive treatment of migraines

AND

2.2.2 BOTH of the following:

- Medication will not be used in combination with a monoclonal antibody targeting CGRP or its receptor (e.g., Aimovig, Ajovy, Emgality, Vyepti)
- Medication will not be used in combination with another small-molecule targeting the CGRP receptor (“gepants”) (e.g., Qulipta, Ubrelvy, Zavzpret)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Qulipta [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition

AND

2 - ONE of the following:

2.1 4 to 7 migraine days per month and at least ONE of the following:

- Less than 15 headache days per month
- Provider attests this is the member's predominant headache diagnosis (i.e., primary driver of headaches is not a different, non-migrainous condition)

OR

2.2 Greater than or equal to 8 migraine days per month

AND

3 - Failure (after a trial of at least two months), contraindication or intolerance to TWO of the following prophylactic therapies (document name and date tried):

- One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
- Divalproex sodium (Depakote/Depakote ER)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- Topiramate (Topamax)

- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - Failure (after a trial of at least three months), contraindication or intolerance to Aimovig (document name and date tried)

AND

5 - BOTH of the following:

- Medication will not be used in combination with a monoclonal antibody targeting CGRP or its receptor (e.g., Aimovig, Ajovy, Emgality, Vyepti)
- Medication will not be used in combination with another small-molecule targeting the CGRP receptor (“gepants”) (e.g., Nurtec ODT, Ubrelvy, Zavzpret)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Qulipta [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - BOTH of the following:

- Medication will not be used in combination with a monoclonal antibody targeting CGRP or its receptor (e.g., Aimovig, Ajovy, Emgality, Vyepti)

• Medication will not be used in combination with another small-molecule targeting the CGRP receptor (“gepants”) (e.g., Nurtec ODT, Ubrelvy, Zavzpret)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Nurtec ODT (rimegepant), Ubrelvy (ubrogepant) and Zavzpret (zavegepant) are calcitonin gene-related peptide receptor antagonists indicated for the acute treatment of migraine with or without aura in adults. Nurtec ODT is also indicated for the preventive treatment of episodic migraine in adults and Qulipta (atogepant) is indicated for the preventive treatment of migraine in adults.

The American Headache Society recommends the use of NSAIDs (including aspirin), non-opioid analgesics, acetaminophen, or caffeinated analgesic combinations (e.g., aspirin/acetaminophen/caffeine) for mild-to-moderate attacks and migraine-specific agents (i.e., triptans, dihydroergotamine [DHE]) for moderate or severe attacks and mild-to-moderate attacks that respond poorly to NSAIDs or caffeinated combinations.

Preventive treatment selection is based on evidence of efficacy, tolerability, patient preference, headache subtype, and comorbidities. The American Academy of Neurology guidelines note that antiepileptic drugs (divalproex sodium, valproate sodium, topiramate) and beta-blockers (metoprolol, propranolol, timolol) have established efficacy and that antidepressants (amitriptyline, venlafaxine) and beta-blockers (atenolol, nadolol) are probably effective for the preventive treatment of migraine headache.

This program requires a member to try lower cost options prior to receiving coverage for Nurtec ODT, Qulipta, Ubrelvy or Zavzpret.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Nurtec ODT [package insert]. New York, NY: Pfizer Inc; March 2025.
2. Qulipta [package insert]. Dublin, Ireland: Forest Laboratories Ireland, Ltd. June 2025.
3. Ubrelvy [package insert]. North Chicago, IL: AbbVie Inc: June 2025.
4. Zavzpret [package insert]. New York, NY: Pfizer Inc.; March 2025
5. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. AHS Consensus Statement. Headache. 2024; 64:333-41.
6. International Headache Society (HIS); Headache Classification Committee. The International Classification of Headache Disorders, 3rd edition. Cephalalgia 2018; 38:1-211.

5 . Revision History

Date	Notes
3/4/2026	Updated language on concomitant CGRP use throughout.

Ocaliva

Prior Authorization Guideline

Guideline ID	GL-461342
Guideline Name	Ocaliva
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	9/15/2021
P&T Revision Date:	06/15/2022 ; 06/21/2023 ; 06/17/2024 ; 12/18/2024 ; 12/17/2025

1 . Indications

Drug Name: Ocaliva (obeticholic acid)
Primary biliary cholangitis Indicated for the treatment of primary biliary cholangitis (PBC), without cirrhosis or with compensated cirrhosis without evidence of portal hypertension, in combination with ursodeoxycholic acid.

2 . Criteria

Product Name:Ocaliva [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary biliary cholangitis

AND

2 - ONE of the following:

- Patient does not have cirrhosis
- Patient has compensated cirrhosis without evidence of portal hypertension

AND

3 - ONE of the following:

3.1 BOTH of the following^:

- Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)
- Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)

OR

3.2 History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol)

AND

4 - Patient is not receiving Ocaliva in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar)

AND

5 - Prescribed by one of the following:

- Hepatologist
- Gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling and/or treatment guidelines.

Product Name:Ocaliva [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in ALP level from pre-treatment baseline (i.e., prior to Ocaliva therapy)

AND

2 - ONE of the following:

- Patient does not have cirrhosis
- Patient has compensated cirrhosis without evidence of portal hypertension

AND

3 - Patient is not receiving Ocaliva in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar)

AND

4 - Prescribed by ONE of the following:

• Hepatologist • Gastroenterologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Ocaliva (obeticholic acid), a farnesoid X receptor (FXR) agonist, is indicated for the treatment of primary biliary cholangitis (PBC), without cirrhosis or with compensated cirrhosis without evidence of portal hypertension, in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. On September 11, 2025, Intercept Pharmaceuticals announced the voluntary market withdrawal of Ocaliva following a request from the US Food and Drug Administration. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Ocaliva [package insert]. Morristown, NJ: Intercept Pharmaceuticals, Inc.; May 2022.
2. Intercept Pharmaceuticals, Inc. Intercept announces voluntary withdrawal of Ocaliva® for primary biliary cholangitis (PBC) from the US market; US clinical trials involving

obeticholic acid placed on clinical hold. Intercept Pharmaceuticals. Published September 11, 2025. Accessed November 3, 2025. https://www.interceptpharma.com/about-us/news/?id=3148535.

5 . Revision History

Date	Notes
12/8/2025	Annual review with no changes to coverage criteria. Updated backgr ound and references to reflect withdrawal of drug from market.

Ohtuvayre

Prior Authorization Guideline

Guideline ID	GL-399228
Guideline Name	Ohtuvayre
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	9/18/2024
P&T Revision Date:	9/25/2025

1 . Indications

Drug Name: Ohtuvayre (ensifentrine)
Chronic obstructive pulmonary disease (COPD) in adult patients. Indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

2 . Criteria

Product Name:Ohtuvayre [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease

AND

2 - Submission of medical records (e.g., chart notes) documenting BOTH of the following:

- Post-bronchodilator FEV1 % predicted greater than or equal to 30% and less than 80%
- Post-bronchodilator forced expiratory volume (FEV1) / forced vital capacity (FVC) ratio less than 0.7

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following (document name):

- A LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat)
- A long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
- A long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
- An ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

AND

3.1.2 ONE of the following:

3.1.2.1 ALL of the following:

- FEV1 less than 50% of predicted
- History of chronic bronchitis
- History of failure, contraindication, or intolerance to a selective phosphodiesterase 4 (PDE4) inhibitor [i.e., roflumilast (Daliresp)]

OR

3.1.2.2 FEV1 is less than 80% of predicted but greater than or equal to 50% of predicted

OR

3.2 BOTH of the following:

3.2.1 Patient has a failure, contraindication, or intolerance to ALL of the following (document name and date tried):

- A long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
- A long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
- A LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat),
- An ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

AND

3.2.2 ONE of the following:

3.2.2.1 ALL of the following:

- FEV1 less than 50% of predicted
- History of chronic bronchitis
- History of failure, contraindication, or intolerance to a selective phosphodiesterase 4 (PDE4) inhibitor [i.e., roflumilast (Daliresp)]

OR

3.2.2.2 FEV1 is less than 80% of predicted but greater than or equal to 50% of predicted

OR

3.3 ALL of the following:

3.3.1 Patient is unable to use a metered-dose, dry powder or slow mist inhaler (e.g. Spiriva Respimat) to control their COPD due to ONE of the following:

- Cognitive or physical impairment limiting coordination of handheld devices (e.g., cognitive decline, arthritis in the hands) (Document impairment)
- Patient is unable to generate adequate inspiratory force (e.g., peak inspiratory flow rate (PIFR) resistance is <60 L/min)

AND

3.3.2 Patient requires the use of BOTH of the following (document date)

- A nebulized LABA [i.e., arformoterol (generic Brovana), formoterol (generic Perforomist)]
- A nebulized long-acting antimuscarinic agent [LAMA (i.e.,Yupelri)]

AND

3.3.3 ONE of the following:

3.3.3.1 ALL of the following:

- FEV1 less than 50% of predicted
- History of chronic bronchitis
- History of failure, contraindication, or intolerance to a selective phosphodiesterase 4 (PDE4) inhibitors [i.e., roflumilast (Daliresp)]

OR

3.3.3.2 FEV1 is less than 80% of predicted but greater than or equal to 50% of predicted

AND

4 - Patient experiences dyspnea during everyday activities (e.g., short of breath when walking up a slight hill)

AND

5 - Prescribed by or in consultation with a Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ohtuvayre [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Ohtuvayre therapy demonstrated by BOTH of the following:

- Improved COPD symptoms (e.g., dyspnea)
- Improved FEV1

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Ohtuvayre™ (ensifentrine) is a phosphodiesterase 3 (PDE3) inhibitor and phosphodiesterase 4 (PDE4) inhibitor indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

Additional Clinical Rules:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis

	codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Ohtuvayre [package insert]. Raleigh, NC: Verona Pharma; June 2024.
2. Global strategy for the diagnosis, management and prevention of COPD. Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2025.
3. Anzueto, A, Barjaktarevic, IZ, Siler, TM, et.al. Ensifentrine, a Novel Phosphodiesterase 3 and 4 Inhibitor for the Treatment of Chronic Obstructive Pulmonary Disease: Randomized, Double-Blind, Placebo-controlled, Multicenter Phase III Trials (the ENHANCE Trials. Am J Respir Crit Care Med. 2023; 208: 406-16.

5 . Revision History

Date	Notes
9/17/2025	Annual review. Updated references.

Ojjaara

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436514
Guideline Name	Ojjaara
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	11/17/2023
P&T Revision Date:	11/22/2024 ; 11/21/2025

1 . Indications

Drug Name: Ojjaara (momelotinib)
Myelofibrosis (MF) Indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [postpolycythemia vera (PV) and post-essential thrombocythemia (ET)] with anemia.

2 . Criteria

Product Name:Ojjaara [a]	
Diagnosis	Myeloproliferative Neoplasms
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of symptomatic lower-risk myelofibrosis

OR

2 - BOTH of the following:

2.1 Diagnosis of higher-risk myelofibrosis

AND

2.2 ONE of the following:

2.2.1 ALL of the following:

- Patient is not a transplant candidate or transplant not currently feasible
- Platelets ≥ 50 x 109/L
- Presence of symptomatic splenomegaly and/or constitutional symptoms

OR

2.2.2 BOTH of the following:

- Patient is not a transplant candidate or transplant not currently feasible
- Platelets < 50 x 109/L

OR

2.2.3 Patient is a transplant candidate

OR

3 - Diagnosis of myelofibrosis-associated anemia

OR

4 - BOTH of the following:

4.1 Diagnosis of accelerated/blast phase myeloproliferative neoplasm

AND

4.2 ONE of the following:

- Used for the improvement of splenomegaly or other disease-related symptoms
- Continued treatment as a single agent near to the start of conditioning therapy in transplant candidates for the improvement of splenomegaly and other disease-related symptoms

Notes	NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Ojjaara, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ojjaara [a]	
Diagnosis	Myeloproliferative Neoplasms
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Ojjaara

Notes	NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Ojjaara, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ojjaara [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
Approval Criteria **1** - Ojjaara will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ojjaara [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to Ojjaara therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Ojjaara (momelotinib) is a kinase inhibitor indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [postpolycythemia vera (PV) and post-essential thrombocythemia (ET)] with anemia. The National Cancer Comprehensive Network (NCCN) also recommends Ojjaara for the treatment of symptomatic lower-risk, higher-risk myelofibrosis, and accelerated/blast phase myeloproliferative neoplasms. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limit may be in place**.**

4 . References

1. Ojjaara [package insert]. Durham, NC: GlaxoSmithKline; September 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/ Accessed October 11, 2024.

5 . Revision History

Date	Notes
11/3/2025	Annual review. Updated coverage criteria for higher-risk myelofibrosi s per NCCN recommendations.

Olumiant

Prior Authorization Guideline

Guideline ID	GL-399234
Guideline Name	Olumiant
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 05/21/2021 ; 02/18/2022 ; 08/19/2022 ; 09/21/2022 ; 09/20/2023 ; 12/13/2023 ; 10/01/2024 ; 9/25/2025

1 . Indications

Drug Name: Olumiant (baricitinib)
Rheumatoid Arthritis Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. Use of Olumiant in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. [1] **Alopecia Areata** Indicated for the treatment of adult patients with severe alopecia areata.

2 . Criteria

Product Name:Olumiant [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

- History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)
- • Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

AND

2.1.2 ONE of the following:

- History of failure, contraindication, or intolerance to at least ONE TNF antagonist therapy ^
- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria [3])

OR

2.2 BOTH of the following:

2.2.1 Patient is currently on Olumiant therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

AND

2.2.2 Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Eli Lilly sponsored Olumiant Together program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Olumiant*

AND

3 - Patient is not receiving Olumiant in combination with EITHER of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Eli Lilly sponsored Olumiant Together program shall be required to meet initial authorization criteria as if patient were new to therapy. ^ Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Olumiant [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Olumiant therapy

AND

2 - Patient is not receiving Olumiant in combination with ANY of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Olumiant [a]	
Diagnosis	Alopecia Areata [b]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe alopecia areata

AND

2 - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecias, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania)

AND

3 - Patient has a current episode of alopecia areata lasting more than 6 months and at least 50% scalp hair loss

AND

4 - Patient is not receiving Olumiant in combination with EITHER of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

5 - Prescribed by a dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] Alopecia areata is not considered cosmetic use.

Product Name:Olumiant [a]	
Diagnosis	Alopecia Areata [b]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Olumiant therapy

AND

2 - Patient is not receiving Olumiant in combination with EITHER of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] Alopecia areata is not considered cosmetic use.

3 . Background

Benefit/Coverage/Program Information

Background:

Olumiant (baricitinib) is a Janus Kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies and for the treatment of adult patients with severe alopecia areata. Use of Olumiant in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. Olumiant is also indicated for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO. [1]

Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2022.
2. Fraenkel L, Bathon JM, England BR, et al 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2021;73(7):924-939
3. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Arlington, VA: American Psychiatric Publishing. 2013.
4. Messenger AG, McKillop J, Farrant P, et al. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. Br J Dermatol. 2012;166(5):916-926.
5. King B, Ohyama M, Kwon O, et al. BRAVE-AA Investigators. Two Phase 3 Trials of Baricitinib for Alopecia Areata. N Engl J Med. 2022 May 5;386(18):1687-1699.
6. King BA, Mesinkovska NA, Craiglow B, et al. Development of the alopecia areata scale for clinical use: results of an academic-industry collaborative effort. J Am Acad Dermatol. 2022;86(2):359-364.
7. Meah N, Wall D, York K, et al. The Alopecia Areata Consensus of Experts (ACE) study: Results of an international expert opinion on treatments for alopecia areata. J Am Acad Dermatol. 2020;83(1):123-130.

5 . Revision History

Date	Notes
9/17/2025	Updated footnote callouts.

Omnipod 5, Twiist (PA, QL)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-532221
Guideline Name	Omnipod 5, Twiist (PA, QL)
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	3/18/2026
P&T Approval Date:	5/20/2022
P&T Revision Date:	09/21/2022 ; 11/18/2022 ; 04/19/2023 ; 11/17/2023 ; 03/20/2024 ; 11/22/2024 ; 03/19/2025 ; 03/19/2025 ; 05/16/2025 ; 3/18/2026

1 . Criteria

Product Name:Omnipod 5, Twiist [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following:	

- For Omnipod 5: Diagnosis of diabetes
- For Twiist: Diagnosis of Type 1 diabetes

AND

2 - ALL of the following:

- Patient regularly tests blood glucose greater than or equal to 4 times/day or utilizes a continuous glucose monitor (CGM) for greater than or equal to 8 weeks
- Patient has completed a diabetes management program
- Patient injects insulin greater than or equal to 3 times/day

AND

3 - BOTH of the following:

- Patient or caregiver is motivated to assume responsibility for self-care and insulin management
- Patient or caregiver demonstrates knowledge of importance of nutrition including carbohydrate counting and meal planning

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *For Omnipod: If patient meets criteria above, approve using NDC List OMNIPOD5

Product Name:Omnipod 5, Twiist [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *For Omnipod: If patient meets criteria above, approve using NDC List OMNIPOD5

Product Name:Omnipod 5 G6 , Omnipod 5 G7 Pods, or Twiist	
Approval Length	12 month(s)
Guideline Type	Quantity Limit
Approval Criteria **1** - Quantity requests for Omnipod 5 G6, Omnipod 5 G7 pods, or Twiist exceeding the limited amount will be approved based on physician confirmation that the patient requires a greater quantity	
Notes	*Note :Authorization for quantity limit overrides should be entered at the NDC level for the requested Omnipod 5 G6 or Omnipod 5 G7 pods for the requested quantity.

2 . Background

Benefit/Coverage/Program Information

Background:

External insulin pumps are used for managing individuals with type 1 or type 2 diabetes and deliver insulin by continuous subcutaneous infusion. Members will be required to meet the following coverage criteria.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

- Coverage is not provided for indications unproven per medical benefit drug policy.

3 . References

1. American Diabetes Association Professional Practice Committee for Diabetes. (2026). 7. Diabetes Technology: Standards of Care in Diabetes—2026. Diabetes Care, 49(Suppl. 1), S150–S165
2. Blonde L, Umpierrez G, Reddy S, et al.; American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan-2022 Update. Endocrine Practice 28(2022)923-1049.

4 . Revision History

Date	Notes
3/2/2026	Updated footnotes with no change to clinical criteria. Updated references.

Omvoh

Prior Authorization Guideline

Guideline ID	GL-555212
Guideline Name	Omvoh
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	1/17/2024
P&T Revision Date:	01/15/2025 ; 03/19/2025 ; 03/19/2025 ; 3/18/2026

Note:

*This program applies to the subcutaneous formulation of Omvoh.

1 . Indications

Drug Name: Omvoh (mirikizumab-mrkz)
Ulcerative colitis Indicated for the treatment of moderately to severely active ulcerative colitis in adults. **Crohn's disease** Indicated for the treatment of moderately to severely active Crohn's disease in adults.

2 . Criteria

Product Name:Omvoh [a]	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization for Maintenance Dosing
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - ONE of the following:

2.1 Patient has been approved for loading dose of Omvoh under an active UnitedHealthcare medical benefit prior authorization for moderately to severely active ulcerative colitis

OR

2.2 BOTH of the following:

- Patient is currently on Omvoh therapy for moderately to severely active ulcerative colitis as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from an Eli Lilly sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Omvoh*

AND

3 - Patient is not receiving Omvoh in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Zeposia (ozanimod)] for treatment of the same indication.

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from an Eli Lilly sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Omvoh [a]	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Omvoh therapy

AND

2 - Patient is not receiving Omvoh in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Zeposia (ozanimod)] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Omvoh [a]

Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization for Maintenance Dosing
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - ONE of the following:

2.1 Patient has been approved for the loading dose of Omvoh under an active UnitedHealthcare medical benefit prior authorization for moderately to severely active Crohn's disease

OR

2.2 BOTH of the following:

- Patient is currently on Omvoh therapy for moderately to severely active Crohn's disease as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from an Eli Lilly sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Omvoh*

AND

3 - Patient is not receiving Omvoh in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), ustekinumab,] for treatment of the same indication.

AND

4 - Prescribed by or in consultation with a gastroenterologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from an Eli Lilly sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Omvoh [a]	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Omvoh therapy

AND

2 - Patient is not receiving Omvoh in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), ustekinumab) for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Omvoh (mirikizumab-mrkz) is an interleukin-23 antagonist indicated for the treatment of

moderately to severely active ulcerative colitis in adults and moderately to severely active Crohn's disease in adults.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limit may be in place.

4 . References

1. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company; November 2025.

5 . Revision History

Date	Notes
3/18/2026	Updated establishment of therapy on the medical benefit and combin ation examples and language with no change to clinical intent. Updat ed reference.

Opfolda

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-159412
Guideline Name	Opfolda
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2025
P&T Approval Date:	11/17/2023
P&T Revision Date:	11/22/2024

1 . Indications

Drug Name: Opfolda (miglustat)
Pompe disease Indicated, in combination with Pombiliti, a hydrolytic lysosomal glycogen-specific enzyme, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).

2 . Criteria

Product Name:Opfolda [a]	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of late-onset Pompe disease

AND

2 - Patient has an active UnitedHealthcare medical benefit prior authorization for Pombiliti (cipaglucosidase alfa-atga) for the treatment of late-onset Pompe disease.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Opfolda [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Opfolda plus Pombiliti

AND

2 - Opfolda continues to be prescribed in combination with Pombiliti

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Opfolda (miglustat) is an enzyme stabilizer indicated, in combination with Pombiliti, a hydrolytic lysosomal glycogen-specific enzyme, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limit may be in place.

4 . References

1. Opfolda [prescribing information]. Philadelphia, PA: Amicus Therapeutics US, LLC; September 2024.
2. Pombiliti [prescribing information]. Philadelphia, PA: Amicus Therapeutics US, LLC; September 2024.

5 . Revision History

Date	Notes
11/7/2024	Clarified criteria without change to clinical intent. Updated references .

Opzelura

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-461343
Guideline Name	Opzelura
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	4/20/2022
P&T Revision Date:	07/20/2022 ; 09/21/2022 ; 09/20/2023 ; 12/18/2024 ; 12/17/2025

1 . Indications

Drug Name: Opzelura (ruxolitinib)
Atopic Dermatitis (Mild to Moderate) Indicated for the topical short term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. **Nonsegmental Vitiligo** Indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

2 . Criteria

Product Name:Opzelura [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of mild to moderate atopic dermatitis

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to BOTH of the following therapeutic classes of topical therapies^:

2.1.1 ONE of the following:

- For mild atopic dermatitis: a topical corticosteroid [e.g., desonide (generic DesOwen), hydrocortisone] (any potency)
- For moderate atopic dermatitis: a topical corticosteroid of at least a medium- to high-potency (e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]

AND

2.1.2 One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]

OR

2.2 BOTH of the following:

- Patient is currently on Opzelura therapy
- Patient has not received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Incyte sponsored Opzelura IncyteCARES

program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Opzelura¥

AND

3 - Patient is NOT receiving Opzelura in combination with a biologic medication or JAK inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), Rinvoq (upadacitinib)]

AND

4 - Patient is NOT receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ¥ Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Incyte sponsored Opzelura IncyteCARES program shall be required to meet initial authorization criteria as if patient were new to therapy. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Opzelura [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is NOT receiving Opzelura in combination with a biologic medication or JAK inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), Rinvoq (upadacitinib)]

AND

3 - Patient is NOT receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Opzelura [a]	
Diagnosis	Nonsegmental Vitiligo
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of nonsegmental vitiligo

AND

2 - Other causes of depigmentation have been ruled out (e.g., nevus depigmentosus, pityriasis alba, idiopathic guttate hypomelanosis, tinea (pityriasis) versicolor, halo nevus, piebaldism, progressive macular hypomelanosis, lichen sclerosus, chemical leukoderma, drug-induced leukoderma, hypopigmented mycosis fungoides)

AND

3 - Affected areas not to exceed 10% body surface area

AND

4 - History of failure, contraindication, or intolerance to previous nonsegmental vitiligo treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors)

AND

5 - Patient is NOT receiving Opzelura in combination with a biologic medication or JAK inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), Rinvoq (upadacitinib)]

AND

6 - Patient is NOT receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Opzelura [a]	
Diagnosis	Nonsegmental Vitiligo
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is NOT receiving Opzelura in combination with another biologic medication or JAK

inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), Rinvoq (upadacitinib)] **AND** **3** - Patient is NOT receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Opzelura (ruxolitinib) is a Janus kinase (JAK) inhibitor indicated for the topical short term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Opzelura is also indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older. Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine is not recommended. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; September 2025.
2. Frazier W, Bhardwaj N. Atopic Dermatitis: Diagnosis and Treatment. Am Fam Physician. 2020;101(10):590-598.
3. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71(1):116-132.
4. Taieb A, Alomar A, Böhm M, et al. Guidelines for the management of vitiligo: the European Dermatology Forum consensus. Br J Dermatol. 2013;168(1):5-19.
5. Grimes PE. Vitiligo: Management and prognosis. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com. Accessed on August 15, 2022.
6. Bergqvist C, Ezzedine K. Vitiligo: A Review. Dermatology. 2020;236(6):571-592.

5 . Revision History

Date	Notes
12/8/2025	Annual review. Updated combination examples and language with no change to clinical intent. Updated background to reflect new age recommendation for AD. Updated reference.

Orilissa

Prior Authorization Guideline

Guideline ID	GL-523265
Guideline Name	Orilissa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 09/21/2022 ; 02/17/2023 ; 02/16/2024 ; 2/20/2026

1 . Indications

Drug Name: Orilissa (elagolix)
Endometriosis Indicated for the management of moderate to severe pain associated with endometriosis.

2 . Criteria

Product Name:Orilissa 150 mg [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - Failure after a three month trial (e.g., inadequate pain relief), contraindication or intolerance of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen)

AND

3 - Failure after a three month trial, contraindication, or intolerance to ONE of the following:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Orilissa 150 mg [a]	
Approval Length	Authorization will be issued for 12 months up to a maximum treatment duration of 24 months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Impact to bone mineral density has been considered

AND

3 - Treatment duration has not exceeded a total of 24 months

Notes	NOTE: Orilissa 150 mg once daily is indicated for a maximum treatment duration of 24 months; [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Orilissa 200 mg [a]	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - Failure after a three month trial (e.g., inadequate pain relief), contraindication or intolerance of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen)

AND

3 - Failure after a three month trial, contraindication, or intolerance to ONE of the following: • Hormonal contraceptives • Progestins [e.g., norethindrone (generic Aygestin)] **AND** **4** - Prescribed by or in consultation with ONE of the following: • Obstetrics/Gynecologist (OB/GYN) • Reproductive endocrinologist	
Notes	NOTE: Orilissa 200 mg twice daily is indicated for a maximum treatment duration of 6 months; [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Orilissa (elagolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Orilissa [package insert]. AbbVie Inc. North Chicago, IL. June 2023.
2. Taylor H, Giudice L, Lessey B, et al. Treatment of endometriosis-associated pain with elagolix, an oral GnRH antagonist. N Engl J Med 2017; 377:28-40.
3. The American College of Obstetricians and Gynecologists. Management of endometriosis. Practice Bulletin 114. July 2010 (Reaffirmed 2022).

5 . Revision History

Date	Notes
2/20/2026	Annual review. Updated references.

Orkambi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-291194
Guideline Name	Orkambi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 10/20/2021 ; 10/19/2022 ; 06/21/2023 ; 06/17/2024 ; 6/18/2025

1 . Indications

Drug Name: Orkambi (lumacaftor/ivacaftor)
Cystic fibrosis (CF) Indicated for the treatment of cystic fibrosis (CF) in patients aged 1 year and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.

2 . Criteria

Product Name:Orkambi [a]

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results confirming that patient is homozygous for the F508del mutation in the CFTR gene

AND

3 - The patient is greater than or equal to 1 year of age

AND

4 - Prescribed by or in consultation with a provider who specializes in the treatment of CF

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Orkambi [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Orkambi therapy (e.g., improved lung function, stable lung function)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Orkambi is a combination of lumacaftor and ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, indicated for the treatment of cystic fibrosis (CF) in patients aged 1 year and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. [1] Limitations of Use: The efficacy and safety of Orkambi have not been established in patients with CF other than those homozygous for the F508del mutation. [1] **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Orkambi [Package Insert]. Cambridge, MA: Vertex Pharmaceuticals, Inc.; December 2024.

5 . Revision History

Date	Notes
6/9/2025	Annual review. No changes to coverage criteria. Updated reference.

Orladeyo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-493415
Guideline Name	Orladeyo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	8/18/2023
P&T Revision Date:	03/30/2024 ; 03/19/2025 ; 1/21/2026

1 . Indications

Drug Name: Orladeyo (berotralstat)
Prophylaxis of HAE attacks Orladeyo is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 2 years and older. Orladeyo should not be used for the treatment of acute HAE attacks.

2 . Criteria

Product Name:Orladeyo [a]	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - ALL of the following:

- Prescribed for the prophylaxis of HAE attacks
- Not used in combination with other approved products indicated for prophylaxis against HAE attacks (i.e., Cinryze, Haegarda, Takhzyro)
- Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Orladeyo

AND

3 - Prescribed by ONE of the following:

- Immunologist

- Allergist

AND

4 - ONE of the following:

- Patient is greater than or equal to 2 years of age and less than 6 years of age
- Submission of medical records documenting a history of failure, contraindication, or intolerance to Haegarda (C1 esterase inhibitor, human)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Orladeyo [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Orladeyo therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest), as confirmed by claims history or submission of medical records, while on Orladeyo therapy

AND

3 - BOTH of the following:

- Prescribed for the prophylaxis of HAE attacks

• Not used in combination with other products indicated for prophylaxis against HAE attacks (i.e., Cinryze, Haegarda, Takhzyro) **AND** **4** - Prescribed by ONE of the following: • Immunologist • Allergist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Orladeyo is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older. Orladeyo should not be used for the treatment of acute HAE attacks.[1] **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Orladeyo [package insert]. Durham, NC: BioCryst Pharmaceuticals Inc.; December 2025.
2. Busse, P., Christiansen, S., Riedl, M., et. al. “US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema.” The Journal of Allergy and Clinical Immunology. 2020 September 05.
3. Maurer, M., Magerl, M., et. al. “The international WAO/EAACI guideline for the management of hereditary angioedema – the 2017 revision and update.” World Allergy Organization Journal. 2018 February 27.

5 . Revision History

Date	Notes
1/10/2026	Updated coverage criteria based on updated FDA indication by separating tried/failed therapies based on age limitations for Haegarda. Updated background and references.

Orphenadrine, aspirin and caffeine tablets

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-424215
Guideline Name	Orphenadrine, aspirin and caffeine tablets
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	10/15/2025
P&T Revision Date:	

1 . Indications

Drug Name: Orphenadrine, acetaminophen, caffeine tablets (generic Norgesic)
Acute musculoskeletal pain Indicated for symptomatic relief of mild to moderate pain of acute musculoskeletal disorders.

2 . Criteria

Product Name:Orphenadrine, acetaminophen, caffeine tablets (generic Norgesic) [a]	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate acute musculoskeletal pain

AND

2 - History of failure, contraindication, or intolerance to THREE of the following solid oral formulary products:

- Carisoprodol
- Chlorzoxazone
- Cyclobenzaprine
- Etodolac
- Flurbiprofen
- Ibuprofen (prescription strength)
- Ketoprofen
- Metaxalone
- Methocarbamol
- Naproxen (prescription strength)
- Orphenadrine citrate extended release
- Tizanidine

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Orphenadrine, acetaminophen, and caffeine tablets (generic Norgesic®) are indicated for symptomatic relief of mild to moderate pain of acute musculoskeletal disorders.

Additional Clinical Rules:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Norgesic® [package insert]. Sylacauga, AL: ATLAND Pharmaceuticals, LLC. July 2024.

5 . Revision History

Date	Notes
10/17/2025	New program

Osphena

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-555213
Guideline Name	Osphena
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	1/20/2021
P&T Revision Date:	09/15/2021 ; 03/16/2022 ; 03/20/2024 ; 03/19/2025 ; 3/18/2026

1 . Indications

Drug Name: Osphena (ospemifene)
Moderate to severe dyspareunia Indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause. **Moderate to severe vaginal dryness** Indicated for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy due to menopause.

2 . Criteria

Product Name:Osphena [a]	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA) due to menopause*	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Note: Medications for the treatment of moderate to severe dyspareunia are excluded and are to be denied as a benefit exclusion.

Product Name:Osphena [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy*	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Note: Medications for the treatment of moderate to severe dyspareunia are excluded and are to be denied as a benefit exclusion.

3 . Background

Benefit/Coverage/Program Information
Background:

Osphena (ospemifene) is indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause and for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA) due to menopause.

Additional Clinical Rules:

- Supply limits may be in place
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Osphena [package insert]. Princeton, NJ: Duchesnay USA, Inc; February 2025.

5 . Revision History

Date	Notes
3/18/2026	Annual review. Updated references.

Otezla and Otezla XR

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-550193
Guideline Name	Otezla and Otezla XR
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 02/18/2022 ; 02/17/2023 ; 06/17/2024 ; 01/15/2025 ; 06/18/2025 ; 3/18/2026

1 . Indications

Drug Name: Otezla (apremilast), Otexla XR (apremilast ER)
Active psoriatic arthritis Indicated for the treatment of adult and pediatric patients 6 years of age and older with active psoriatic arthritis, **Plaque psoriasis** Indicated for the treatment of adult and pediatric patients 6 years of age or older with plaque psoriasis who are candidates for phototherapy or systemic therapy **Behcet's disease** Indicated for the treatment of adult patients with oral ulcers associated with Behçet's disease.

2 . Criteria

Product Name:Otezla, Otezla XR [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of active psoriatic arthritis **AND** **2** - Patient is not receiving Otezla or Otezla XR in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Otezla, Otezla XR [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Otezla or Otezla XR therapy	

AND

2 - Patient is not receiving Otezla or Otezla XR in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Otezla, Otezla XR [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of plaque psoriasis.

AND

2 - Patient is not receiving Otezla or Otezla XR in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Otezla, Otezla XR [a]

Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Otezla or Otezla XR therapy

AND

2 - Patient is not receiving Otezla or Otezla XR in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Otezla, Otezla XR [a]	
Diagnosis	Behcet's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Behcet's disease

AND

2 - Patient has oral ulcers attributed to Behcet's disease

AND **3** - Patient is not receiving Otezla or Otezla XR in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), tocilizumab] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Otezla, Otezla XR [a]	
Diagnosis	Behcet's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Otezla or Otezla XR therapy

AND

2 - Patient is not receiving Otezla or Otezla XR in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), tocilizumab] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Otezla (apremilast) and Otezla XR (apremilast) are phosphodiesterase 4 (PDE4) inhibitors indicated for the treatment of adult and pediatric patients 6 years of age and older with active psoriatic arthritis, for the treatment of adult and pediatric patients 6 years of age or older with plaque psoriasis who are candidates for phototherapy or systemic therapy, and for the treatment of adult patients with oral ulcers associated with Behçet's disease. In the pediatric population, Otezla is indicated for patients weighing at least 20 kg and Otezla XR is indicated for patients weighing at least 50 kg. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Otezla/Otezla XR [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2025.

5 . Revision History

Date	Notes
3/16/2026	Added Otezla XR to program. Updated step therapy and combination therapy exclusion to specify systemic targeted immunomodulators and for treatment of the same indication where applicable. Removed candidates for phototherapy or systemic therapy from PsO criteria. Updated background and reference.

Oxervate

Prior Authorization Guideline

Guideline ID	GL-165000
Guideline Name	Oxervate
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	7/17/2024
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Oxervate (cenegermin-bkbj) ophthalmic solution
Neurotrophic keratitis Indicated for the treatment of neurotrophic keratitis.

2 . Criteria

Product Name:Oxervate [a]	
Diagnosis	Neurotrophic Keratitis
Approval Length	8 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Stage 2 or 3 neurotrophic keratitis

AND

2 - History of failure to at least ONE OTC ocular artificial tear product (e.g., Systane® Ultra, Akwa® Tears, Refresh Optive®, Soothe® XP)

AND

3 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Oxervate (cenegermin-bkbj) ophthalmic solution is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

• Supply limits may be in place

4 . References

1. Oxervate [prescribing information]. Boston, MA: Dompé U.S. Inc..; December 2024.
2. Sacchetti, M., Lambiase, A. Diagnosis and management of neurotrophic keratitis. Clinical Ophthalmology 2014;8: 571-9.

5 . Revision History

Date	Notes
2/11/2025	Annual review with no change to clinical criteria. Updated reference.

PAH Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-458255
Guideline Name	PAH Agents
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 06/16/2021 ; 09/15/2021 ; 06/15/2022 ; 07/20/2022 ; 11/18/2022 ; 03/15/2023 ; 08/18/2023 ; 02/16/2024 ; 05/17/2024 ; 10/01/2024 ; 09/25/2025

1 . Indications

Drug Name: Adcirca (tadalafil)
Pulmonary arterial hypertension (PAH) Indicated for the treatment of PAH (WHO Group 1) to improve exercise ability. [5]
Drug Name: Adempas (riociguat)
Pulmonary arterial hypertension (PAH) Indicated for the treatment of adults with PAH (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening. **Chronic thromboembolic pulmonary hypertension (CTEPH)** Indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)

(WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class. [10]
Drug Name: Alyq (tadalafil)
Pulmonary arterial hypertension (PAH) Indicated for the treatment of PAH (WHO Group 1) to improve exercise ability. [13]
Drug Name: Letairis (ambrisentan)
Pulmonary arterial hypertension (PAH) Indicated for the treatment of PAH (WHO Group 1) to improve exercise ability and delay clinical worsening. It is also indicated in combination with tadalafil to reduce the risk of disease progression and hospitalization for worsening PAH, and to improve exercise ability. [2]
Drug Name: Opsumit (macitentan)
Pulmonary arterial hypertension (PAH) Indicated for the treatment of PAH (WHO Group 1) to reduce the risks of disease progression and hospitalization for PAH. [8]
Drug Name: Orenitram (treprostinil)
Pulmonary arterial hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to delay disease progression and to improve exercise capacity. [9]
Drug Name: Revatio (sildenafil), Liqrev (tadalafil)
Pulmonary arterial hypertension (PAH) Indicated in pediatric patients 1 to 17 years old for the treatment of PAH (WHO Group I) to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise. Revatio is also indicated in adult patients for the treatment of PAH (WHO Group 1) to improve exercise ability and delay clinical worsening. [4]
Drug Name: Tracleer (bosentan)
Pulmonary arterial hypertension (PAH) Indicated for the treatment of PAH (WHO Group 1) to improve exercise ability and to decrease clinical worsening in adult patients, and improve pulmonary vascular resistance, which is expected to result in an improvement in exercise ability in pediatric patients aged 3 years and older. [3]
Drug Name: Tyvaso (treprostinil), Tyvaso DPI (treprostinil), Yutrepia (treprostinil)
Pulmonary arterial hypertension (PAH) Indicated for the treatment of PAH (WHO Group 1) to improve exercise ability. [7] **Pulmonary hypertension associated with interstitial lung disease** Indicated for the

treatment of pulmonary hypertension associated with interstitial lung disease (WHO Group 3) to improve exercise ability. [7, 13]
Drug Name: Ventavis (iloprost)
Pulmonary arterial hypertension (PAH) Indicated for the treatment of PAH (WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration. [6]
Drug Name: Uptravi (selexipag)
Pulmonary arterial hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. [12]
Drug Name: Tadliq (tadalafil)
Pulmonary arterial hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability.
Drug Name: Opsynvi (macitentan/tadalafil),
Pulmonary Arterial Hypertension Indicated for the chronic treatment of adults with pulmonary arterial hypertension (PAH, WHO Group I and WHO Functional Class (FC) II–III).

2 . Criteria

Product Name:Brand Adcirca, generic sildenafil 20 mg tabs, Adempas, Alyq, Brand Letairis, generic ambrisentan, Opsumit, Orenitram, Brand Revatio tabs, generic tadalafil 20 mg tabs, Brand Tracleer, generic bosentan, Tyvaso, Tyvaso DPI, Ventavis [a]	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Pulmonary arterial hypertension is symptomatic

- Diagnosis of pulmonary arterial hypertension that is confirmed by right heart catheterization
- The medication is prescribed by or in consultation with a cardiologist, pulmonologist or rheumatologist.

OR

2 - BOTH of the following:

- Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension
- The medication is prescribed by or in consultation with a cardiologist, pulmonologist or rheumatologist.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Brand Adcirca, generic sildenafil 20 mg tabs, Adempas, Alyq, Brand Letairis, generic ambrisentan, Opsumit, Orenitram, Brand Revatio tabs, generic tadalafil 20 mg tabs, Brand Tracleer, generic bosentan, Tyvaso, Tyvaso DPI, Ventavis [a]	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation the patient is receiving clinical benefit to therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Liqrev, Brand revatio suspension, generic sildenafil suspension,Tadliq [a]	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following

- Pulmonary arterial hypertension is symptomatic
- Diagnosis of pulmonary arterial hypertension that is confirmed by right heart catheterization

OR

1.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

2 - Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to ONE of the following:

- Age
- oral-motor difficulties
- dysphagia

AND

3 - For requests other than sildenafil citrate suspension (generic Revatio), the patient has a history of failure, contraindication, or intolerance to sildenafil citrate suspension (generic Revatio suspension)

AND

4 - Prescribed by or in consultation with a cardiologist, pulmonologist or rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply

Product Name:Liqrev, Brand revatio suspension, generic sildenafil suspension,Tadliq [a]	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation the patient is receiving clinical benefit to Revatio oral suspension, Liqrev oral suspension or Tadliq therapy.

AND

2 - Patient remains unable to ingest a solid dosage form (e.g., an oral tablet) due to ONE of the following:

- Age
- oral-motor difficulties
- dysphagia

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply

Product Name:Uptravi, Yutrepia [a]	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 As continuation of therapy

AND

1.2 Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the manufacturer sponsored support program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Uptravi or Yutrepia

AND

1.3 Patient is not taking Uptravi or Yutrepia in combination with a prostanoid/prostacyclin analogue (e.g., epoprostenol, iloprost, treprostinil)

AND

1.4 Prescribed by or in consultation with a cardiologist, pulmonologist or rheumatologist

OR

2 - ALL of the following:

2.1 ONE of the following:

2.1.1 BOTH of the following:

- Pulmonary arterial hypertension is symptomatic
- Diagnosis of pulmonary arterial hypertension that is confirmed by right heart catheterization

OR

2.1.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

2.2 History of failure, contraindication, or intolerance to BOTH of the following:

2.2.1 ONE of the following:

- A PDE-5 inhibitor [e.g., sildenafil citrate (generic Revatio), tadalafil (generic Adcirca)]
- Adempas

AND

2.2.2 An ERA [e.g., ambrisentan (generic Letairis), Opsumit, or bosentan (generic Tracleer)]

AND

2.3 Patient is not taking Uptravi or Yutrepia in combination with a prostanoid/prostacyclin analogue (e.g., epoprostenol, iloprost, treprostinil)

AND

2.4 Prescribed by or in consultation with a cardiologist, pulmonologist or rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Uptravi, Yutrepia [a]	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation the patient is receiving clinical benefit to therapy

AND

2 - Patient is not taking Uptravi or Yutrepia in combination with a prostanoid/prostacyclin analogue (e.g., epoprostenol, iloprost, treprostinil)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Opsynvi [a]	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

- Pulmonary arterial hypertension is symptomatic
- Diagnosis of pulmonary arterial hypertension that is confirmed by right heart catheterization
- The medication is prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist.

OR

1.2 BOTH of the following:

- Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension
- The medication is prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist

AND

2 - Failure to BOTH of the following TAKEN TOGETHER as confirmed by claims history or submission of medical records:

- A formulary PDE-5 inhibitor
- A formulary ERA

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Opsynvi [a]	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation the patient is receiving clinical benefit to therapy.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Adempas [a]	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)
- CTEPH is symptomatic
- Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist

OR

2 - BOTH of the following:

- Patient is currently on any therapy for the diagnosis of CTEPH
- Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Adempas [a]	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation the patient is receiving clinical benefit to Adempas therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Tyvaso, Tyvaso DPI, Yutrepia [a]	
Diagnosis	Pulmonary Hypertension Associated with Interstitial Lung Disease

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Diagnosis of pulmonary hypertension associated with interstitial lung disease (WHO group 3) confirmed by right heart catheterization
- Interstitial lung disease is diagnosed based on evidence of diffuse parenchymal lung disease on computed tomography of the chest
- Pulmonary hypertension is symptomatic

AND

2 - Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Tyvaso, Tyvaso DPI, Yutrepia [a]	
Diagnosis	Pulmonary Hypertension Associated with Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improved exercise ability)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3 . Background

Benefit/Coverage/Program Information
Background: Pulmonary arterial hypertension (PAH) is often a progressive disease characterized by elevated pressure in the vessels that carry blood between the heart and the lungs. This results in ventricular dysfunction, reduced exercise capacity, the potential for right sided heart failure, and even death. Several mechanisms have been identified in the pathogenesis of PAH, leading to the development of four classes of medications to treat the disorder. Endothelin receptor antagonists (ERAs), phosphodiesterase-5 (PDE-5) inhibitors, prostacyclin analogs, and soluble guanylate cyclase (sGC) stimulators may be used as monotherapy, sequential combination therapy, or simultaneous combination therapy to treat PAH. [1] Letairis (ambrisentan), Tracleer (bosentan), and Opsumit (macitentan) are oral endothelin receptor antagonists (ERA). Letairis is indicated for the treatment of PAH (WHO Group 1) to improve exercise ability and delay clinical worsening. It is also indicated in combination with tadalafil to reduce the risk of disease progression and hospitalization for worsening PAH, and to improve exercise ability. [2] Tracleer is indicated for the treatment of PAH (WHO Group 1) to improve exercise ability and to decrease clinical worsening in adult patients, and improve pulmonary vascular resistance, which is expected to result in an improvement in exercise ability in pediatric patients aged 3 years and older. [3] Opsumit is indicated for the treatment of PAH (WHO Group 1) to reduce the risks of disease progression and hospitalization for PAH. [8] Revatio (sildenafil), Liqrev (tadalafil), Adcirca (tadalafil), Tadliq (tadalafil), and Alyq (tadalafil) are oral PDE-5 inhibitors. Revatio and Liqrev is indicated in pediatric patients 1 to 17 years old for the treatment of PAH (WHO Group 1) to improve exercise ability, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise. Revatio is also indicated in adult patients for the treatment of PAH (WHO Group 1) to improve exercise ability and delay clinical worsening. [4] Adcirca and Alyq are indicated for the treatment of PAH (WHO Group 1) to improve exercise ability. [5, 13]

Ventavis (iloprost) and Tyvaso (treprostinil) are prostacyclin analogs administered as inhalation solutions. Tyvaso DPI (treprostinil) and Yutrepia (treprostinil) are prostacyclin analogs administered as a powder for inhalation. Ventavis is indicated for the treatment of PAH (WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration. [6] Tyvaso, Tyvaso DPI, and Yutrepia are indicated for the treatment of PAH (WHO Group 1) to improve exercise ability. They are also indicated for the treatment of pulmonary hypertension associated with interstitial lung disease (WHO Group 3) to improve exercise ability. [7,13,19]

Orenitram (treprostinil) is an orally administered prostacyclin analog indicated for the treatment of PAH (WHO Group 1) to delay disease progression and to improve exercise capacity. [9]

Adempas (riociguat) is a soluble guanylate cyclase (sGC) stimulator indicated for the treatment of adults with PAH (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening. Adempas is also indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class. [10]

Uptravi (selexipag) is a prostacyclin receptor agonist indicated for the treatment of PAH (WHO Group 1) to delay disease progression and reduce the risk of hospitalization for PAH. [12]

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place.

Additional Information regarding the endothelin receptor antagonists (Letairis, Opsumit, and Tracleer):

These agents should be used with caution in patients with liver disease. Use is not recommended in moderate to severe hepatic impairment. Tracleer product labeling includes a black box warning regarding the risk of liver injury. Prescribers are cautioned to consider

whether benefits of use offset the risk of liver injury in WHO Class II patients. Early liver injury may preclude future use as disease progresses. [3]

Additional Information regarding the oral PDE-5 inhibitors (Revatio, Adcirca, Tadliq, Liqrev and Alyq):

Administration of the oral PDE-5 inhibitors to patients taking any form of organic nitrate, either regularly or intermittently, is contraindicated. [4,5] In addition, the concomitant administration of oral PDE-5 inhibitors with Adempas is contraindicated. [9]

4 . References

1. Letairis [package insert]. Foster City, CA: Gilead Sciences, Inc; April 2025.
2. Tracleer [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; February 2024.
3. Revatio [package insert]. New York, NY: Pfizer Labs; January 2023.
4. Adcirca [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2020.
5. Ventavis [package insert]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; March 2022.
6. Tyvaso [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; March 2021.
7. Opsumit [package insert]. Titusville, NJ: Actelion Pharmaceuticals US Inc.; April 2025
8. Orenitram [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; August 2023.
9. Adempas [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2021.
10. Waxman, A., Restrepo-Jaramillo, R., Thenappan, T., Ravichandran, A., Engel, P., Bajwa, A., Allen, R., Feldman, J., Argula, R., Smith, P., Rollins, K., Deng, C., Peterson, L., Bell, H., Tapson, V., & Nathan, S. D. (2021). Inhaled Treprostinil in Pulmonary Hypertension Due to Interstitial Lung Disease. The New England journal of medicine, 384(4), 325–334.
11. Alyq [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; January 2019.
12. Uptravi [package insert]. South Titusville, NJ: Actelion Pharmaceuticals US, Inc; July 2022.
13. Tyvaso DPI [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; October 2024,
14. Tadliq [package insert]. Farmville, NC: CMP Pharma, Inc.; October 2023.
15. Liqrev [package insert]. Farmville, NC: CMP Pharma, Inc.; April 2023.
16. Opsynvi [package insert]. Titusville, NJ: Janssen Pharmaceutical Company; April 2025.
17. Yutrepia [package insert]. Morrisville, NC. Liquidia Technologies, Inc.; June 2025. 18. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: Developed by the task force for the diagnosis and treatment of pulmonary hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Endorsed by the International Society for Heart and Lung Transplantation (ISHLT) and the European Reference Network on rare respiratory diseases (ERN-LUNG), European Heart Journal, Volume 44, Issue 15, 14 April 2023, Page 1312, https://doi.org/10.1093/eurheartj/ehad005.

5 . Revision History

Date	Notes
12/1/2025	Updated Tyvaso GPI

Palsonify

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-552190
Guideline Name	Palsonify
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	3/18/2026
P&T Revision Date:	

1 . Indications

Drug Name: Palsonify (paltusotine)
Acromegaly Indicated for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option.

2 . Criteria

Product Name:Palsonify [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - Patient is ≥ 18 years old

AND

3 - Diagnosis confirmed by ONE of the following:

- Serum growth hormone (GH) level > 1 ng/mL after a 2-hour oral glucose tolerance test (OGTT) at time of diagnosis
- Elevated serum insulin-like growth factor 1 (IGF-1) levels (above the age and gender adjusted normal range as provided by the provider's lab) at time of diagnosis

AND

4 - ONE of the following:

- Inadequate response to surgery
- Patient is not a candidate for surgery

AND

5 - Prescribed by or in consultation with an endocrinologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Palsonify [a]	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to Palsonify therapy (e.g., age-normalized serum IGF-1 level)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Palsonify (paltusotine) is a somatostatin receptor agonist indicated for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Palsonify [package insert]. San Diego, CA: Crinetics Pharmaceuticals, Inc.; September 2025.
2. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014;99(11):3933-3951.

3. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. Pituitary. 2021;24(1):1-13.

5 . Revision History

Date	Notes
3/16/2026	New program

Palynziq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436515
Guideline Name	Palynziq
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	10/1/2024
P&T Revision Date:	07/16/2025 ; 11/21/2025

1 . Indications

Drug Name: Palynziq (pegvaliase-pqpz)
Reduction of blood phenylalanine concentrations Indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

2 . Criteria

Product Name:Palynziq [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Patient is actively on a phenylalanine-restricted diet

AND

3 - ONE of the following:

- Patient has a contraindication to sapropterin (list reason)
- History of failure or intolerance to sapropterin therapy (document date of trial and list reason for therapeutic failure or intolerance) as determined by a trial of sapropterin
- Patient is not an appropriate candidate for sapropterin therapy due to two null mutations in trans

AND

4 - Physician attestation that the patient will not be receiving Palynziq in combination with sapropterin dihydrochloride or Sephience (sepiapterin)

AND

5 - Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration greater than 600 micromol/L

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Palynziq [a]	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Patient is actively on a phenylalanine-restricted diet

AND

2 - ONE of the following:

- Patient is in initial titration/maintenance phase of dosing regimen and dose is being titrated based on blood phenylalanine concentration response up to maximum labeled dosage of 60mg once daily
- Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration less than 600 micromol/L
- Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is not receiving Palynziq in combination with sapropterin dihydrochloride or Sephience (sepiapterin) [Prescription claim history that does not show any concomitant sapropterin dihydrochloride or Sephience (sepiapterin) claim within 60 days of reauthorization request may be used as documentation]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background:

Palynziq is a phenylalanine-metabolizing enzyme indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Palynziq [package insert], Novato, CA: BioMarin Pharmaceutical Inc.; November 2020.
2. Thomas J, Levy H, Amato S, et al. Pegvaliase for the treatment of phenylketonuria: Results of a long-term phase 3 clinical trial program (PRISM). Mol Genet Metab. 2018;124(1):27-38.
3. Vockley et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. American College of Medical Genetics and Genomics Practice Guidelines. Genetics in Medicine 2014;16 (2):188-200.
4. Smith WE, Berry SA, Bloom K, et al. Phenylalanine hydroxylase deficiency diagnosis and management: A 2023 evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2025;27(1):101289. doi:10.1016/j.gim.2024.101289

5 . Revision History

Date	Notes
11/3/2025	Added Sephience to combination use criteria. Revised requirement f or trial of sapropterin therapy to remove specified length of trial and t o exclude patients with two null mutations in trans. Updated referenc es.

Piqray

Prior Authorization Guideline

Guideline ID	GL-555214
Guideline Name	Piqray
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 08/20/2021 ; 09/15/2021 ; 08/19/2022 ; 08/18/2023 ; 03/20/2024 ; 03/19/2025 ; 3/18/2026

1 . Indications

Drug Name: Piqray (alpelisib)
Breast Cancer Indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.

2 . Criteria

Product Name:Piqray (alpelisib) [a]	
Diagnosis	Breast Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - ONE of the following:

- Advanced
- Metastatic

AND

3 - Disease is hormone receptor (HR)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of one or more PIK3CA mutations

AND

6 - Used in combination with fulvestrant

AND

7 - Disease has progressed on or after an endocrine-based regimen

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Piqray (alpelisib) [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Piqray therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Piqray (alpelisib) [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Piqray will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Piqray (alpelisib) [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Piqray therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Piqray (alpelisib) is a kinase inhibitor indicated in combination with fulvestrant for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Piqray [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. January 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed February 7, 2025.

5 . Revision History

Date	Notes
3/18/2026	Annual review with no changes to coverage criteria.

Pomalyst

Prior Authorization Guideline

Guideline ID	GL-533197
Guideline Name	Pomalyst
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/15/2026
P&T Approval Date:	9/15/2021
P&T Revision Date:	05/20/2022 ; 05/25/2023 ; 05/17/2024 ; 12/18/2024 ; 05/16/2025 ; 09/25/2025

1 . Indications

Drug Name: Pomalyst (pomalidomide)
Multiple myeloma Indicated for the treatment of adult patients, in combination with dexamethasone, for patients with multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy. **Kaposi sarcoma** Indicated for patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV-negative.

2 . Criteria

Product Name:Brand Pomalyst, generic pomalidomide [a]	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to ONE of the following^:

- Immunomodulatory agent [e.g., Revlimid (lenalidomide)]
- Proteasome inhibitor [e.g.,Velcade (bortezomib)]
- Anti CD-38 therapy [e.g., Darzalex (daratumumab), Sarclisa (isatuximab)]

OR

2.2 Induction therapy for the management of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Brand Pomalyst, generic pomalidomide [a]	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Pomalyst therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Pomalyst, generic pomalidomide [a]	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of systemic light chain amyloidosis **AND** **2** - Used in combination with dexamethasone

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Pomalyst, generic pomalidomide [a]	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Pomalyst therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Pomalyst, generic pomalidomide [a]	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV-negative Kaposi Sarcoma

OR

2 - BOTH of the following:

- Diagnosis of AIDS-related Kaposi Sarcoma
- Patient is currently being treated with antiretroviral therapy (ART)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Pomalyst, generic pomalidomide [a]	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Pomalyst therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Pomalyst, generic pomalidomide [a]	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary CNS lymphoma

AND

2 - ONE of the following:

- Used as second-line or a subsequent therapy
- Use as induction therapy if patient is unsuitable for or intolerant to high-dose methotrexate

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Pomalyst, generic pomalidomide [a]

Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Pomalyst therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Pomalyst, generic pomalidomide [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Pomalyst will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Pomalyst, generic pomalidomide [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Pomalyst therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Pomalyst (pomalidomide) is a thalidomide analogue indicated for the treatment of adult patients, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor [e.g., Velcade® (bortezomib)] and have demonstrated disease progression on or within 60 days of completion of the last therapy. Pomalyst is also indicated for adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV-negative.[1]

The National Comprehensive Cancer Network (NCCN) also recommends use of Pomalyst for the treatment of relapsed/refractory systemic light chain amyloidosis in combination with dexamethasone and, for the treatment of primary central nervous system (CNS) lymphoma. Additionally, Pomalyst is recommended in NCCN for treatment of multiple myeloma in combination of dexamethasone after receiving only one prior line of therapy or for induction therapy for the management of POEMS. [2]

Due to embryo-fetal risk (pregnancy category X) associated with Pomalyst; it is available only through the Pomalyst Risk Evaluation and Mitigation Strategy (REMS) Program. Prescribers and pharmacies must be certified with the Pomalyst REMS Program by enrolling and complying with the REMS requirements. Patients must sign a Patient-Physician agreement form and comply with the REMS requirements. Specifically, female patients who are not pregnant but can become pregnant must comply with the pregnancy testing and contraception requirements and males must comply with contraception requirements. Pharmacies must only dispense to patients who are authorized to receive the drug and must

comply with REMS requirements. Additional information may be found at: https://www.pomalystrems.com/index.html

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Pomalyst [package insert]. Summit, NJ: Celgene Corporation; February 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 9, 2025
3. Pomalyst REMS®. Available at https://www.pomalystrems.com/index.html Accessed April 9, 2025.

5 . Revision History

Date	Notes
2/26/2026	added generic

Praluent

Prior Authorization Guideline

Guideline ID	GL-552191
Guideline Name	Praluent
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	10/20/2021
P&T Revision Date:	06/15/2022 ; 01/18/2023 ; 06/21/2023 ; 10/18/2023 ; 02/16/2024 ; 05/17/2024 ; 02/20/2025 ; 3/18/2026

1 . Indications

Drug Name: Praluent (alirocumab)
Primary hyperlipidemia Indicated to reduce the risk of major adverse cardiovascular (CV) events (coronary heart disease death, myocardial infarction, stroke, or unstable angina requiring hospitalization) in adults at increased risk for these events **Homozygous Familial Hypercholesterolemia** Indicated as an adjunct to diet and exercise to reduce low- density lipoprotein cholesterol (LDL-C) in: -adults with hypercholesterolemia. -adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH). -adults with homozygous familial hypercholesterolemia (HoFH).

2 . Criteria

Product Name:Praluent [a]	
Diagnosis	Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia) and ASCVD
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - ONE of the following diagnoses:

- Heterozygous familial hypercholesterolemia (HeFH)
- Atherosclerotic cardiovascular disease (ASCVD) (e.g., acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin)
- Primary hyperlipidemia

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

2.1 Patient has been receiving at least 12 consecutive weeks OF HIGH-INTENSITY STATIN THERAPY [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a high-intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

- Myalgia [muscle symptoms without creatine kinase (CK) elevations]

- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin ≥ 10 mg, pravastatin ≥ 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin) ≥ 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate LOW OR MODERATE-, AND HIGH-INTENSITY STATINS as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

2.3.2 Patient has a contraindication to all statins as documented in medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - Patient has LDL-C greater than or equal to 55 mg/dL

AND

4 - ONE of the following:

- Patient is less than 10 years of age
- History of failure, contraindication, or intolerance to Repatha (evolocumab) (document date of trial and list reason for therapeutic failure, contraindication, or intolerance)

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Lerochol (lerodalcibep-liga), Repatha (evolocumab)]

AND

6 - Not used in combination with Leqvio (inclisiran)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Praluent [a]	
Diagnosis	Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia) and ASCVD
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C reduction while on Praluent therapy

AND

2 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Lerochol (lerodalcibep-liga), Repatha (evolocumab)]

AND

3 - Not used in combination with Leqvio (inclisiran)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Praluent [a]	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) confirming genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) genes or ≥ 2 such variants at different loci

OR

1.2 BOTH of the following:

1.2.1 Untreated LDL-C greater than 400 mg/dL

AND

1.2.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of familial hypercholesterolemia in at least one parent

AND

2 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

AND

3 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Lerochol (lerodalcibep-liga), Repatha (evolocumab)]

AND

4 - Not used in combination with Juxtapid (lomitapide)

AND

5 - History of failure, contraindication, or intolerance to Repatha (evolocumab) (document date of trial and list reason for therapeutic failure, contraindication, or intolerance)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Praluent [a]	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C reduction while on Praluent therapy **AND** **2** - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Lerochol (lerodalcibep-liga), Repatha (evolocumab)] **AND** **3** - Not used in combination with Juxtapid (lomitapide)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Praluent® (alirocumab) is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor indicated to reduce the risk of major adverse cardiovascular (CV) events (coronary heart disease death, myocardial infarction, stroke, or unstable angina requiring hospitalization) in adults at increased risk for these events. Praluent is also indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in: • adults with hypercholesterolemia • adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH) • adults with homozygous familial hypercholesterolemia (HoFH) **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Praluent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2025.
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5 . Revision History

Date	Notes
3/16/2026	Removed ezetimibe trial requirement for primary hyperlipidemia and ASCVD. Removed specialist prescriber requirement. Updated backgr ound and references.

Prior Authorization Administrative

Prior Authorization Guideline

Guideline ID	GL-133919
Guideline Name	Prior Authorization Administrative
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	1/21/2021
P&T Revision Date:	01/21/2021

Note:

Technician Note Link to Exclusions and Limitations Grid:
https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x01200027C80175A8369D44AC45A99A99328B80&View=%7B4B6D25AD%2D6A95%2D496D%2D9937%2D65CECD43AFE7%7D&viewid=c2ad0afa%2D814c%2D499e%2Dbf25%2D3411fac9171f&id=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FUHCGP%20Exchange

1 . Criteria

Product Name:Medications with a Prior Authorization Requirement without a Drug Specific Guideline, Medications with New FDA-Approved Indications	
Diagnosis	Prior Authorization Required Medications Used for Non-Cancer Indications [a]

Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - For formulary drugs with a prior authorization requirement, for which a guideline is unavailable, the requested drug will be approved based on BOTH of the following criteria:

1.1 One of the following:

1.1.1 Both of the following:

1.1.1.1 Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert)

AND

1.1.1.2 Additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information (or package insert) have been met (e.g.: first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.1.2 Off-label criteria are met*

AND

1.2 The use is not excluded as documented in the limitations and exclusions section of the certificate of coverage (see technician note for the Exclusions and Limitations Grid URL)

OR

2 - For new FDA-approved indications, which are not addressed in the existing drug-specific prior authorization guideline, the requested drug will be approved based on all of the following criteria:

2.1 Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert)

AND

2.2 Additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information (or package insert) have been met (e.g.: first line therapies have been tried and failed, any testing requirements have been met, etc.)

AND

2.3 The use is not excluded as documented in the limitations and exclusions section of the certificate of coverage (see technician note for the Exclusions and Limitations Grid URL)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. Authorization will be issued for 12 months. *Reference the Off-label Administrative Guideline.

Product Name:Medications with a Prior Authorization Requirement without a Drug Specific Guideline, Medications with New FDA-Approved Indications	
Diagnosis	Prior Authorization Required Medications Used for Cancer Indications [a]
Approval Length	12 month(s)
Guideline Type	Administrative Prior Authorization

Approval Criteria

1 - For formulary drugs with a prior authorization requirement, for which a guideline is unavailable, the requested drug will be approved based on ONE of the following criteria:

1.1 Both of the following:

1.1.1 Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert)

AND

1.1.2 Additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information (or package insert) have been met (e.g.: first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.2 Off-label criteria are met*

OR

2 - For new FDA-approved indications, which are not addressed in the existing drug-specific prior authorization guideline, the requested drug will be approved based on both of the following criteria:

2.1 Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert)

AND

2.2 Additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information (or package insert) have been met (e.g.: first line therapies have been tried and failed, any testing requirements have been met, etc.)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. Authorization will be issued for 12 months. *Reference the Off-label Administrative Guideline.

2 . Background

Benefit/Coverage/Program Information
Background: This program is to be administered to medications that have a prior authorization requirement but do not have a drug specific guideline. The program is also to be administered when new FDA-approved indications are not addressed in an existing drug-specific prior authorization guideline. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

3 . Revision History

Date	Notes
9/28/2023	Updated guideline name, cleaned up criteria, indications, and notes, updated background, and removed references.

Progesterone

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-555215
Guideline Name	Progesterone
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	10/20/2021
P&T Revision Date:	09/21/2022 ; 12/14/2022 ; 08/18/2023 ; 04/17/2024 ; 10/01/2024 ; 09/17/2025 ; 3/18/2026

1 . Indications

Drug Name: Endometrin (progesterone vaginal insert)
Infertility Indicated to support embryo implantation and early pregnancy by supplementation of corpus luteal function as part of an ART treatment program for infertile women.
Drug Name: Crinone (progesterone vaginal gel)
Infertility Indicated for progesterone supplementation or replacement as part of an Assisted Reproductive Technology (ART) treatment for infertile women with progesterone deficiency. **Secondary amenorrhea** Crinone is also indicated for the treatment of secondary amenorrhea.

2 . Criteria

Product Name:Brand Endometrin, progesterone (generic Endometrin), Crinone [a]	
Diagnosis	Infertility**
Approval Length	2 month(s)
Guideline Type	Non Formulary
Approval Criteria **1** - Diagnosis of infertility **AND** **2** - Documentation of an approved assisted reproductive technology (ART) protocol	
Notes	**NOTE: Requests for an infertility related diagnosis other than ovulation induction for members in Iowa, New Jersey, New York, North Carolina, Kansas, and Texas should be denied as a benefit exclusion. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Endometrin, progesterone (generic Endometrin), Crinone [a]	
Diagnosis	Non-Infertility
Approval Length	6 month(s)
Guideline Type	Non Formulary
Approval Criteria **1** - Treatment is for non-infertility use (e.g., secondary amenorrhea, reduce the risk of recurrent spontaneous preterm birth)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: This program is designed to provide coverage for these medications to be used in conjunction with Assisted Reproductive Technologies (ART) (i.e., in vitro fertilization). Endometrin® (progesterone inserts) is indicated to support embryo implantation and early pregnancy by supplementation of corpus luteal function as part of an ART treatment program for infertile women. Crinone (progesterone gel) is indicated for progesterone supplementation or replacement as part of an Assisted Reproductive Technology (ART) treatment for infertile women with progesterone deficiency. Crinone is also indicated for the treatment of secondary amenorrhea. **Additional Clinical Rules** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Endometrin [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc; January 2025.
2. Crinone [package insert]. Parsippany, NJ: Actavis Pharma; May 2014.

5 . Revision History

Date	Notes
3/18/2026	Annual review with no changes to clinical criteria. Updated reference s.

Promacta, Alvaiz

Prior Authorization Guideline

Guideline ID	GL-355232
Guideline Name	Promacta, Alvaiz
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	10/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 10/20/2021 ; 11/19/2021 ; 01/19/2022 ; 01/18/2023 ; 01/17/2024 ; 06/17/2024 ; 08/16/2024 ; 8/22/2025

1 . Indications

Drug Name: Promacta (eltrombopag), Alvaiz (eltrombopag)
Chronic immune thrombocytopenia (ITP) Indicated for the treatment of thrombocytopenia in adult and pediatric patients (1 year and older for Promacta and 6 years and older for Alvaiz) with persistent or chronic immune thrombocytopenia (ITP) who have experienced an insufficient response to corticosteroids, immunoglobulins, or splenectomy. **Chronic hepatitis C-associated thrombocytopenia** Indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. **Aplastic Anemia** Indicated for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

2 . Criteria

Product Name:Brand Promacta, generic eltrombopag, Alvaiz [a]	
Diagnosis	Chronic immune thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic immune thrombocytopenia (ITP) **AND** **2** - History of failure, contraindication, or intolerance to at least ONE of the following: • Corticosteroids • Immunoglobulins • Splenectomy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Promacta, generic eltrombopag, Alvaiz [a]	
Diagnosis	Chronic immune thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Promacta or Alvaiz therapy	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Promacta, generic eltrombopag, Alvaiz [a]	
Diagnosis	Chronic hepatitis C-associated thrombocytopenia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C-associated thrombocytopenia

AND

2 - ONE of the following:

- Planning to initiate and maintain interferon-based treatment
- Currently receiving interferon-based treatment

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Promacta, generic eltrombopag, Alvaiz [a]	
Diagnosis	Chronic hepatitis C-associated thrombocytopenia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Promacta or Alvaiz therapy

AND

2 - Patient is currently on antiviral interferon therapy for treatment of chronic hepatitis C

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Promacta, generic eltrombopag, Alvaiz [a]	
Diagnosis	Aplastic Anemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe aplastic anemia

AND

2 - ONE of the following:

- Used in combination with standard immunosuppressive therapy (e.g., Atgam [antithymocyte globulin equine], Thymoglobulin [antithymocyte globulin rabbit], cyclosporine)
- History of failure, contraindication, or intolerance to at least one course of immunosuppressive therapy (e.g., Atgam [antithymocyte globulin equine], Thymoglobulin [antithymocyte globulin rabbit], cyclosporine)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Promacta, generic eltrombopag, Alvaiz [a]	
Diagnosis	Aplastic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Promacta or Alvaiz therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Promacta and Alvaiz (eltrombopag) are thrombopoietin receptor agonists indicated for the treatment of thrombocytopenia in adult and pediatric patients (1 year and older for Promacta and 6 years and older for Alvaiz) with persistent or chronic immune thrombocytopenia (ITP) who have experienced an insufficient response to corticosteroids, immunoglobulins, or splenectomy, for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy, and for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy. [1] Promacta is also approved in combination with standard immunosuppressive therapy for the first line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia. Promacta and Alvaiz should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. [1]

Promacta and Alvaiz should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection. [1]

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Promacta [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2025.
2. Alvaiz [Package Insert]. Parsippany, NJ: Teva Pharmaceuticals; July 2024.

5 . Revision History

Date	Notes
8/5/2025	Annual review with no change to coverage criteria. Updated referenc es.

Prudoxin and Zonalon

Prior Authorization Guideline

Guideline ID	GL-122959
Guideline Name	Prudoxin and Zonalon
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	8/14/2020
P&T Revision Date:	01/15/2020 ; 03/17/2021 ; 09/15/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Prudoxin and Zonalon cream
Atopic dermatitis or lichen simplex chronicus Indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

2 . Criteria

Product Name:Brand Prudoxin, Brand Zonalon cream, generic doxepin cream [a]	
Approval Length	1 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate pruritus due to one of the following:

1.1 Atopic dermatitis

OR

1.2 Lichen simplex chronicus

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Brand Prudoxin, Brand Zonalon cream, generic doxepin cream [a]	
Approval Length	1 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Diagnosis of moderate pruritis due to either atopic dermatitis or lichen simplex chronicus

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3 . Background

Benefit/Coverage/Program Information
Background: Prudoxin and Zonalon cream are indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus. **Additional Clinical Rules** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits may be in place

4 . References

1. Prudoxin [package insert]. Morgantown, WV: Mylan Pharmaceuticals; June 2017.
2. Zonalon [package insert]. San Antonio, TX: DPT Laboratories, Ltd.; June 2017.

5 . Revision History

Date	Notes
3/22/2023	Annual review. Added state mandate language.

Pulmozyme

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523270
Guideline Name	Pulmozyme
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/18/2022 ; 02/17/2023 ; 02/20/2025 ; 2/20/2026

1 . Indications

Drug Name: Pulmozyme (dornase alfa)
Cystic fibrosis Indicated in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.

2 . Criteria

Product Name:Pulmozyme [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis **AND** **2** - Used in conjunction with standard CF therapies [e.g., chest physiotherapy, bronchodilators, antibiotics, anti-inflammatory therapy (e.g., ibuprofen, oral/inhaled corticosteroids)]	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Pulmozyme [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Pulmozyme therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background

Pulmozyme (dornase alfa) is a recombinant deoxyribonuclease (DNase) enzyme indicated in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.

In CF patients with a forced vital capacity (FVC) ≥ 40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Pulmozyme [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.
2. Mogayzel P, Naureckas E, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. American Journal of Respiratory and Critical Care Medicine 2013;187:680-689.

5 . Revision History

Date	Notes
2/23/2026	Annual review with no changes to coverage criteria. Updated references.

Pyrukynd

Prior Authorization Guideline

Guideline ID	GL-270215
Guideline Name	Pyrukynd
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	5/20/2022
P&T Revision Date:	05/17/2024 ; 5/16/2025

1 . Indications

Drug Name: Pyrukynd (mitapivat)
Hemolytic anemia Indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

2 . Criteria

Product Name:Pyrukynd [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pyruvate kinase (PK) deficiency based on ALL of the following:

- Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 is a missense variant
- Patient is not homozygous for the c.1436G>A (p.R479H) variant
- Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

AND

2 - Used for the treatment of hemolytic anemia

AND

3 - ONE of the following:

3.1 BOTH of the following:

- Baseline hemoglobin less than or equal to 10 g/dL
- Patient has had no more than 4 transfusions in the previous 52 weeks and no transfusions in the preceding 3-month period

OR

3.2 Patient has had a minimum of 6 transfusion episodes in the preceding 52 weeks

AND

4 - Prescribed by a nephrologist or hematologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Pyrukynd [a]	
Diagnosis	Documentation of positive clinical response to Pyrukynd therapy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to Pyrukynd therapy **AND** **2** - Prescribed by, or in consultation with, a nephrologist or hematologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Pyrukynd [a]	
Diagnosis	Documentation does NOT provide evidence of positive clinical response to Pyrukynd therapy
Approval Length	4 Week(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Additional Clinical Programs: • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program. • Supply limitations may be in place **Background** Pyrukynd® (mitapivat) is a pyruvate kinase activator indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

4 . References

1. Pyrukynd [package insert]. Cambridge, MA: Agios Pharmaceuticals, Inc.; January 2025.

5 . Revision History

Date	Notes
5/19/2025	Annual review. No changes to clinical criteria.

Qlosi, Vizz, Vuity

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-381207
Guideline Name	Qlosi, Vizz, Vuity
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	4/20/2022
P&T Revision Date:	03/15/2023 ; 01/17/2024 ; 01/15/2025 ; 9/25/2025

1 . Indications

Drug Name: Vuity (pilocarpine) 0.4% ophthalmic solution, Vizz (acelidine) 1.44% ophthalmic solution, Qlosi (pilocarpine) 1.25% ophthalmic solution
Presbyopia FDA approved indication for the treatment of presbyopia in adults.

2 . Criteria

Product Name:Brand Vuity, pilocarpine (generic Vuity), Vizz, Qlosi [a]	
Diagnosis	Treatment of Presbyopia
Guideline Type	Non Formulary

Approval Criteria **1** - Qlosi, Vizz, Brand Vuity, or pilocarpine (generic Vuity) are not considered medically necessary for the treatment of presbyopia based on the definition of medically necessary health care services in the certificate of coverage. All requests for authorization will be denied.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3 . Background

Benefit/Coverage/Program Information

Background:

Qlosi (pilocarpine) 0.4% ophthalmic solution, Vizz (acelidine) 1.44% ophthalmic solution, and Vuity (pilocarpine) 1.25% ophthalmic solution are indicated for the treatment of presbyopia in adults. The efficacy of Qlosi was established in clinical trials with patients aged 45 to 64 years of age with presbyopia, for Vizz in patients 45 to 75 years of age with presbyopia, and for Vuity in patients aged 40 to 55 years of age with presbyopia. The standard of therapy for the treatment of presbyopia is use of corrective lenses, such as glasses and contact lenses, or refractive surgery.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Qlosi [package insert]. Ponte Vedra, FL: Orasis Pharmaceuticals, Ltd.; May 2025.
2. Vizz [package insert]. Solana Beach, CA: LENZ Therapeutics, Inc; July 2025.
3. Vuity [package insert]. North Chicago, IL: AbbVie Inc.; March 2023.

4. Mian, SI. Visual impairment in adults: Refractive disorders and presbyopia. In: UpToDate, Gardiner, MF, UpToDate, Waltham, MA, 2024.

5 . Revision History

Date	Notes
9/4/2025	Added Vizz. Updated references.

Quantity Limits Administrative



Prior Authorization Guideline

Guideline ID	GL-161909
Guideline Name	Quantity Limits Administrative
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	12/11/2024
P&T Approval Date:	1/20/2021
P&T Revision Date:	05/21/2021 ; 10/20/2021 ; 10/20/2021

Note:

Technician Note: Link to Exclusions and Limitations Grid: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x01200027C80175A8369D44AC45A99A99328B80&View=%7B4B6D25AD%2D6A95%2D496D%2D9937%2D65CECD43AFE7%7D&viewid=c2ad0afa%2D814c%2D499e%2Dbf25%2D3411fac9171f&id=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FUHCGP%20Exchange

1 . Criteria

Product Name:Opioid containing medications for malignant pain	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - In the absence of an opioid-specific quantity limit override guideline, the following approval criteria will be used:

1.1 Diagnosis of malignant (cancer) pain

AND

1.2 For opioid containing combination products, the total daily dose of the non-opioid component is supported by one of the following references:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX Information System
- National Comprehensive Cancer Network (NCCN)
- Clinical pharmacology
- Wolters Kluwer Lexi-Drugs
- United States Pharmacopoeia-National Formulary (USP-NF)
- Drug Facts and Comparisons

Product Name:Opioid containing medications for non-malignant pain	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements*

AND

2 - One of the following:

2.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

2.2 Higher dose or quantity is supported by one of the following references:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX Information System
- Clinical pharmacology
- Wolters Kluwer Lexi-Drugs
- United States Pharmacopoeia-National Formulary (USP-NF)
- Drug Facts and Comparisons

AND

3 - Quantity requests exceeding the plan's quantity limits will be approved if one of the following criteria are met:

3.1 The prescriber maintains and provides chart documentation of the patient's evaluation, including all of the following:

- An appropriate patient medical history and physical examination
- A description of the nature and intensity of the pain
- Documentation of appropriate dose escalation
- Documentation of ongoing, periodic review of the course of opioid therapy
- An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function)
- Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian

OR

3.2 All of the following:

3.2.1 Medication is being used to treat postoperative pain

AND

3.2.2 Medication is not being prescribed for pain related to a dental procedure

AND

3.2.3 The dose being prescribed is the dose that the patient was stable on prior to discharge

AND

4 - For opioid combination products, the total daily dose of the non-opioid component must be supported by one of the following references:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX Information System
- Clinical pharmacology
- Wolters Kluwer Lexi-Drugs
- United States Pharmacopoeia-National Formulary (USP-NF)
- Drug Facts and Comparisons

Notes	*Reference the Off-label Administrative Guideline.

Product Name:Opioid containing medications for non-pain uses	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements*

AND

2 - One of the following:

2.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

2.2 Higher dose or quantity is supported by one of the following resources:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX Information System
- Clinical pharmacology
- Wolters Kluwer Lexi-Drugs
- United States Pharmacopoeia-National Formulary (USP-NF)
- Drug Facts and Comparisons

AND

3 - The use is not excluded as documented in the limitations and exclusions section of the certificate of coverage (see technician note for the Exclusions and Limitations Grid URL)

Notes	*Reference the Off-label Administrative Guideline.

Product Name:Non-opioid medications (except eye drops, topical applications, condoms, spermicides, emergency contraceptive products, non-hormonal vaginal contraceptives, and contraceptive implants) (in the absence of a drug-specific guideline)*	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria*

AND

2 - One of the following:

2.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

2.2 Higher dose or quantity is supported by one of the following resources:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX Information System
- Clinical pharmacology
- Wolters Kluwer Lexi-Drugs
- United States Pharmacopoeia-National Formulary (USP-NF)
- Drug Facts and Comparisons
- National Comprehensive Cancer Network (NCCN)

AND

3 - One of the following:

3.1 The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation (for example, for titration or loading-dose purposes, dose-alternating schedule)

OR

3.2 For glycemic agents prescribed for hypoglycemia treatment (e.g., glucagon), the patient is experiencing or is prone to hypoglycemia

OR

3.3 For diabetic testing products (e.g., glucose control solution), the patient is experiencing or is prone to hypoglycemia or hyperglycemia and requires additional testing to achieve glycemic control

OR

3.4 For antiemetics (e.g., ondansetron), the patient requires a larger quantity due to chemotherapy cycle or surgery

OR

3.5 One of the following:

3.5.1 Requested strength/dose is commercially unavailable

OR

3.5.2 There is a medically necessary justification why patient cannot use a higher commercially available strength to achieve the same dosage and remain within the same dosing frequency

AND

4 - The use is not excluded as documented in the limitations and exclusions section of the certificate of coverage (refer to the Exclusions and Limitations Grid found in the link in the Background section)

Notes	*Reference the Off-label Administrative Guideline. For requested drugs containing acetaminophen where the cumulative

	acetaminophen dose exceeds 4 grams per day, apply the Therdose g uideline.

Product Name:Eye Drops	
Approval Length	12 months. Authorization will be for one additional bottle of eye drops per 30 days.
Guideline Type	Administrative

Approval Criteria

1 - One additional bottle of eye drops may be approved based on BOTH of the following:

1.1 One of the following:

- Quantity limit override requests must involve an FDA-approved indication
- Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria*

AND

1.2 The patient requires a larger quantity due to a medical condition making it difficult to accurately administer a single drop**

Notes	**Examples of medical conditions making it difficult to accurately admi nister a single drop include: arthritis, tremor, Parkinson disease, neuro logical condition, musculoskeletal condition, etc. The request may als o be approved if the provider states an additional bottle is needed by t he insured for use in a day care center, school, or adult day program. *Reference the Off-label Administrative Guideline.

Product Name:Condoms, Spermicides (e.g., Encare), Emergency Contraceptive Products (e.g., Ella), Non-Hormonal Vaginal Contraceptives (e.g., Phexxi), and Contraceptive Implants (e.g., Nexplanon)	
Approval Length	12 months. Authorization will be for the requested quantity.
Guideline Type	Administrative

Approval Criteria

1 - Physician attests that the patient requires a larger quantity

Product Name:Topical Applications	
Approval Length	12 months. Authorization will be for the requested quantity.
Guideline Type	Administrative
Approval Criteria **1** - One of the following: **1.1** Quantity limit override requests must involve an FDA-approved indication **OR** **1.2** Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria* **AND** **2** - Physician attests that the patient requires a larger quantity to cover a larger surface area	
Notes	*Reference the Off-label Administrative Guideline.

2 . Revision History

Date	Notes
12/11/2024	Updated topical criteria

Radicava ORS

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-424222
Guideline Name	Radicava ORS
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	7/20/2022
P&T Revision Date:	07/17/2024 ; 03/19/2025 ; 10/15/2025

1 . Indications

Drug Name: Radicava ORS (edaravone)
Amyotrophic lateral sclerosis (ALS) Indicated for the treatment of amyotrophic lateral sclerosis (ALS).

2 . Criteria

Product Name:Radicava ORS [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - BOTH of the following:

1.1 Patient has been established on therapy with edaravone for amyotrophic lateral sclerosis under an active UnitedHealthcare medical benefit prior authorization

AND

1.2 ALL of the following:

- Diagnosis of ALS
- Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS
- Patient is currently receiving edaravone therapy
- Patient is not dependent on invasive ventilation

OR

2 - ALL of the following:

2.1 Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support the diagnosis of ALS

AND

2.2 Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

AND

2.3 Submission of the most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score confirming that the patient has scores greater than or equal to 2 in all items of the ALSFRS-R criteria at the start of treatment

AND

2.4 Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a % forced vital capacity (%FVC) greater than or equal to 80% at the start of treatment

AND

2.5 History of failure, contraindication, or intolerance to riluzole (document date and duration of trial).

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Radicava ORS [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of ALS

AND

2 - Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

AND

3 - Patient is currently receiving Radicava ORS therapy

AND **4** - Patient is NOT dependent on invasive ventilation	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Radicava ORS is indicated for the treatment of amyotrophic lateral sclerosis (ALS). [1] **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Radicava ORS [package insert]. Jersey City, NJ: Mitsubishi Tanabe Pharma Corporation. November 2022.
2. Subcommittee on Motor Neuron Diseases of World Federation of Neurology Research Group on Neuromuscular Diseases, El Escorial “Clinical Limits of ALS” Workshop Contributors. El Escorial World Federation of Neurology criteria for the diagnosis of amyotrophic lateral sclerosis. J Neurol Sci 1994; 124: 96–107.
3. Takahashi F, Takei K, Tsuda K, Palumbo J. Post-hoc analysis of MCI186-17, the extension study to MCI186-16, the confirmatory double-blind, parallel-group, placebo-control006Ced study of edaravone in amyotrophic lateral sclerosis. Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration. 2017;18(sup1):32-39.

5 . Revision History

Date	Notes
10/17/2025	Added step through riluzole.

Redemplo

Prior Authorization Guideline

Guideline ID	GL-523202
Guideline Name	Redemplo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	2/20/2026
P&T Revision Date:	

1 . Indications

Drug Name: Redemplo (plozasiran)
Familial chylomicronemia syndrome (FCS) Indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

2 . Criteria

Product Name:Redemplo [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of familial chylomicronemia syndrome (FCS) (i.e., monogenic chylomicronemia, type 1 hyperlipoproteinemia)

AND

1.2 Diagnosis has been confirmed by BOTH of the following:

1.2.1 ONE of the following:

- Genetic confirmation of FCS (e.g., homozygous, compound heterozygous, or double heterozygote for loss-of-function or otherwise inactivating mutations in genes affecting lipoprotein lipase activity including LPL, GPIHBP1, APOA5, APOC2, or LMF1)
- North American FCS (NAFCS) Score ≥ 45

AND

1.2.2 Untreated fasting triglyceride levels greater than or equal to 880 mg/dL

AND

2 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Gastroenterologist
- Lipid specialist (lipidologist)

AND

3 - Not used in combination with Tryngolza (olezarsen)

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Redemplo [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Redemplo therapy (e.g., reduction in triglycerides, reduction in episodes of acute pancreatitis)

AND

2 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Gastroenterologist
- Lipid specialist (lipidologist)

AND

3 - Not used in combination with Tryngolza (olezarsen)

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information

Background:

Redemplo® is an apolipoprotein C-III (apoC-III)-directed small interfering ribonucleic acid (siRNA) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Redemplo [package insert]. Pasadena, CA: Arrowhead Pharmaceuticals, Inc.; November 2025.
2. Watts GF, Rosenson RS, Hegele RA, et al. Plozasiran for Managing Persistent Chylomicronemia and Pancreatitis Risk. N Engl J Med. 2025;392(2):127-137. doi:10.1056/NEJMoa2409368
3. Hegele RA, Ahmad Z, Ashraf A, et al. Development and validation of clinical criteria to identify familial chylomicronemia syndrome (FCS) in North America. J Clin Lipidol. Published online November 12, 2024. doi:10.1016/j.jacl.2024.09.008
4. Javed F, Hegele RA, Garg A, et al. Familial chylomicronemia syndrome: An expert clinical review from the National Lipid Association. J Clin Lipidol. 2025;19(3):382-403. doi:10.1016/j.jacl.2025.03.013
5. Saadatagah S, Larouche M, Naderian M, et al. Recognition and management of persistent chylomicronemia: A Joint Expert Clinical Consensus by the National Lipid Association and the American Society for Preventive Cardiology. J Clin Lipidol. 2025;19(4):723-736. doi:10.1016/j.jacl.2025.03.012

5 . Revision History

Date	Notes
2/13/2026	New program.

Regranex

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-555216
Guideline Name	Regranex
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 12/15/2021 ; 11/18/2022 ; 08/18/2023 ; 3/18/2026

1 . Indications

Drug Name: Regranex (becaplermin gel)
Lower extremity diabetic neuropathic ulcers Indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue, or beyond, and have an adequate blood supply.

2 . Criteria

Product Name:Regranex [a]	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient has a lower extremity diabetic neuropathic ulcer	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Regranex is indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue, or beyond, and have an adequate blood supply. Regranex should be used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control. The efficacy of Regranex gel has not been established for the treatment of pressure ulcers or venous stasis ulcers. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Regranex [package insert]. Franklin, TN: Lynch Regenerative Medicine; June 2025.

5 . Revision History

Date	Notes
3/18/2026	Annual review. Updated reference.

Relistor

Prior Authorization Guideline

Guideline ID	GL-334212
Guideline Name	Relistor
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	9/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 07/21/2021 ; 07/20/2022 ; 07/19/2023 ; 07/17/2024 ; 7/16/2025

1 . Indications

Drug Name: Relistor (methylnaltrexone bromide)
Opioid-induced constipation Indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Relistor injection is also indicated for the treatment of opioid-induced constipation in patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

2 . Criteria

Product Name:Relistor injection [a]

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Relistor injection will be approved based on documentation (e.g. chart notes) demonstrating ONE of the following:

1.1 Diagnosis of opioid induced constipation in patients with advanced illness receiving palliative care

OR

1.2 BOTH of the following:

1.2.1 ONE of the following:

- Diagnosis of opioid induced constipation with chronic, non-cancer pain
- Diagnosis of opioid induced constipation in patients with chronic pain related to prior cancer diagnosis or cancer treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

AND

1.2.2 Trial and failure, contraindication or intolerance to BOTH of the following:

- lubiprostone (generic Amitiza)
- Symproic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Relistor injection [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Relistor injection therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Relistor (methylnaltrexone bromide) is an opioid antagonists indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Relistor injection is also indicated for the treatment of opioid-induced constipation in patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care. Physicians and patients should periodically assess the need for continued treatment with Relistor. This prior authorization program is intended to encourage the use of lower cost alternatives. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Relistor [package insert]. Bridgewater, NJ: Bausch Health US, LLC; May 2024.
2. Chang, L, Sultan, S, et al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome with Constipation. Gastroenterology: 2022; 162:118-36.

5 . Revision History

Date	Notes
7/17/2025	Annual review. Updated references.

Repatha

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-552192
Guideline Name	Repatha
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	06/16/2021 ; 10/20/2021 ; 06/15/2022 ; 01/18/2023 ; 06/21/2023 ; 10/18/2023 ; 02/16/2024 ; 02/20/2025 ; 12/17/2025 ; 3/18/2026

1 . Indications

Drug Name: Repatha (evolocumab)
Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia) and ASCVD Indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia. **Homozygous familial hypercholesterolemia (HoFH)** Indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH). **Heterozygous familial hypercholesterolemia (HeFH)** Indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH). **Cardiovascular disease** Indicated to reduce the risk of major adverse cardiovascular (CV)

events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults with increased risk for these events.

2 . Criteria

Product Name:Repatha [a]	
Diagnosis	Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia), ASCVD and ASCVD prevention
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of heterozygous familial hypercholesterolemia (HeFH)

OR

1.2 Diagnosis of atherosclerotic cardiovascular disease (ASCVD) (e.g., acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin)

OR

1.3 Diagnosis of primary hyperlipidemia

OR

1.4 Patient is at increased risk for a major adverse cardiovascular (CV) event (CV death,

myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) but without established cardiovascular disease

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY STATIN THERAPY [i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a high-intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

- Myalgia [muscle symptoms without creatine kinase (CK) elevations]
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin ≥ 10 mg, pravastatin ≥ 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin) ≥ 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate LOW OR MODERATE-, AND HIGH-INTENSITY STATINS as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)

- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

2.3.2 Patient has a contraindication to all statins as documented in medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - Patient has LDL-C greater than or equal to 55 mg/dL

AND

4 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Lerochol (lerodalcibep-liga), Praluent (alirocumab)]

AND

5 - Not used in combination with Leqvio (inclisiran)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Repatha [a]	
Diagnosis	Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia), ASCVD and ASCVD prevention
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C reduction while on Repatha therapy

AND

2 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Lerochol (lerodalcibep-liga), Praluent (alirocumab)]

AND

3 - Not used in combination with Leqvio (inclisiran)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Repatha [a]	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

1.1 Genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) genes or ≥ 2 such variants at different loci

OR

1.2 BOTH of the following:

1.2.1 Untreated low-density lipoprotein cholesterol (LDL-C) greater than 400 mg/dL

AND

1.2.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of familial hypercholesterolemia in at least one parent

AND

2 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Lerochol (lerodalcibep-liga), Praluent (alirocumab)]

AND

3 - Not used in combination with Juxtapid (lomitapide)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Repatha [a]	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C reduction while on Repatha therapy **AND** **2** - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Lerochol (lerodalcibep-liga), Praluent (alirocumab)] **AND** **3** - Not used in combination with Juxtapid (lomitapide)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Repatha (evolocumab) is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor indicated:

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults with increased risk for these events.
- As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in:
    - adults with hypercholesterolemia.
    - adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH).
    - adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH).

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.

4 . References

1. Repatha [package insert]. Thousand Oaks, CA : Amgen Inc.; August 2025.
2. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014;63:2889-934.
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5 . Revision History

Date	Notes
3/16/2026	Removed ezetimibe trial requirement for primary hyperlipidemia and ASCVD. Removed specialist prescriber requirement. Updated refere nces.

Repository Corticotropins



Prior Authorization Guideline

Guideline ID	GL-555217
Guideline Name	Repository Corticotropins
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	5/20/2022
P&T Revision Date:	08/19/2022 ; 03/15/2023 ; 03/20/2024 ; 03/19/2025 ; 10/15/2025 ; 3/18/2026

1 . Criteria

Product Name:Acthar Gel multi-dose vial, Purified Cortrophin Gel multi-dose vial [a]	
Diagnosis	Infantile Spasm
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	

1 - Diagnosis of infantile spasms (i.e., West Syndrome)

AND

2 - Patient is less than 2 years old

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Acthar Gel multi-dose vial, Purified Cortrophin Gel multi-dose vial [a]	
Diagnosis	Opsoclonus-Myoclonus Syndrome
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of opsoclonus-myoclonus syndrome (i.e., Kinsbourne Syndrome)

AND

2 - If the request is for Acthar Gel, provider provides a reason or special circumstance patient cannot use Purified Cortrophin Gel

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Acthar Gel Selfject (single-dose prefilled injector) and Purified Cortrophin Gel single-dose prefilled syringes [a]	
Approval Length	All requests for authorization will be denied
Guideline Type	Non Formulary

Approval Criteria

1 - Acthar Gel Selfject (single-dose prefilled injector) and Purified Cortrophin Gel single-dose prefilled syringes provide similar efficacy as vials; therefore, these prefilled products are not medically necessary since their use is mainly for convenience as compared to administration from the multi- or multiple-dose vials.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Acthar Gel, Purified Cortrophin Gel [a]	
Diagnosis	Other Diagnoses
Guideline Type	Non Formulary

Approval Criteria

1 - Acthar Gel and Purified Cortrophin Gel are unproven and/or not medically necessary for treatment of the following disorders and diseases:

- Allergic States: Serum sickness, atopic dermatitis
- Collagen Diseases: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
- Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome, severe psoriasis
- Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
- Multiple sclerosis: for treatment of acute exacerbations
- Respiratory Diseases: Symptomatic sarcoidosis
- Rheumatic Disorders: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis, acute gouty arthritis
- Any indication outside of the proven indications listed in the coverage criteria

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background: Acthar Gel (repository corticotropin injection) and Purified Cortrophin Gel (repository corticotropin injection USP) are adrenocorticotropic hormone (ACTH) analogues **medically necessary** for: • **Infantile Spasms:** As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. • **Opsoclonus-myoclonus syndrome** (i.e., OMS, Kinsbourne Syndrome) The Acthar Gel and Purified Cortrophin Gel package inserts have listed other conditions in which they may be used without providing supporting clinical evidence. UHCP has determined that use of Acthar Gel and Purified Cortrophin Gel is not medically necessary for treatment of the following disorders and diseases: multiple sclerosis; rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits may be in place.

3 . References

1. Acthar Gel [package insert]. Bridgewater, NJ: Mallinckrodt ARD LLC.; February 2024.
2. Purified Cortrophin Gel [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; August 2025.
3. Pranzatelli MR, Chun KY, Moxness M, Tate ED, Allison TJ. Cerebrospinal fluid ACTH and cortisol in opsoclonus-myoclonus: effect of therapy. Pediatr Neurol. 2005;33(2):121-126.
4. Tate ED, Pranzatelli MR, Verhulst SJ, et al. Active comparator-controlled, rater-blinded study of corticotropin-based immunotherapies for opsoclonus-myoclonus syndrome [published correction appears in J Child Neurol. 2012 Oct;27(10):1364. Dosage error in article text]. J Child Neurol. 2012;27(7):875-884.

4 . Revision History

Date	Notes
3/18/2026	Annual review with no changes to coverage criteria. Updated backgr ound and references.

Revlimid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-328226
Guideline Name	Revlimid
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	9/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	05/21/2021 ; 10/20/2021 ; 05/20/2022 ; 05/25/2023 ; 05/17/2024 ; 05/16/2025 ; 7/16/2025

1 . Indications

Drug Name: Revlimid (lenalidomide)
Multiple Myeloma (MM) Indicated for the treatment of adult patients with multiple myeloma (MM), in combination with dexamethasone. Revlimid is indicated as maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT). **Myelodysplastic syndromes (MDS)** Indicated for the treatment of adult patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities. **Mantle cell lymphoma (MCL)** Indicated for the treatment of adult patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Follicular Lymphoma (FL) Indicated for the treatment of adult patients with previously treated follicular lymphoma (FL), in combination with a rituximab product. **Marginal Zone Lymphoma (MZL)** Indicated for the treatment of adult patients with previously treated marginal zone lymphoma (MZL), in combination with a rituximab product.

2 . Criteria

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple myeloma	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Revlimid therapy	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Myelodysplastic Syndromes (MDS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) associated WITH a deletion 5q

OR

2 - BOTH of the following:

2.1 Diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) WITHOUT deletion 5q

AND

2.2 ONE of the following:

2.2.1 BOTH of the following:

2.2.1.1 Ring sideroblasts ≥ 15% (or ≥ 5% with an SF3B1 mutation)

AND

2.2.1.2 History of failure, contraindication, or intolerance to ONE of the following^:

- Rytelo (imetelstat)

- Reblozyl (luspatercept-aamt)

OR

2.2.2 ALL of the following:

- Serum erythropoietin levels ≤ 500 mU/mL
- Ring sideroblasts < 15% (or < 5% with an SF3B1 mutation)
- Used in combination with an erythropoietin stimulating agent (ESA) [e.g., Epogen, Procrit, Retacrit (epoetin alfa)] or darbepoetin alfa

OR

2.2.3 ALL of the following:

- Serum erythropoietin levels > 500 mU/mL
- Ring sideroblasts < 15% (or < 5% with an SF3B1 mutation)
- History of failure, contraindication, intolerance to, or a poor probability of responding to immunosuppressive therapy (e.g., azacitidine, decitabine)

OR

3 - BOTH of the following:

3.1 Diagnosis of MDS/MPN overlap neoplasm

AND

3.2 ONE of the following:

- Patient has SF3B1 mutation and thrombocytosis
- Patient has ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Myelodysplastic Syndromes (MDS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following criteria:

1.1 Diagnosis of ONE of the following:

- Mantle cell lymphoma (MCL)
- Extranodal marginal zone lymphoma of nongastric sites (noncutaneous)
- Extranodal marginal zone lymphoma (EMZL) of the stomach
- Classic follicular lymphoma
- Nodal marginal zone lymphoma
- Splenic marginal zone lymphoma

OR

1.2 BOTH of the following:

1.2.1 ONE of the following diagnoses:

- HIV-related B-cell lymphoma
- Diffuse large B-cell lymphoma
- High-grade B-cell lymphoma
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Post-transplant lymphoproliferative disorders

AND

1.2.2 Used as second line and subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelofibrosis-associated anemia

AND

2 - Presence of del(5q) mutation

AND

3 - No symptomatic splenomegaly and/or constitutional symptoms

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response while on Revlimid

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Hodgkin Lymphoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hodgkin lymphoma

AND

2 - Used for primary refractory disease or suspected relapse

AND

3 - Patient is not a candidate for high-dose therapy and autologous stem cell rescue (HDT/ASCR)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic light chain amyloidosis

AND

2 - Used in combination with ONE of the following:

- Dexamethasone
- Dexamethasone and cyclophosphamide
- Dexamethasone and Ninlaro (ixazomib)
- Dexamethasone and Darzalex (daratumumab)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL)

AND

2 - Disease is relapsed or refractory

AND

3 - Used after prior therapy with Bruton Tyrosine Kinase (BTK) inhibitor- and venetoclax-based regimens

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of peripheral T-cell lymphoma

AND

1.2 ONE of the following:

- Used as initial palliative intent therapy
- Used as second-line and subsequent therapy

OR

2 - BOTH of the following:

- Diagnosis of adult T-cell lymphoma
- Used as second-line and subsequent therapy

OR **3** - BOTH of the following: • Diagnosis of hepatosplenic T-cell lymphoma • Used for refractory disease after two first-line therapy regimens

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Revlimid therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Central Nervous System Cancers-Primary CNS Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of primary central nervous system lymphoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Central Nervous System Cancers-Primary CNS Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of HIV-negative Kaposi Sarcoma

OR

1.2 BOTH of the following:

- Diagnosis of HIV-related Kaposi Sarcoma
- Patient is currently being treated with antiretroviral therapy (ART)

AND

2 - Disease has progressed or not responded to two different systemic first-line systemic therapies (e.g., liposomal doxorubicin, sirolimus, paclitaxel)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following histiocytic neoplasms:

- Langerhans cell histiocytosis
- Rosai-Dorfman disease

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Castleman Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multicentric Castleman disease

AND

2 - ONE of the following:

- Progressed following treatment of relapsed/refractory disease
- Considered progressive disease

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	Castleman Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Revlimid will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Revlimid, generic lenalidomide [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Revlimid therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Revlimid® (lenalidomide) is a thalidomide analogue indicated for the treatment of adult patients with the following: multiple myeloma (MM), in combination with dexamethasone; MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT); transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional

cytogenetic abnormalities; mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib; previously treated follicular lymphoma (FL), in combination with a rituximab product; and previously treated marginal zone lymphoma (MZL), in combination with a rituximab product. [1]

The National Cancer Comprehensive Network (NCCN) also recommends use of Revlimid for treatment of the following B-Cell lymphomas: histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, mantle cell lymphoma, nodal marginal zone lymphoma, classic follicular lymphoma (grade 1-2), extranodal marginal zone lymphoma of nongastric sites (noncutaneous), extranodal marginal zone lymphoma (EMZL) of the stomach, high-grade B-cell lymphoma, splenic marginal zone lymphoma, post-transplant lymphoproliferative disorders, diffuse large B-cell lymphoma, and HIV-related B-cell lymphomas. Additionally, NCCN recommends the use of Revlimid for Kaposi Sarcoma, primary CNS lymphoma, Castleman disease, chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), MDS/MPN overlap neoplasms, myelofibrosis-associated anemia, systemic light chain amyloidosis, classic Hodgkin lymphoma, Langerhans cell histiocytosis, Rosai-Dorfman disease, and the following T-cell lymphomas: hepatosplenic gamma-delta T-cell lymphoma, peripheral T-cell lymphoma, and adult T-cell leukemia/lymphoma.

Because of the risk of serious malformations if given during pregnancy, there is an extensive risk management program requiring registration by patients, prescribers and dispensing pharmacies. Additional information about the lenalidomide Risk Evaluation and Mitigation Strategy (REMS) [Lenalidomide REMS] program may be found at **Error! Hyperlink reference not valid.**. [4]

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Revlimid [package insert]. Summit, NJ: Celgene Corporation; March 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 10, 2025.

3. Lenalidomide REMS®. Available at http://www.revlimidrems.com/. Accessed April 10, 2025.

5 . Revision History

Date	Notes
7/15/2025	Updated to simplify criteria for diagnosis of myelofibrosis per NCCN guidance.

Reyvow

Prior Authorization Guideline

Guideline ID	GL-216268
Guideline Name	Reyvow
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	4/17/2024
P&T Revision Date:	3/19/2025

1 . Indications

Drug Name: Reyvow (lasmiditan)
Migraine with or without aura Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Reyvow is not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name:Reyvow [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Used for acute treatment of migraine

AND

2 - Patient is 18 years of age or older

AND

3 - History of a therapeutic failure (after at least 3 migraine episodes and a minimum of a 30-day trial), contraindication or intolerance to BOTH of the following (document name and date tried):

3.1 TWO of the following:

- naratriptan (Amerge)
- rizatriptan (Maxalt/Maxalt MLT)
- sumatriptan (Imitrex)

AND

3.2 Ubrelvy

AND

4 - Prescriber attests to BOTH of the following:

- Patient has been informed the use of Reyvow may result in significant CNS impairment, and may impact the patient's ability to drive or operate machinery for 8 hours after each dose
- If used concurrently with a benzodiazepine or other drugs that could potentially cause central nervous system (CNS) depression, the prescriber has acknowledged that they have completed an assessment of increased risk for sedation and other cognitive and/or neuropsychiatric adverse events

AND

5 - ONE of the following:

5.1 Patient is currently treated with ONE of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- Candesartan (Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab)*, Emgality (galcanezumab), Qulipta, Vyepti (eptinezumab-jjmr)^]
- Divalproex sodium (Depakote/Depakote ER)
- OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

5.2 Patient has less than 4 migraine days per month

OR

5.3 Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to ONE of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)
- Candesartan (Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab)*, Emgality (galcanezumab), Qulipta, Vyepti (eptinezumab-jjmr)^]
- Divalproex sodium (Depakote/Depakote ER)
- OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements]
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Reyvow [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Reyvow (lasmiditan) is a serotonin 5-HT_{1F} receptor agonist indicated for the acute treatment of migraine with or without aura in adults. Sedation was reported up to 8 hours after a single dose of Reyvow. Patients should be advised to not engage in activities requiring complete mental alertness, such as driving a motor vehicle or operating machinery, for at least 8 hours after each dose of Reyvow. The American Headache Society recommends use of NSAIDs (including aspirin), non-opioid analgesics, acetaminophen, or caffeinated analgesic combinations (e.g., aspirin/acetaminophen/caffeine) for mild-to-moderate attacks and migraine-specific agents (i.e., triptans, dihydroergotamine [DHE]) for moderate or severe attacks and mild-to-moderate attacks that respond poorly to NSAIDs or caffeinated combinations.

4 . References

1. Reyvow [package insert]. Indianapolis, IN: Lilly USA, LLC,; September 2022.
2. The American Headache Society Position Statement on Integrating New Migraine Treatments Into Clinical Practice. AHS Consensus Statement. Headache. 2021; 61:1021-39.

5 . Revision History

Date	Notes
3/18/2025	Annual review. Updated list of prophylactic agents and removed pres criber requirement.

Rezdiffra

Prior Authorization Guideline

Guideline ID	GL-436516
Guideline Name	Rezdiffra
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	4/17/2024
P&T Revision Date:	01/15/2025 ; 11/21/2025

1 . Indications

Drug Name: Rezdiffra (resmetirom)
Noncirrhotic nonalcoholic steatohepatitis (NASH) Indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis)

2 . Criteria

Product Name:Rezdiffra [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as nonalcoholic steatohepatitis (NASH)]

AND

2 - Submission of medical records documenting that disease is fibrosis stage F2 or F3 as confirmed by ONE of the following:

- Liver stiffness measurement (LSM) by vibration-controlled transient elastography (VCTE) (e.g., FibroScan)
- LSM by magnetic resonance elastography (MRE)
- Liver biopsy within the past 12 months

AND

3 - Patient has received comprehensive counseling regarding lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

AND

4 - Provider attests that Rezdiffra will not be initiated at the same time as Wegovy (semaglutide) for treatment of the same indication

AND

5 - Prescribed by or in consultation with a gastroenterologist or hepatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rezdiffra [a]

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Rezdiffra therapy (e.g., improvement in or stabilization of fibrosis)

AND

2 - Patient has not progressed to cirrhosis

AND

3 - Prescribed by or in consultation with a gastroenterologist or hepatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Rezdiffra™ (resmetirom) is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place.

4 . References

1. Rezdiffra [package insert]. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; March 2024.
2. Harrison SA, Bedossa P, Guy CD, Schattenberg JM, Loomba R, Taub R, Labriola D, Moussa SE, Neff GW, Rinella ME, Anstee QM, Abdelmalek MF, Younossi Z, Baum SJ, Francque S, Charlton MR, Newsome PN, Lanthier N, Schiefke I, Mangia A, Pericàs JM, Patil R, Sanyal AJ, Noureddin M, Bansal MB, Alkhouri N, Castera L, Rudraraju M, Ratziu V; MAESTRO-NASH Investigators. A Phase 3, Randomized, Controlled Trial of Resmetirom in NASH with Liver Fibrosis. N Engl J Med. 2024 Feb 8;390(6):497-509. doi: 10.1056/NEJMoa2309000. PMID: 38324483.
3. Rinella ME, Lazarus JV, Ratziu V, et al. A multisociety Delphi consensus statement on new fatty liver disease nomenclature. Hepatology. 2023;78(6):1966-1986. doi:10.1097/HEP.0000000000000520
4. Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology. 2023;77(5):1797-1835. doi:10.1097/HEP.0000000000000323
5. Wattacheril JJ, Abdelmalek MF, Lim JK, Sanyal AJ. AGA Clinical Practice Update on the Role of Noninvasive Biomarkers in the Evaluation and Management of Nonalcoholic Fatty Liver Disease: Expert Review. Gastroenterology. 2023;165(4):1080-1088. doi:10.1053/j.gastro.2023.06.013
6. European Association for the Study of the Liver (EASL). Electronic address: easloffice@easloffice.eu; European Association for the Study of Diabetes (EASD); European Association for the Study of Obesity (EASO); European Association for the Study of the Liver (EASL). EASL-EASD-EASO Clinical Practice Guidelines on the management of metabolic dysfunction-associated steatotic liver disease (MASLD). J Hepatol. 2024;81(3):492-542. doi:10.1016/j.jhep.2024.04.031
7. Chen VL, Morgan TR, Rotman Y, et al. Resmetirom therapy for metabolic dysfunction-associated steatotic liver disease: October 2024 updates to AASLD Practice Guidance. Hepatology. Published online October 18, 2024. doi:10.1097/HEP.0000000000001112
8. Noureddin M, Charlton MR, Harrison SA, et al. Expert Panel Recommendations: Practical Clinical Applications for Initiating and Monitoring Resmetirom in Patients With MASH/NASH and Moderate to Noncirrhotic Advanced Fibrosis. Clin Gastroenterol Hepatol. 2024;22(12):2367-2377. doi:10.1016/j.cgh.2024.07.003

5 . Revision History

Date	Notes
11/4/2025	Added combination use language. Added medical record submission requirement to initial authorization criteria for confirming fibrosis stag e F2 or F3. Updated references.

Rhapsido

Prior Authorization Guideline

Guideline ID	GL-523205
Guideline Name	Rhapsido
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	2/20/2026
P&T Revision Date:	

1 . Indications

Drug Name: Rhapsido (remibrutinib)
Chronic spontaneous urticaria (CSU) Indicated for the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite H1 antihistamine treatment.

2 . Criteria

Product Name:Rhapsido [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic spontaneous urticaria

AND

2 - ONE of the following:

2.1 Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, TWO H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]^

OR

2.2 Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to BOTH of the following taken in combination^:

2.2.1 A second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

AND

2.2.2 ONE of the following:

- A different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]
- A first generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]
- An H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]
- A leukotriene modifier [e.g., Singulair (montelukast)]

AND

3 - Patient is not receiving Rhapsido in combination with Dupixent (dupilumab) or Xolair (omalizumab) for treatment of the same indication.

AND

4 - Prescribed by ONE of the following:

- Allergist
- Dermatologist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Rhapsido [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Rhapsido therapy (e.g., reduction in exacerbations, itch severity, hives)

AND

2 - Patient is not receiving Rhapsido in combination with Dupixent (dupilumab) or Xolair (omalizumab) for treatment of the same indication.

AND

3 - Prescribed by ONE of the following:

- Allergist
- Dermatologist

• Immunologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Rhapsido is a kinase inhibitor indicated for the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite H1 antihistamine treatment. Limitations of Use: • Rhapsido is not indicated for other forms of urticaria.

4 . References

1. Rhapsido [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. September 2025.

5 . Revision History

Date	Notes
2/13/2026	New program.

Rinvoq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436517
Guideline Name	Rinvoq
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 05/21/2021 ; 02/18/2022 ; 03/16/2022 ; 05/20/2022 ; 06/15/2022 ; 07/20/2022 ; 09/21/2022 ; 10/19/2022 ; 12/14/2022 ; 07/19/2023 ; 09/20/2023 ; 06/17/2024 ; 01/15/2025 ; 04/16/2025 ; 06/18/2025 ; 09/25/2025 ; 11/21/2025

1 . Indications

Drug Name: Rinvoq (upadacitinib)
Rheumatoid Arthritis Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. **Atopic Dermatitis** Indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. **Ulcerative Colitis** Indicated for the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.

Ankylosing Spondylitis Indicated for the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.

Non-radiographic axial spondyloarthritis Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.

Crohn's Disease Indicated in adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers.

Giant Cell Arteritis Indicated for the treatment of adults with giant cell arteritis.

Drug Name: Rinvoq (upadacitinib), Rinvoq LQ (upadacitinib) oral solution

Polyarticular juvenile idiopathic arthritis Indicated in patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have an inadequate response or intolerance to one or more TNF blockers.

Psoriatic Arthritis Indicated for the treatment of adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have an inadequate response or intolerance to one or more TNF blockers.

2 . Criteria

Product Name:Rinvoq [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

- History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)
- Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

AND

2.1.2 ONE of the following:

- History of failure, contraindication, or intolerance to at least ONE TNF inhibitor^
- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria [6])

OR

2.2 BOTH of the following:

- Patient is currently on Rinvoq therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the AbbVie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq*

AND

3 - Patient is not receiving Rinvoq in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the AbbVie sponsored Rinvoq Complete program shall be required to meet initial authorization criteria as if patient were new to therapy. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Rinvoq [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rinvoq therapy

AND

2 - Patient is not receiving Rinvoq in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

• Potent immunosuppressant (e.g., azathioprine or cyclosporine)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rinvoq, Rinvoq LQ [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.1.1.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab]

AND

2.1.2 ONE of the following:

- History of failure, contraindication, or intolerance to at least ONE TNF inhibitor^
- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria [6])

OR

2.2 BOTH of the following:

- Patient is currently on Rinvoq or Rinvoq LQ therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the AbbVie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq or Rinvoq LQ*

AND

3 - Patient is not receiving Rinvoq or Rinvoq LQ in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the AbbVie sponsored Rinvoq Complete program shall be required to meet initial authorization criteria as if patient were new to therapy. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Rinvoq, Rinvoq LQ [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rinvoq or Rinvoq LQ therapy

AND

2 - Patient is not receiving Rinvoq or Rinvoq LQ in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rinvoq [a]

Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe chronic atopic dermatitis

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 History of failure, contraindication, or intolerance to BOTH of the following therapeutic classes of topical therapies (document drug, date of trial, and/ or contraindication to medication)

- Medium to very-high potency topical corticosteroids [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]
- Topical calcineurin inhibitor [e.g., tacrolimus (Protopic)]

AND

2.1.2 ONE of the following:

2.1.2.1 BOTH of the following^:

- Submission of medical records (e.g., chart notes, laboratory values) documenting a 3 month trial of a systemic drug product for the treatment of atopic dermatitis [examples include, but are not limited to, Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), etc.] (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration)
- Physician attests that the patient was not adequately controlled with the documented systemic drug product

OR

2.1.2.2 Physician attests that systemic treatment with ALL of the following, FDA-approved chronic atopic dermatitis therapies is inadvisable. (Document drug and contraindication rationale)^

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)
- Ebglyss (lebrikizumab-lbkz)
- Nemluvio (nemolizumab-ilto)

OR

2.1.2.3 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria [6]).

OR

2.2 BOTH of the following:

- Patient is currently on Rinvoq therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the AbbVie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq*

AND

3 - Patient is NOT receiving Rinvoq in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Cibinqo (abrocitinib), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto)] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the AbbVie sponsored Rinvoq Complete program shall be required to meet initial authorization criteria as if patient were new to therapy. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Rinvoq [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rinvoq therapy

AND

2 - Patient is not receiving Rinvoq in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Cibinqo (abrocitinib), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto)] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

3 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rinvoq [a]	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active UC

AND

2 - ONE of the following:

2.1 ONE of the following:

- Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)
- History of an inadequate response or intolerance to at least one TNF inhibitor.^
- Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)].

- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria6).

OR

2.2 BOTH of the following:

- Patient is currently on Rinvoq therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the AbbVie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq*

AND

3 - Patient is not receiving Rinvoq in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the AbbVie sponsored Rinvoq Complete program shall be required to meet initial authorization criteria as if patient were new to therapy. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Rinvoq [a]	
Diagnosis	Ulcerative Colitis (UC)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rinvoq therapy

AND

2 - Patient is not receiving Rinvoq in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rinvoq [a]	
Diagnosis	Ankylosing Spondylitis and non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

- History of failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)
- Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis or non-radiographic axial spondyloarthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Simponi (golimumab), Taltz (ixekizumab), Xeljanz (tofacitinib)].

AND

2.1.2 ONE of the following:

- History of failure, contraindication, or intolerance to at least ONE TNF inhibitor^
- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria [5])

OR

2.2 BOTH of the following:

- Patient is currently on Rinvoq therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the AbbVie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq*

AND

3 - Patient is not receiving Rinvoq in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Simponi (golimumab), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the AbbVie sponsored Rinvoq Complete program shall be required to meet initial authorization criteria as if patient were new to therapy. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Rinvoq [a]	
Diagnosis	Ankylosing Spondylitis and non-radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rinvoq therapy

AND

2 - Patient is not receiving Rinvoq in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Simponi (golimumab), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rinvoq [a]	
Diagnosis	Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - ONE of the following:

2.1 ONE of the following:

2.1.1 History of failure to ONE of the following conventional systemic therapies at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

OR

2.1.2 History of inadequate response or intolerance to at least one TNF inhibitor.^

OR

2.1.3 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of Crohn's disease as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab]

OR

2.1.4 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria5).

OR

2.2 BOTH of the following:

- Patient is currently on Rinvoq therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the AbbVie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq*

AND

3 - Patient is not receiving Rinvoq in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with a gastroenterologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the AbbVie sponsored Rinvoq Complete program shall be required to meet initial authorization criteria as if patient were new to therapy. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Rinvoq [a]	
Diagnosis	Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rinvoq therapy

AND

2 - Patient is not receiving Rinvoq in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rinvoq, Rinvoq LQ [a]	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to at least ONE TNF inhibitor^

OR

2.2 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria [5]).

OR

2.3 BOTH of the following:

- Patient is currently on Rinvoq or Rinvoq LQ therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the AbbVie sponsored Rinvoq Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rinvoq or Rinvoq LQ*

AND

3 - Patient is not receiving Rinvoq or Rinvoq LQ in combination with EITHER of the following:

- Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the AbbVie sponsored Rinvoq Complete program shall be required to meet initial authorization criteria as if patient were new to therapy. ^ Tried/failed alternative(s) are supported by FDA labeling

Product Name:Rinvoq, Rinvoq LQ [a]	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rinvoq or Rinvoq LQ therapy

AND

2 - Patient is not receiving Rinvoq or Rinvoq LQ in combination with EITHER of the following:

• Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication. • Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the AbbVie sponsored Rinvoq Complete program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Rinvoq [a]	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of giant cell arteritis **AND** **2** - Patient is not receiving Rinvoq in combination with EITHER of the following: • Systemic targeted immunomodulator for treatment of the same indication. • Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil) **AND** **3** - Prescribed by or in consultation with a rheumatologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Rinvoq [a]	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Rinvoq therapy **AND** **2** - Patient is not receiving Rinvoq in combination with EITHER of the following: • Systemic targeted immunomodulator for treatment of the same indication. • Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Rinvoq is a Janus kinase (JAK) inhibitor, Rinvoq and/or Rinvoq LQ is indicated for the treatment of:

- Adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blocker.

Limitation of Use: The use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

- Adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have an inadequate response or intolerance to one or more TNF blockers.

Limitation of Use: Rinvoq/Rinvoq LQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

- Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.

Limitation of Use: Rinvoq is not recommended in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

- Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. If TNF blockers are clinically inadvisable, patients should have received at least one approved systemic therapy prior to use of Rinvoq.

Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biological therapies for ulcerative colitis, or with other potent immunosuppressants such as azathioprine and cyclosporine.

Rinvoq should be discontinued if adequate therapeutic response is not achieved with the 30 mg dosage. Use the lowest effective dosage needed to maintain response.

- Adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

- Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.

Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

- Adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers. If TNF blockers are clinically inadvisable, patients should have received at least one approved systemic therapy prior to use of Rinvoq.

Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biological therapies for Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine

- Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have an inadequate response or intolerance to one or more TNF blockers.

Limitation of Use: Rinvoq/Rinvoq LQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

- Adults with giant cell arteritis.

Limitation of Use:

Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

Table 1: Relative potencies of topical corticosteroids[8]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
	Amcinonide	Cream, lotion, ointment	0.1

High Potency	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05

	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Table 2: Systemic immunomodulatory agents recommended by the 2014 American Academy of Dermatology guidelines for the treatment of refractory atopic dermatitis [Ω,9]

Cyclosporine
Azathioprine
Methotrexate
Mycophenolate mofetil

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; October 2025.
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8. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
9. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.

5 . Revision History

Date	Notes
11/4/2025	Updated criteria to reflect updated UC and CD indication regarding T NF blockers. Updated background and reference. Updated combinati on examples and language with no change to clinical intent.

Rivfloza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-255195
Guideline Name	Rivfloza
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	4/17/2024
P&T Revision Date:	05/17/2024 ; 5/16/2025

1 . Indications

Drug Name: Rivfloza (nedosiran)
Primary hyperoxaluria type 1 (PH1) Indicated to lower urinary oxalate levels in children 2 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m2

2 . Criteria

Product Name:Rivfloza [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - ALL of the following:

- Patient has been established on therapy with Rivfloza under an active UnitedHealthcare prior authorization for the treatment of primary hyperoxaluria type 1 (PH1)
- Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response to therapy from pre-treatment baseline (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate: creatinine ratio, decreased plasma oxalate concentrations)
- Patient has not received a liver transplant
- Patient has relatively preserved kidney function (e.g., eGFR ≥ 30 mL/min/1.73 m2)
- Patient is not receiving Rivfloza in combination with Oxlumo (lumasiran)
- Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1

OR

2 - ALL of the following:

2.1 Diagnosis of primary hyperoxaluria type 1 (PH1)

AND

2.2 Confirmation of diagnosis based on BOTH of the following:

2.2.1 Metabolic testing demonstrating ONE of the following:

- Increased urinary oxalate excretion (e.g. greater than 1 mmol/1.73 m2 per day [90 mg/1.73 m2 per day], increased urinary oxalate: creatinine ratio relative to normative values for age)
- Increased plasma oxalate and glyoxylate concentrations

AND

2.2.2 Genetic testing has confirmed a mutation in the alanine: glyoxylate aminotransferase (AGT or AGXT) gene

AND

2.3 Patient has not received a liver transplant

AND

2.4 Patient is at least 2 years of age and older

AND

2.5 Patient has relatively preserved kidney function (e.g., eGFR ≥ 30 mL/min/1.73 m2)

AND

2.6 Patient is not receiving Rivfloza in combination with Oxlumo (lumasiran)

AND

2.7 Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rivfloza [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response to therapy from pre-treatment baseline (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate: creatinine ratio, decreased plasma oxalate concentrations) **AND** **2** - Patient has not received a liver transplant **AND** **3** - Patient has relatively preserved kidney function (e.g., eGFR ≥ 30 mL/min/1.73 m2) **AND** **4** - Patient is not receiving Rivfloza in combination with Oxlumo (lumasiran) **AND** **5** - Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Rivfloza (nedosiran) is an LDHA-directed small interfering RNA indicated to lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m2.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place

4 . References

1. Rivfloza [package insert]. Plainsboro, NJ: Novo Nordisk, Inc.; March 2025.
2. Baum MA, Langman C, Cochat P, et al. PHYOX2: a pivotal randomized study of nedosiran in primary hyperoxaluria type 1 or 2. Kidney Int. 2023;103(1):207-217. doi:10.1016/j.kint.2022.07.025
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5 . Revision History

Date	Notes
5/5/2025	Annual review. Removed background information on Oxlumo. Updat ed background and coverage criteria to lower the age limit to 2 years of age and older due to updated indication.

Rozlytrek

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-493416
Guideline Name	Rozlytrek
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 10/20/2021 ; 10/19/2022 ; 01/18/2023 ; 01/17/2024 ; 01/15/2025 ; 1/21/2026

1 . Indications

Drug Name: Rozlytrek™ (entrectinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with ROS1- positive metastatic non-small cell lung cancer (NSCLC). **Solid Tumors** Indicated for the treatment of adult and pediatric patients 1 month of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy

2 . Criteria

Product Name:Rozlytrek [a]	
Diagnosis	Ampullary Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ampullary adenocarcinoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - ONE of the following:

- Used for metastatic disease
- Used for disease progression

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Ampullary Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Appendiceal Neoplasms and Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following appendiceal neoplasms and cancers:

- Appendiceal adenocarcinoma
- Goblet cell adenocarcinoma
- Undifferentiated carcinoma not otherwise specified

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Appendiceal Neoplasms and Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Rozlytrek therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Biliary Tract Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of biliary tract cancer (e.g., gallbladder, cholangiocarcinoma) **AND** **2** - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.) **AND** **3** - Disease is ONE of the following:	

- Gross Residual (R2)
- Metastatic
- Resectable locoregionally advanced
- Unresectable

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Biliary Tract Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

AND

4 - Disease is ONE of the following:

- Metastatic
- Recurrent unresectable
- Unresponsive to preoperative systemic therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Rozlytrek [a]	
Diagnosis	Central Nervous System Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Circumscribed glioma
- Glioblastoma
- High-grade glioma
- Brain metastases

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Metastatic
- Recurrent or progressive

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Rozlytrek [a]

Diagnosis	Central Nervous System Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Cervical Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cervical cancer

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Rozlytrek [a]	
Diagnosis	Cervical Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Rozlytrek therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Rozlytrek [a]	
Diagnosis	Colorectal Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of colon or rectal cancer **AND** **2** - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)	

AND **3** - Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Colorectal Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Esophageal, Esophagogastric Junction, and Gastric Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of esophageal, esophagogastric junction, or gastric cancer

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Metastatic
- Recurrent
- Unresectable locally advanced

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Esophageal, Esophagogastric Junction, and Gastric Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Gastrointestinal Stromal Tumors

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Used in ONE of the following settings:

- Neoadjuvant therapy to decrease surgical morbidity
- Gross residual disease (R2 resection)
- Unresectable primary disease
- Preoperative/intraoperative tumor rupture
- Recurrent/metastatic disease

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Gastrointestinal Stromal Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Rozlytrek therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Head and Neck Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of salivary gland tumor **AND** **2** - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.) **AND** **3** - Used as second-line or subsequent therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Head and Neck Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is recurrent or metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]

Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of histiocytic neoplasm

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Metastatic
- Relapsed/refractory

• Symptomatic unresectable or multifocal	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Rozlytrek therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cutaneous melanoma **AND**	

2 - Disease is positive for ONE of the following gene fusions:

- ROS1-gene fusion
- NTRK-gene fusion

AND

3 - Disease is metastatic or unresectable

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuroendocrine tumor

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

AND

4 - Disease is ONE of the following:

- Locoregional unresectable
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Rozlytrek therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Disease is positive for ONE of the following gene fusions:

- ROS1-gene fusion
- NTRK-gene fusion

AND

3 - Disease is ONE of the following:

- Advanced
- Metastatic
- Recurrent

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Rozlytrek therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Occult Primary [Cancer of Unknown Primary (CUP)] Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following occult primary cancers:

- Adenocarcinoma
- Carcinoma not otherwise specified
- Squamous cell carcinoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

AND

4 - Used in ONE of the following settings:

- Asymptomatic patients with PS 0 and aggressive disease
- Symptomatic patients with performance status (PS) 1-2

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Occult Primary [Cancer of Unknown Primary (CUP)] Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Ovarian/Fallopian Tube/Primary Peritoneal Cancers

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Fallopian tube cancer
- Ovarian cancer
- Primary peritoneal cancer

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - ONE of the following histologies:

- Endometrioid
- Carcinosarcoma (Malignant Mixed Müllerian Tumors)
- Clear cell carcinoma of the ovary
- Mucinous carcinoma
- Serous carcinoma

AND

4 - Disease is persistent or recurrent

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Ovarian/Fallopian Tube/Primary Peritoneal Cancers

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Pancreatic Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic adenocarcinoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Locally advanced
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Pancreatic Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Rozlytrek therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Small Bowel Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of small bowel adenocarcinoma **AND** **2** - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)	

AND **3** - Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Small Bowel Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of soft tissue sarcoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Advanced
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following thyroid cancers:

- Papillary carcinoma
- Follicular carcinoma
- Oncocytic carcinoma
- Anaplastic carcinoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Metastatic
- Persistent
- Unresectable locoregional recurrent

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Uterine Neoplasm
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following uterine neoplasms:

- Endometrial carcinoma
- Uterine Sarcoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Advanced
- Inoperable
- Recurrent
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Uterine Neoplasm
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Vaginal/Vulvar Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vaginal or vulvar cancer

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND **3** - Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	Vaginal/Vulvar Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Rozlytrek will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Rozlytrek [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Rozlytrek therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Rozlytrek™ (entrectinib) is a kinase inhibitor indicated for the treatment of:

- Adult patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC).
- Adult and pediatric patients 1 month of age and older with solid tumors that:
  - have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation,
  - are metastatic or where surgical resection is likely to result in severe morbidity, and
  - have progressed following treatment or have no satisfactory alternative therapy

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon

verification and description of clinical benefit in the confirmatory trials.[1]

The National Comprehensive Cancer Network (NCCN) also recommends the use of Rozlytrek in solid tumors that are (NTRK) gene fusion positive with differing clinical circumstances.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Rozlytrek [package insert]. Genentech USA, Inc.: South San Francisco, CA; January 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed November 18, 2025.

5 . Revision History

Date	Notes
1/12/2026	Annual review. Expanded section on solid tumors to specify each typ e with their own criteria based on FDA label and NCCN guidance.

Ruconest

Prior Authorization Guideline

Guideline ID	GL-399293
Guideline Name	Ruconest
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	07/21/2021 ; 09/15/2021 ; 04/20/2022 ; 04/19/2023 ; 08/18/2023 ; 04/17/2024 ; 04/16/2025 ; 9/25/2025

1 . Indications

Drug Name: Ruconest (C1 esterase inhibitor [recombinant])
Hereditary angioedema (HAE) Indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE).

2 . Criteria

Product Name:Ruconest [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - BOTH of the following:

- Prescribed for the acute treatment of HAE attacks
- Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr)

AND

3 - Submission of medical records documenting a history of failure, contraindication, or intolerance to icatibant acetate (generic Firazyr)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ruconest [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Ruconest therapy

AND

2 - BOTH of the following:

2.1 Prescribed for the acute treatment of HAE attacks

AND

2.2 Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr)

AND

3 - Prescribed by ONE of the following:

- Immunologist

• Allergist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Ruconest (C1 esterase inhibitor [recombinant]) is indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). Effectiveness was not established in HAE patients with laryngeal attacks. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limitations may be in place.

4 . References

1. Ruconest [package insert]. Warren, NJ: Pharming Healthcare, Inc.; April 2020.
2. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018 Jan 10.
3. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2024.
4. Busse, P., Christiansen, S., Riedl, M., et. al. “US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema.” The Journal of Allergy and Clinical Immunology. 2020 September 05
5. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2021 revision and update. Allergy. 2022;77(7):1961-1990. doi:10.1111/all.15214

5 . Revision History

Date	Notes
9/23/2025	Updating for 2026 implementation to remove Sajazir as a step therap y option. Sajazir moving to NF in 2026.

Samsca

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-254192
Guideline Name	Samsca
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	5/16/2025
P&T Revision Date:	

1 . Indications

Drug Name: Samsca (tolvaptan)
Hypervolemic or Euvolemic Hyponatremia Indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH)

2 . Criteria

Product Name:Brand Samsca, generic tolvaptan [a]

Diagnosis	Hypervolemic or Euvolemic Hyponatremia
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Diagnosis of clinically significant euvolemic hyponatremia
- Diagnosis of clinically significant hypervolemic hyponatremia

AND

2 - Patient has not responded to fluid restriction

AND

3 - Treatment has been initiated or re-initiated in a hospital setting prior to discharge

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Samsca is a selective vasopressin V_2-receptor antagonist indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH). [1]

Limitations of Use:

- Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Samsca.
- It has not been established that Samsca provides a symptomatic benefit to patients.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Samsca [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; April 2021.

5 . Revision History

Date	Notes
5/6/2025	Policy reviewed and approved for application to UnitedHealthcare Val ue & Balance Exchange for 7/2025 implementation.

Sandostatin

Prior Authorization Guideline

Guideline ID	GL-577263
Guideline Name	Sandostatin
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/15/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 10/20/2021 ; 01/19/2022 ; 08/19/2022 ; 01/18/2023 ; 01/17/2024 ; 05/16/2025

1 . Indications

Drug Name: Sandostatin (octreotide acetate)
Acromegaly Indicated to reduce blood levels of growth hormone and IGF-I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation and bromocriptine mesylate at maximally tolerated doses. **Metastatic carcinoid tumors** Indicated for the symptomatic treatment of patients with metastatic carcinoid tumors, where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease, and for the treatment of profuse watery diarrhea associated with VIP-secreting tumors.

2 . Criteria

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - ONE of the following:

2.1 Inadequate response to ONE of the following:

- Surgical resection
- Pituitary irradiation
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

2.2 Not a candidate for ANY of the following:

- Surgical resection
- Pituitary irradiation
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]

Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Sandostatin or generic octreotide therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of meningioma

AND

2 - Disease is surgically inaccessible

AND

3 - ONE of the following:

- Disease is recurrent
- Disease is progressive

AND **4** - Radiation is not possible

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sandostatin or generic octreotide therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Neuroendocrine tumor [i.e., carcinoid tumors, Islet cell tumors, gastrinomas, glucagonomas, insulinomas, lung tumors, somatostatinomas, tumors of the pancreas, GI tract, lung, thymus, adrenal glands, and vasoactive intestinal polypeptidomas (VIPomas)]

OR

2 - BOTH of the following:

2.1 ONE of the following:

- Diagnosis of Pheochromocytoma or Paraganglioma
- Well-differentiated grade 3 neuroendocrine tumor

AND

2.2 Disease is ONE of the following:

- Locally unresectable
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sandostatin or generic octreotide therapy

OR

2 - Documentation of positive clinical response (e.g., suppression of severe diarrhea, flushing, etc.) to Sandostatin or generic octreotide therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Thymoma or Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymoma or thymic carcinoma

AND

2 - ONE of the following:

2.1 Used as a second-line therapy for ONE of the following:

- Unresectable locally advanced disease
- Solitary metastasis or ipsilateral pleural metastasis
- Extrathoracic metastatic disease

OR

2.2 BOTH of the following:

2.2.1 Used as first line therapy for ONE of the following:

- Potentially resectable locally advanced disease
- Potentially resectable solitary metastasis or ipsilateral pleural metastasis
- Consideration following surgery for solitary metastasis or ipsilateral pleural metastasis
- Medically inoperable/unresectable solitary metastasis or ipsilateral pleural metastasis

- Extrathoracic metastatic disease
- Postoperative treatment for thymoma after R2 resection
- Preoperative systemic therapy for surgically resectable disease if R0 resection uncertain

AND

2.2.2 Patient is unable to tolerate first-line combination regimens

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Thymoma or Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sandostatin or generic octreotide therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Malignant Bowel Obstruction
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of malignant bowel obstruction **AND** **2** - Gut function cannot be maintained	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Malignant Bowel Obstruction
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Sandostatin or generic octreotide therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Chemotherapy- and/or Radiation-Induced Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of diarrhea due to concurrent cancer chemotherapy and/or radiation

AND

2 - ONE of the following:

- Presence of Grade 3 or 4 severe diarrhea
- Patients in palliative or end of life care

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Chemotherapy- and/or Radiation-Induced Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Sandostatin or generic octreotide therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Bleeding Gastroesophageal Varices
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bleeding gastroesophageal varices associated with liver disease

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	Bleeding Gastroesophageal Varices
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Sandostatin or generic octreotide therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Sandostatin or generic octreotide will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sandostatin, generic octreotide [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Sandostatin or generic octreotide therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background Sandostatin (octreotide acetate) is indicated to reduce blood levels of growth hormone and IGF-I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation and bromocriptine mesylate at maximally tolerated doses. It is also indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease and for the treatment of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors. The National Comprehensive Cancer Network (NCCN) recommends the use of octreotide acetate for the treatment of thyomas and thymic carcinomas as well as meningiomas. The NCCN also recommends octreotide acetate for the treatment of several types of

neuroendocrine and adrenal tumors, including neuroendocrine tumors of the gastrointestinal tract, lung and thymus, neuroendocrine tumors of the pancreas, well-differentiated Grade 3 neuroendocrine tumors, pheochromocytoma/paraganglioma. The NCCN Palliative Care Guidelines recommend octreotide for the treatment of chemotherapy and/or radiation-induced diarrhea and malignant bowel obstruction.[3]

Clinical evidence supports the use of octreotide acetate as an adjunct to endoscopic therapy for bleeding gastroesophageal varices associated with liver disease.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Octreotide acetate [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/. Accessed November 27, 2024.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Palliative Care. Version 1.2022. Available at http://www.nccn.org/professionals/physician_gls/pdf/palliative.pdf. Accessed November 9, 2025.
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14. Shah HA, Mumtaz K, Jafri W, et al. Sclerotherapy plus octreotide versus sclerotherapy alone in the management of gastro-esophageal variceal hemorrhage. J Ayub Med Coll Abbottabad. 2005 Jan-Mar;17(1):10-4.
15. Yucesoy M, Başkol M, Keklik M, et al. Efficacy of five days of subcutaneous octreotide treatment after sclerotherapy in preventing rebleeding from esophageal varices. Turk J Gastroenterol. 2004 Sep;15(3):137-43.
16. Banares R, Albillos A, Rincon D, et al. Endoscopic treatment versus endoscopic plus pharmacologic treatment for acute variceal bleeding: A meta-analysis. Hepatology. 2002;35(3):609-15.
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18. Garcia-Tsao G, Sanyal AJ, Grace ND, et al. Prevention and management of gastroesophageal varices and variceal hemorrhage in cirrhosis. Am J Gastroenterol. 2007 Sep;102(9):2086-102.
19. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014;99(11):3933-3951.
20. Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV. National Institutes of Health, HIV Medicine Association, and Infectious Diseases Society of America. Updated December 16, 2024.

5 . Revision History

Date	Notes
4/14/2026	Updated NCCN Recommendation reauth

Sapropterin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412191
Guideline Name	Sapropterin
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	10/1/2024
P&T Revision Date:	03/19/2025 ; 11/21/2025

1 . Indications

Drug Name: Javygtor (sapropterin dihydrochloride), Kuvan (sapropterin dihydrochloride), Zelvysia (sapropterin dihydrochloride)
Reduction of blood phenylalanine (Phe) levels Indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU).

2 . Criteria

Product Name:Brand Javygtor, Brand Kuvan, generic sapropterin, generic zelvysia [a]

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Patient is actively on a Phe-restricted diet

AND

3 - Patient is not receiving the requested medication in combination with Palynziq (pegvaliase-pqpz) or Sephience (sepiapterin)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Javygtor, Brand Kuvan, generic sapropterin, generic zelvysia [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is actively on a Phe-restricted diet

AND

2 - Blood Phe levels continue to remain lower than baseline level.

AND **3** - Patient is not receiving the requested medication in combination with Palynziq (pegvaliase-pqpz) or Sephience (sepiapterin)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Javygtor, Kuvan, and Zelvysia are phenylalanine hydroxylase activators indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). Javygtor, Kuvan, and Zelvysia are to be used in conjunction with a Phe-restricted diet. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may also be in place.

4 . References

1. Kuvan [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; August 2024.
2. Javygtor [package insert]. Princeton, NJ: Dr. Reddy's Laboratories, Inc.; October 2024.
3. Javygtor powder for oral solution [package insert]. Princeton, NJ: Dr. Reddy's Laboratories, Inc.; October 2024.
4. Zelvysia [package insert]. Piscataway, NJ: Aucta Pharmaceuticals, Inc.; April 2025.
5. Smith WE, Berry SA, Bloom K, et al. Phenylalanine hydroxylase deficiency diagnosis and management: A 2023 evidence-based clinical guideline of the American College of

Medical Genetics and Genomics (ACMG). Genet Med. 2025;27(1):101289. doi:10.1016/j.gim.2024.101289

5 . Revision History

Date	Notes
11/3/2025	Added Zelvysia to program. Added Sephience to combination use crit eria. Updated references.

Sensipar

Prior Authorization Guideline

Guideline ID	GL-216269
Guideline Name	Sensipar
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 08/20/2021 ; 10/20/2021 ; 08/19/2022 ; 09/18/2024 ; 3/19/2025

1 . Indications

Drug Name: Sensipar (cinacalcet)
Secondary hyperparathyroidism Indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease on dialysis. **Parathyroid carcinoma** Indicated for the treatment of hypercalcemia in patients with parathyroid carcinoma. **Primary hyperparathyroidism** Indicated for the treatment of hypercalcemia in patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.

2 . Criteria

Product Name:Brand Sensipar, generic cinacalcet [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Diagnosis of secondary hyperparathyroidism with chronic kidney disease
- Patient is on dialysis

OR

2.2 Diagnosis of hypercalcemia with parathyroid carcinoma

OR

2.3 ALL of the following:

- Diagnosis of primary hyperparathyroidism (HPT)
- Severe hypercalcemia (serum calcium level greater than 12.5 mg/dL) due to primary HPT
- Patient is unable to undergo parathyroidectomy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sensipar, generic cinacalcet [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has experienced a reduction in serum calcium from baseline	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Cinacalcet is a calcium-sensing receptor agonist indicated for the treatment of secondary hyperparathyroidism (HPT) in patients with chronic kidney disease (CKD) on dialysis, hypercalcemia in adult patients with parathyroid carcinoma (PC), and for hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy. Cinacalcet is not indicated for use in patients with CKD who are not on dialysis.[1] **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Sensipar [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2019.
2. Marcocci C1, Bollerslev J, Khan AA, Shoback DM. Medical management of primary hyperparathyroidism: proceedings of the fourth International Workshop on the Management of Asymptomatic Primary Hyperparathyroidism. J Clin Endocrinol Metab. 2014 Oct;99(10):3607-18. doi: 10.1210/jc.2014-1417. Epub 2014 Aug 27.
3. Ketteler M, Block GA, Evenepoel P, Fukagawa M, Herzog CA, McCann L, Moe SM, Shroff R, Tonelli MA, Toussaint ND, Vervloet MG, Leonard MB. KDIGO 2017 Clinical Practice Guideline Update For The Diagnosis, Evaluation, Prevention, And Treatment Of Chronic Kidney Disease–Mineral And Bone Disorder (CKD-MBD) Ann Intern Med. 2018 Mar 20;168(6):422-430.

5 . Revision History

Date	Notes
3/18/2025	Removed step through phosphate binder and vitamin D analog from secondary hyperparathyroidism.

Sephience

Prior Authorization Guideline

Guideline ID	GL-436519
Guideline Name	Sephience
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	11/21/2025
P&T Revision Date:	

1 . Indications

Drug Name: Sephience (sepiapterin)
Hyperphenylalaninemia (HPA) Indicated for the treatment of hyperphenylalaninemia (HPA) in adult and pediatric patients 1 month of age and older with sepiapterin-responsive phenylketonuria (PKU).

2 . Criteria

Product Name:Sephience [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Patient is actively on a phenylalanine(Phe)-restricted diet

AND

3 - ONE of the following:

- Patient has a contraindication to sapropterin (list reason)
- History of failure or intolerance to sapropterin therapy (document date of trial and list reason for therapeutic failure or intolerance) as determined by a trial of sapropterin
- Patient is not an appropriate candidate for sapropterin due to two null mutations in trans

AND

4 - Physician attestation that the patient will not be receiving Sephience in combination with sapropterin dihydrochloride or Palynziq (pegvaliase-pqpz)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Sephience [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria **1** - Patient is actively on a Phe-restricted diet **AND** **2** - Blood Phe levels continue to remain lower than baseline level **AND** **3** - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is not receiving Sephience in combination with sapropterin dihydrochloride or Palynziq (pegvaliase-pqpz) [Prescription claim history that does not show any concomitant sapropterin dihydrochloride or Palynziq (pegvaliase-pqpz) claim within 60 days of reauthorization request may be used as documentation.]

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information

Background:

Sephience is a phenylalanine hydroxylase (PAH) activator indicated for the treatment of hyperphenylalaninemia (HPA) in adult and pediatric patients 1 month of age and older with sepiapterin-responsive phenylketonuria (PKU). Sephience is to be used in conjunction with a phenylalanine (Phe)- restricted diet.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4 . References

1. Sephience [package insert]. Warren, NJ: PTC Therapeutics, Inc.; July 2025.
2. Thomas J, Levy H, Amato S, et al. Pegvaliase for the treatment of phenylketonuria: Results of a long-term phase 3 clinical trial program (PRISM). Mol Genet Metab. 2018;124(1):27-38.
3. Vockley et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. American College of Medical Genetics and Genomics Practice Guidelines. Genetics in Medicine 2014;16 (2):188-200.
4. Smith WE, Berry SA, Bloom K, et al. Phenylalanine hydroxylase deficiency diagnosis and management: A 2023 evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2025;27(1):101289. doi:10.1016/j.gim.2024.101289

5 . Revision History

Date	Notes
11/4/2025	New program.

Signifor

Prior Authorization Guideline

Guideline ID	GL-412202
Guideline Name	Signifor
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 10/19/2022 ; 10/16/2024 ; 10/15/2025

1 . Indications

Drug Name: Signifor (pasireotide diaspartate)
Cushing's disease Indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

2 . Criteria

Product Name:Signifor [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endogenous Cushing's disease (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

2 - ONE of the following:

- Pituitary surgery has not been curative for the patient
- Patient is not a candidate for pituitary surgery

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Signifor [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Signifor therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Signifor (pasireotide diaspartate) is a somatostatin analog indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Signifor [package insert]. Bridgewater, NJ: Recordati Rare Diseases, Inc; July 2024.

5 . Revision History

Date	Notes
10/6/2025	Annual review with no changes to coverage criteria.

Simponi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-437191
Guideline Name	Simponi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 03/17/2021 ; 05/21/2021 ; 05/20/2022 ; 09/21/2022 ; 05/25/2023 ; 06/17/2024 ; 10/16/2024 ; 01/15/2025 ; 10/15/2025 ; 11/21/2025

Note:

*This program applies to the subcutaneous formulation of golimumab.

1 . Indications

Drug Name: Simponi (golimumab)
Rheumatoid Arthritis Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX). **Psoriatic Arthritis** Indicated alone or in combination with methotrexate for the treatment of adult patients with active psoriatic arthritis (PsA). **Ankylosing Spondylitis** Indicated for the treatment of adult patients with active ankylosing

spondylitis (AS).

Ulcerative Colitis Indicated in adult and pediatric patients weighing at least 15 kg with moderate to severe ulcerative colitis

2 . Criteria

Product Name:Simponi [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - ONE of the following:

2.1 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

OR

2.3 BOTH of the following:

- Patient is currently on Simponi therapy as documented by claims history or submission of medical records (Document date, and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Jannsen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Simponi*

AND

3 - Patient is not receiving Simponi in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Jannsen sponsored CarePath Savings program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Simponi [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Simponi therapy

AND

2 - Patient is not receiving Simponi in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Simponi [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - ONE of the following:

2.1 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab]

OR

2.3 BOTH of the following:

- Patient is currently on Simponi therapy as documented by claims history or submission of medical records (Document date, and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Jannsen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Simponi*

AND

3 - Patient is not receiving Simponi in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may ap

	ply. *Patients requesting initial authorization who were established on ther apy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Jannsen sponso red CarePath Savings program shall be required to meet initial authori zation criteria as if patient were new to therapy.

Product Name:Simponi [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Simponi therapy **AND** **2** - Patient is not receiving Simponi in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Simponi [a]	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - ONE of the following:

2.1 History of failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)]

OR

2.3 BOTH of the following:

- Patient is currently on Simponi therapy as documented by claims history or submission of medical records (Document date, and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Jannsen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Simponi*

AND

3 - Patient is not receiving Simponi in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication

AND **4** - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Jannsen sponsored CarePath Savings program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Simponi [a]	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Simponi therapy

AND

2 - Patient is not receiving Simponi in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Simponi [a]

Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severely active ulcerative colitis

AND

2 - ONE of the following:

2.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g. azathioprine, or 6-mercaptopurine)^

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)]

OR

2.3 BOTH of the following:

- Patient is currently on Simponi therapy as documented by claims history or submission of medical records (Document date, and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Jannsen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Simponi*

AND

3 - Patient is not receiving Simponi in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication.

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Jannsen sponsored CarePath Savings program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Simponi [a]	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Simponi therapy

AND

2 - Patient is not receiving Simponi in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Simponi (golimumab) is a tumor necrosis factor (TNF) blocker, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX). [1] Simponi, alone or in combination with methotrexate, is indicated for the treatment of adult patients with active psoriatic arthritis (PsA). [1] It is also indicated for the treatment of adult patients with active ankylosing spondylitis (AS).[1] Simponi is also indicated in adult and pediatric patients weighing at least 15kg with moderate to severe ulcerative colitis. An intravenous formulation of golimumab, Simponi Aria, is also available. Simponi Aria is indicated for adult patients with moderately to severely active rheumatoid arthritis in combination with methotrexate, active psoriatic arthritis in patients 2 years of age and older, adult patients with active ankylosing spondylitis, and active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Simponi [package insert]. Horsham, PA: Janssen Biotech Inc.; October 2025.
2. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2023.
3. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2016;68(1):1-26.

4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis -- Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65:137-174.
5. Yu D, van Tubergen A. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. Sieper, J (Ed). UpToDate. Accessed January 14, 2019.
6. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158(5):1450-61.

5 . Revision History

Date	Notes
11/5/2025	Updated background and criteria to address new pediatric indication for UC. Updated reference.

Sirturo

Prior Authorization Guideline

Guideline ID	GL-500240
Guideline Name	Sirturo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	11/17/2023
P&T Revision Date:	12/18/2024 ; 1/21/2026

1 . Indications

Drug Name: Sirturo (bedaquiline fumarate)
Pulmonary multi-drug resistant tuberculosis Indicated as part of combination therapy in adult and pediatric patients (2 years and older and weighing at least 8 kg) with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to at least rifampin and isoniazid.

2 . Criteria

Product Name:Sirturo [a]	
Diagnosis	Pulmonary multi-drug resistant tuberculosis
Approval Length	12 month(s)

Guideline Type	Prior Authorization
Approval Criteria **1** - Sirturo will be approved as continuation of therapy upon hospital discharge **OR** **2** - ALL of the following: • Diagnosis of pulmonary multi-drug resistant tuberculosis due to Mycobacterium tuberculosis • Prescribed as part of a combination regimen with other anti-tuberculosis agents • Prescribed by an infectious disease specialist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Sirturo is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in adult and pediatric patients (2 years and older and weighing at least 8 kg) with pulmonary tuberculosis (TB) due to *Mycobacterium tuberculosis* resistant to at least rifampin and isoniazid. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Sirturo [package insert]. Horhsam, PA: Janssen Products, LP; July 2025.

5 . Revision History

Date	Notes
1/20/2026	Annual review. Updated background to reflect expanded label. Updated reference.

Sivextro

Prior Authorization Guideline

Guideline ID	GL-500241
Guideline Name	Sivextro
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	10/1/2024
P&T Revision Date:	1/21/2026

1 . Indications

Drug Name: Sivextro (tedizolid)
Skin and Skin Structure Infections Indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following gram-positive microorganisms: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), and Enterococcus faecalis.

2 . Criteria

Product Name:Sivextro [a]

Diagnosis	Skin and Skin Structure Infections
Approval Length	Authorization will be issued for up to 6 days.
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - ALL of the following:

3.1 Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)

AND

3.2 ONE of the following:

- Infection is caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report
- Presence of MRSA infection is likely and empiric treatment is warranted

AND

3.3 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

3.4 History of failure, contraindication, or intolerance to ONE of the following:

- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A tetracycline
- Clindamycin

OR

4 - ALL of the following:

4.1 Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)

AND

4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Sivextro

AND

4.3 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

4.4 History of failure, contraindication, or intolerance to TWO of the following:

- A penicillin
- A cephalosporin
- A tetracycline
- Clindamycin
- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A fluoroquinolone

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Sivextro [a]

Diagnosis	Off-Label Uses
Approval Length	Authorization duration based on provider and IDSA recommended treatment durations, up to 6 months.
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - BOTH of the following:

- The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)
- History of failure, contraindication, or intolerance to linezolid (generic Zyvox), if susceptibility is confirmed by culture

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Sivextro is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following gram-positive microorganisms: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible

[MSSA] isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), and Enterococcus faecalis.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Sivextro and other antibacterial drugs, Sivextro should be used only to treat ABSSSI that are proven or strongly suspected to be caused by susceptible bacteria.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Sivextro [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2025.
2. Stevens DL, Bisno AL, Chambers HF, et al. Practice Guidelines for Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Disease Society of America. Clin Infect Dis. 2014;59(2);e:10-52.

5 . Revision History

Date	Notes
1/20/2026	Annual review with no changes to coverage criteria. Updated references.

Skyclarys

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399246
Guideline Name	Skyclarys
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	5/25/2023
P&T Revision Date:	05/17/2024 ; 05/16/2025 ; 9/25/2025

1 . Indications

Drug Name: Skyclarys (omaveloxolone)
Friedreich's ataxia Indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older

2 . Criteria

Product Name:Skyclarys [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Friedreich's ataxia

AND

2 - Confirmed presence of a mutation in the frataxin (FXN) gene

AND

3 - Prescribed by, or in consultation with, ONE of the following

- Neurologist
- Neurogeneticist
- Physical Medicine and Rehabilitation physician (i.e., physiatrist)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Skyclarys [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Skyclarys therapy

AND

2 - Prescribed by, or in consultation with, ONE of the following • Neurologist • Neurogeneticist • Physical Medicine and Rehabilitation physician (i.e., physiatrist)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background Skyclarys (omaveloxolone) is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits may be in place.

4 . References

1. Skyclarys™ [package insert]. Plano, TX: Reata Pharmaceuticals, Inc.; December 2024.

5 . Revision History

Date	Notes

9/18/2025	Added state mandate language.

Skyrizi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-334213
Guideline Name	Skyrizi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	9/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 05/21/2021 ; 06/16/2021 ; 09/15/2021 ; 03/16/2022 ; 08/19/2022 ; 09/21/2022 ; 12/13/2023 ; 05/17/2024 ; 07/17/2024 ; 01/15/2025 ; 7/16/2025

Note:

*This program applies to the subcutaneous formulations of Skyrizi

1 . Indications

Drug Name: Skyrizi (risankizumab-rzaa)
Plaque Psoriasis Indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis** Indicated for the treatment of active psoriatic arthritis in adults. **Crohn's Disease** Indicated for the treatment of moderately to severely active Crohn's disease in adults.

Ulcerative Colitis Indicated for the treatment of moderately to severely active ulcerative colitis in adults.

2 . Criteria

Product Name:Skyrizi (subcutaneous formulations) [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

2.1.2 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

- Coal tar

AND

2.1.3 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab]

OR

2.3 BOTH of the following:

- Patient is currently on Skyrizi therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Skyrizi Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Skyrizi*

AND

3 - Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab]

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Skyrizi Complete program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Skyrizi (subcutaneous formulations) [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Skyrizi therapy **AND** **2** - Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab]	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Skyrizi (subcutaneous formulations) [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - ONE of the following:

2.1 History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab]

OR

2.3 BOTH of the following:

- Patient is currently on Skyrizi therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Skyrizi Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Skyrizi*

AND

3 - Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq

(upadacitinib), Simponi (golimumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Skyrizi Complete program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Skyrizi (subcutaneous formulations) [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Skyrizi therapy

AND

2 - Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Skyrizi (subcutaneous formulations) [a]	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization for Maintenance Dosing
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - ONE of the following:

2.1 Patient has been approved for loading dose of Skyrizi under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active Crohn's disease

OR

2.2 BOTH of the following:

- Patient is currently on Skyrizi therapy for moderately to severely active Crohn's disease as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Skyrizi Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Skyrizi*

AND

3 - Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Tremfya (guselkumab), ustekinumab]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Skyrizi Complete program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Skyrizi (subcutaneous formulations) [a]	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Skyrizi therapy

AND

2 - Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Tremfya (guselkumab), ustekinumab]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Skyrizi (subcutaneous formulations) [a]	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization for Maintenance Dosing
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - ONE of the following:

2.1 Patient has been approved for loading dose of Skyrizi under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis

OR

2.2 BOTH of the following:

- Patient is currently on Skyrizi therapy for moderately to severely active ulcerative colitis as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Abbvie sponsored Skyrizi Complete program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Skyrizi*

AND

3 - Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)]

AND **4** - Prescribed by or in consultation with a gastroenterologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Abbvie sponsored Skyrizi Complete program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Skyrizi (subcutaneous formulations) [a]	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Skyrizi therapy **AND** **2** - Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)]	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Skyrizi is an interleukin-23 antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy and active psoriatic arthritis in adults, and moderately to severely active Crohn's disease in adults, and moderately to severely active ulcerative colitis in adults. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; May 2025.
2. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.
3. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80:1029-72.

5 . Revision History

Date	Notes
7/17/2025	Annual review with no change to coverage criteria. Updated drug exa mples and medical benefit loading dose language with no change to clinical intent. Updated references.

Sohonos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399247
Guideline Name	Sohonos
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	1/17/2024
P&T Revision Date:	10/16/2024 ; 9/25/2025

1 . Indications

Drug Name: Sohonos (palovarotene)
Fibrodysplasia ossificans progressiva (FOP) Indicated for reduction in the volume of new heterotopic ossification in adults and children aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP).

2 . Criteria

Product Name:Sohonos [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of fibrodysplasia ossificans progressiva (FOP)

AND

2 - Diagnosis has been confirmed by the presence of a mutation in the activin receptor IA (ACVR1) gene

AND

3 - ONE of the following:

3.1 BOTH of the following:

- Patient is female
- Patient is aged 8 years and older

OR

3.2 BOTH of the following:

- Patient is male
- Patient is aged 10 years and older

AND

4 - Sohonos is being used to reduce the volume of new heterotopic ossification (HO)

AND

5 - Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Sohonos [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response (e.g., reduction in new HO volume, improved CAJIS and FOP-PFQ scores, improved quality of life) **AND** **2** - Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Sohonos (palovarotene) is a retinoid indicated for reduction in the volume of new heterotopic ossification in adults and children aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP). **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Sohonos [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; August 2023.
2. 2. The International Clinical Council (ICC) on Fibrodysplasia Ossificans Progressiva (FOP) . The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. July 2024. Available at: Guidelines | International Clinical Council (ICC) on Fibrodysplasia Ossificans Progressiva (FOP) (iccfop.org). (Accessed on August 29, 2024).

5 . Revision History

Date	Notes
9/18/2025	Added state mandate language.

Somavert

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-334214
Guideline Name	Somavert
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	9/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 07/21/2021 ; 07/20/2022 ; 07/19/2023 ; 07/17/2024 ; 7/16/2025

1 . Indications

Drug Name: Somavert (pegvisomant)
Acromegaly Indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate.

2 . Criteria

Product Name:Somavert [a]	
Diagnosis	Acromegaly

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of acromegaly confirmed by ONE of the following:

- Serum GH level greater than 1 ng/mL after a 2-hour oral glucose tolerance test (OGTT) at time of diagnosis
- Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis

AND

1.2 ONE of the following:

1.2.1 Inadequate response to ONE of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

1.2.2 Not a candidate for ANY of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

AND

1.3 Inadequate response, intolerance, or contraindication to a long-acting somatostatin analog [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)]

OR **2** - Patient is currently on Somavert therapy for acromegaly

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Somavert [a]	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Somavert therapy (e.g., age-normalized serum IGF-1 level)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Additional Clinical Rules: • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

Background

Somavert (pegvisomant) is a growth hormone receptor antagonist indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin-like growth factor-I (IGF-I) levels.[1]

The American Association of Clinical Endocrinologists (AACE), Pituitary Society (PS) and Acromegaly Consensus Group (ACG) recommend pegvisomant in patients for whom surgical treatment and somatostatin analogues (SSAs) have proved ineffective or for those who are intolerant of SSAs.[2,4-6] The AACE, Endocrine Society (ES), and ACG also recommend that dopamine agonists may be considered as first-line medical therapy, particularly in patients with mild biochemical activity, such as in the setting of modestly elevated serum IGF-I levels in the absence or concomitant presence of SSA therapy.[2,3,5,6]

4 . References

1. Somavert [prescribing information]. New York, NY: Pfizer Inc.; July 2023
2. Katznelson L, Atkinson JL, Cook DM, et al.; American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly--2011 update. Endocr Pract. 2011 Jul-Aug;17Suppl 4:1-44.
3. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. Nov 2014;99(11):3933-3951.
4. Fleseriu, M, Biller, BMK, Freda, PU, et al. A Pituitary Society update to acromegaly management guidelines. Pituitary. 2021;24(1):1–13.
5. Giustina A, Barkan A, Beckers A, et al. A Consensus on the Diagnosis and Treatment of Acromegaly Comorbidities: An Update. J Clin Endocrinol Metab. 2020;105(4):dgz096.
6. Ogedegbe OJ, Cheema AY, Khan MA, et al. A Comprehensive Review of Four Clinical Practice Guidelines of Acromegaly. Cureus. 2022;14(9):e28722. Published 2022 Sep 3.

5 . Revision History

Date	Notes

7/17/2025	Annual review with no changes to coverage criteria. Removed footnote for FDA supported tried/failed alternatives that had referenced radiation and surgery. Updated background and references.

Spevigo

Prior Authorization Guideline

Guideline ID	GL-402264
Guideline Name	Spevigo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	5/17/2024
P&T Revision Date:	05/16/2025 ; 10/15/2025

Note:

This program applies to the subcutaneous formulations of Spevigo

1 . Indications

Drug Name: Spevigo® (spesolimab-sbzo) prefilled syringe
Generalized pustular psoriasis (GPP) Indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg.

2 . Criteria

Product Name:Spevigo [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of generalized pustular psoriasis (GPP) based on BOTH of the following:

- Presence of primary, sterile, macroscopically visible pustules on erythematous base
- Pustulation is not restricted to the acral region or within psoriatic plaques

AND

2 - BOTH of the following:

- Used to prevent GPP flares
- Patient is not currently experiencing a GPP flare

AND

3 - ONE of the following:

3.1 Patient has been established on therapy with Spevigo for GPP under an active UnitedHealthcare medical benefit prior authorization

OR

3.2 BOTH of the following:

- Patient is currently on Spevigo therapy for GPP as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has not received a manufacturer supplied sample at no cost in the prescriber's office, or via manufacturer's patient assistance programs (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Spevigo*

OR

3.3 ALL of the following:

3.3.1 Patient has not previously been treated with Spevigo

AND

3.3.2 During the previous 12 months prior to initiating subcutaneous Spevigo the patient has had one or more moderate to severe GPP flares based on one of the following:

- Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate)
- GPPPGA pustulation subscore ≥ 2 (mild)
- Erythema and pustules cover ≥ 5% of body-surface area
- New appearance or worsening of pustules

AND

3.3.3 Prescriber attests that the patient has experienced flares of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with subcutaneous Spevigo

AND

4 - Patient is NOT receiving Spevigo in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)] for treatment of the same indication

AND

5 - Prescribed by a dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the

	prescriber's office or via manufacturer's patient assistance programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Spevigo [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy [(e.g., preventing flares, reducing frequency of flares, prolonging time between flares, controlling signs and symptoms of GPP (e.g. pustules, erythema, pain, itching) between flares]

AND

2 - Reduction in the utilization of therapy (e.g., intravenous Spevigo) used for GPP flares

AND

3 - Patient is not receiving Spevigo in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)] for treatment of the same indication

AND

4 - Prescribed by a dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Spevigo is an interleukin-36 receptor antagonist indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limitations may be in place.

4 . References

1. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; May 2025.
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5 . Revision History

Date	Notes

9/30/2025	Added coverage criteria for self- or caregiver-administered subcutaneous loading dose. Updated references.

Spravato (PA, QL)



Prior Authorization Guideline

Guideline ID	GL-232234
Guideline Name	Spravato (PA, QL)
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	06/15/2022 ; 12/14/2022 ; 12/13/2023 ; 06/17/2024 ; 12/18/2024 ; 3/19/2025

1 . Indications

Drug Name: Spravato (esketamine)
Treatment-resistant depression Indicated for the treatment of treatment-resistant depression (TRD) in adults, as monotherapy or in conjunction with an oral antidepressant. **Major depressive disorder with acute suicidal ideation or behavior** Indicated for depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant.

2 . Criteria

Product Name:Spravato [a]	
Diagnosis	Major depressive disorder (treatment-resistant)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of major depressive disorder (treatment-resistant), according to the current DSM (i.e., DSM-5-TR) criteria, by a mental health professional

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting baseline scoring (prior to starting Spravato) on at least ONE of the following clinical assessments has been completed:

- Beck Depression Inventory (BDI)
- Hamilton Rating Scale for Depression (HAMD)
- Montgomery-Asberg Depression Rating Scale (MADRS)
- 9-item Patient Health Questionnaire (PHQ-9)
- Quick Inventory of Depressive Symptomatology (QIDS)

AND

3 - History of failure of a trial of at least TWO different antidepressant medications or treatment regimens for a duration of at least 8 weeks each (document medication, date, and duration of trial). An antidepressant or treatment regimen would include any of the following classes or combinations:

- Selective serotonin reuptake inhibitors (e.g., citalopram, fluoxetine, paroxetine, sertraline)
- Serotonin norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine, etc.)
- Bupropion
- Tricyclic antidepressants (e.g, amitriptyline, clomipramine, nortriptyline, etc.)
- Mirtazapine
- Monoamine oxidase inhibitors (e.g., selegiline, tranylcypromine, etc.)
- Serotonin modulators (e.g., nefazodone, trazodone, etc.)
- Augmentation with antipsychotics, lithium, or thyroid hormone

AND

4 - Provider and/or the provider's healthcare setting is certified in the Spravato REMS program

AND

5 - Prescribed by or in consultation with a psychiatrist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Spravato [a]	
Diagnosis	Major depressive disorder (treatment-resistant)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of remission or a positive clinical response to Spravato therapy

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting baseline and recent (within the last month) scoring on at least ONE of the following assessments demonstrating remission or clinical response (e.g., score reduction from baseline):

- BDI
- HAMD
- MADRS
- PHQ-9
- QIDS

AND

3 - Provider and/or the provider's healthcare setting is certified in the Spravato REMS program

AND

4 - Prescribed by or in consultation with a psychiatrist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Spravato* [a]	
Diagnosis	Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of major depressive disorder according to the current DSM (i.e., DSM-5-TR) criteria, by a mental health professional

AND

2 - Patient is experiencing an acute suicidal ideation or behavior

AND

3 - Spravato will be used in combination with a newly initiated or optimized oral antidepressant

AND **4** - Provider and/or the provider's healthcare setting is certified in the Spravato REMS program

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Note: Spravato is hard-coded with a quantity of 0.29 per day for the 56mg strength and 0.43 per day for the 84mg strength. If criteria are met, enter one GPI-12 authorization with an MDD override of 1 and a PQE of 24 per 28 days.

Product Name:Spravato* [a]	
Diagnosis	Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria **1** - The drug is prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in the compendia of current literature

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Note: Spravato is hard-coded with a quantity of 0.29 per day for the 56mg strength and 0.43 per day for the 84mg strength. If criteria are met, enter one GPI-12 authorization with an MDD override of 1 and a PQE of 24 per 28 days.

3 . Background

Benefit/Coverage/Program Information

Background:

Spravato (esketamine) is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, for the treatment of :

- Treatment-resistant depression (TRD) in adults, as monotherapy or in conjunction with an oral antidepressant.
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant.

Limitations of Use: The effectiveness of Spravato in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of Spravato does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of Spravato. Spravato is not approved as an anesthetic agent. The safety and effectiveness of Spravato as an anesthetic agent have not been established.

Because of the risks of serious adverse outcomes resulting from sedation, dissociation, and abuse and misuse, Spravato is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Spravato REMS.

For the purposes of this program, a trial and failure of a given antidepressant is defined as the patient unable to achieve a clinical meaningful improvement of the maximally tolerated dose(s) for at least 8 weeks.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Spravato [prescribing information]. Lakewood, NJ; Janssen Pharmaceuticals, Inc.; January 2025.
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14. Coley RY, Boggs JM, Beck A, Hartzler AL, Simon GE. Defining Success in Measurement-Based Care for Depression: A Comparison of Common Metrics. Psychiatr Serv. 2020;71(4):312-318. doi:10.1176/appi.ps.201900295
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5 . Revision History

Date	Notes

4/3/2025	Revised options for clinical assessments to reflect different item versi ons of the same scale as well as added BDI. Removed requirement f or combination with oral antidepressant for TRD per updated label. R evised coverage criteria for TRD to require history of failure of a trial of at least two different antidepressant medications or treatment regi mens, remove reference to current depressive episode, and remove augmentation with anticonvulsants as a treatment regimen based on latest clinical evidence. Updated references.

Sprycel, Phyrago

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-437193
Guideline Name	Sprycel, Phyrago
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 10/20/2021 ; 10/19/2022 ; 10/18/2023 ; 10/16/2024 ; 10/15/2025 ; 11/21/2025

1 . Indications

Drug Name: Sprycel (dasatinib), Phyrago (dasatinib)
Philadelphia Chromosome-Positive Chronic Myeloid Leukemia (Ph+ CML) Indicated for newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. It is also indicated for the treatment of pediatric patients 1 year of age and older with Ph+ CML in chronic phase. **Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)** FDA-labeled for treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia with resistance or intolerance to prior therapy. It is also indicated for the treatment of pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy. **Gastrointestinal stromal tumor** National Comprehensive Cancer Network (NCCN) also recommends the use of Sprycel as second line therapy in certain gastrointestinal stromal tumors with PDGFRA exon 18 mutations that are insensitive to imatinib

Metastatic chondrosarcoma The National Comprehensive Cancer Network (NCCN) also recommends the use of Sprycel in metastatic chondrosarcoma.

Chordoma The National Comprehensive Cancer Network (NCCN) also recommends the use of Sprycel in recurrent chordoma.

BCR-ABL1-Positive Chronic Myelogenous / Myeloid Leukemia The National Comprehensive Cancer Network (NCCN) also recommends the use of Sprycel in BCR-ABL1 positive CML.

Myeloid/lymphoid neoplasms The National Comprehensive Cancer Network (NCCN) also recommends the use of Sprycel in myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement.

2 . Criteria

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Philadelphia Chromosome-Positive or BCR-ABL1-Positive Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive or BCR-ABL1-Positive chronic myeloid leukemia

AND

2 - ONE of the following:

- Patient is not a candidate for imatinib as attested by physician
- Patient is currently on Sprycel or Phyrago therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Philadelphia Chromosome-Positive or BCR-ABL1-Positive Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Sprycel or Phyrago therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Sprycel or Phyrago therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of gastrointestinal stromal tumor (GIST) **AND** **2** - Tumor is PDGFRA exon 18 mutation positive that is insensitive to imatinib **AND** **3** - Patient has previously received Ayvakit (avapritinib)	

AND

4 - ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Preoperative/intraoperative tumor rupture
- Recurrent/metastatic disease with progression

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sprycel or Phyrago therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Chondrosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic chondrosarcoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Chondrosarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sprycel or Phyrago therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent chordoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Sprycel or Phyrago therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia **AND** **2** - Patient has an ABL1 rearrangement	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Sprycel or Phyrago therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib [a]	
Diagnosis	Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cutaneous melanoma **AND** **2** - Tumors are metastatic or unresectable	

AND **3** - Contains activating mutations of KIT **AND** **4** - Used as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib [a]	
Diagnosis	Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sprycel therapy.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Sprycel or Phyrago will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sprycel, generic dasatinib, Phyrago [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Sprycel or Phyrago therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Sprycel® (dasatinib) and Phyrago™ (dasatinib) are kinase inhibitors indicated for newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, for treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib, and for treatment of adults with Ph+

acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy. Sprycel is also indicated for the treatment of pediatric patients 1 year of age and older with Ph+ CML in chronic phase, and for the treatment of pediatric patients 1 year of age and older with Ph+ ALL in combination with chemotherapy.

The National Comprehensive Cancer Network (NCCN) also recommends the use of Sprycel or Phyrago in the following: BCR-ABL1 positive CML, as second line therapy in certain gastrointestinal stromal tumors with PDGFRA exon 18 mutations that are insensitive to imatinib, metastatic chondrosarcoma, in recurrent chordoma and in myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement.

The NCCN recommends the use of Sprycel in cutaneous melanoma with metastatic or unresectable tumors with activating mutations of KIT as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may be in place

4 . References

1. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; July 2024.
2. Phyrago [package insert]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; July 2025.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 8, 2025.

5 . Revision History

Date	Notes
11/5/2025	Added Phyrago to policy. Updated references.

State Mandates Administrative

Prior Authorization Guideline

Guideline ID	GL-550195
Guideline Name	State Mandates Administrative
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	4/15/2026
P&T Approval Date:	11/13/2020
P&T Revision Date:	01/21/2021 ; 10/06/2021 ; 10/20/2021 ; 12/15/2021 ; 02/17/2023 ; 09/20/2023 ; 12/13/2023 ; 12/17/2025 ; 4/15/2026

Note:

Termination date of authorizations approved pursuant to this guideline is stated in the drug specific guideline.

1 . Criteria

Guideline Type	Administrative
Approval Criteria **1** - Please see background section for criteria	

2 . Background

Benefit/Coverage/Program Information

Background:

This document serves as a resource to highlight individual state mandates that may impact existing utilization management programs. Utilization programs include but are not limited to step therapy, prior authorization, supply limits, first-line trial duration limitations and pain therapy/end of life regulations. Select state mandates may require medical records for documentation. New and revised mandates will be reviewed quarterly with the Utilization Management (UM) committee.

This resource only focuses on sections of state mandates that pertain to utilization management programs. This reference document does not cite full state mandates.

1. Core Strategy for ALL Individual and Family Plan (IFP) States

a. **Step Therapy Exceptions*,** All States (effective 1/1/26)

STEP BYPASS EXCEPTIONS: Cannot require alternatives in one of the following scenarios:

1. The drug(s) required under the step therapy protocol is not in the best interest of the member, based on clinical appropriateness or medical necessity, because the member's use of the drug is expected to:

- Be ineffective based on the known clinical characteristics of the member and the known characteristics of the prescription drug regimen
- Be ineffective based on sound clinical evidence or medical and scientific evidence
- Be contraindicated or is detrimental to the member’s health, including:
- Cause a harmful or adverse reaction,
- Cause a clinically predictable negative drug interaction,
- Cause physical or mental harm,
- Worsening a comorbid condition of the patient
- Cause a significant barrier to the member’s adherence to or compliance with the member’s plan of care, or

- Decrease the member's ability to achieve or maintain reasonable functional ability in performing daily activities.

2. The member previously discontinued taking the drug(s) required under the step therapy protocol or another prescription drug in the same pharmacologic class or with the same mechanism of action as the required drug because the drug:

- Lacked efficacy or effectiveness,
- Had a diminished effect, or
- Caused an adverse event or contraindication.

3. Member is new to the plan: The provider attests the member is currently stabilized on the requested medication for the medical condition under consideration.

4. Member is not new to plan:

- The member has a paid claim within the past 120 days OR
- The provider submits medical records showing the member is currently stabilized on the requested medication for the medical condition under consideration.

* This bypass does not apply to AB-rated generic equivalents, biosimilar products, or interchangeable biological products.

Samples and drugs obtained through coupon cards may NOT count to satisfy the requirements of the core step therapy bypass.

This Step Therapy Exception applies to PA with embedded step criteria and step therapy. This exception also applies to non-formulary drugs in some states.

2. Colorado:

a. Step Therapy Exception for Metastatic Cancer, CO22-21309458 C.R.S. §10-16-145.5 (effective 01/01/2023)

A carrier that provides coverage under a health benefit plan for the treatment of stage four advanced metastatic cancer shall not limit or exclude coverage under the health benefit plan for a drug approved by the FDA and that is on the carrier's prescription drug formulary by mandating that a covered person with stage four advanced metastatic cancer undergo STEP THERAPY if the use of the approved drug is consistent with:

- The FDA-approved indication or
- The National Comprehensive Cancer Network Drugs and Biologics Compendium

indication for the treatment of stage four advanced metastatic cancer; or
- Peer-reviewed medical literature.

b. Step Therapy Exception for Serious Mental Illness, CO25.5-5-516 (effective 1/1/2025)

If a covered person's provider attests that any of the criteria are met, the carrier, private utilization review organization, or PBM must cover the drug prescribed by the covered person's provider without requiring step therapy.

Serious mental illness means the following psychiatric illnesses, as defined by the American Psychiatric Association in the most recent version of the Diagnostic and Statistical Manual of Mental Disorders: bipolar disorders, depression in childhood and adolescence, major depressive disorders, obsessive-compulsive disorders, paranoid and other psychotic disorders, schizoaffective disorders, schizophrenia.

3. Georgia:

a. Terminal Condition, GA15-1507096 O.C.G.A §33-24-59.18 (effective 7/1/2015)

No health benefit plan shall restrict coverage for treatment of a terminal condition when such treatment has been prescribed by a physician as medically appropriate and such treatment has been agreed to by an insured patient or by a person to whom the insured patient has legally delegated such authority or to whom otherwise has the legal authority to consent on behalf of the insured patient. The health benefit plan shall not refuse to pay or otherwise reimburse for the treatment diagnosed under this subsection, including any drug or device, so long as such end of life care is consistent with best practices for the treatment of the terminal condition and such treatment is supported by peer reviewed medical literature.

'Terminal condition' means any disease, illness, or health condition that a Physician has diagnosed as expected to result in death in 24 months or less.

b. Step Therapy Exception for Metastatic Cancer, GA Code §33-24-59.20 (effective 1/1/20)

No health benefit plan issued, delivered, or renewed in this state that, as a provision of hospital, medical, or surgical services, directly or indirectly covers the treatment of stage four

advanced, metastatic cancer shall limit or exclude coverage for a drug approved by the United States Food and Drug Administration by mandating that the insured shall first be required to fail to successfully respond to a different drug or drugs or prove a history of failure of such drug or drugs; provided, however, that the use of such drug or drugs is consistent with best practices for the treatment of stage four advanced, metastatic cancer and is supported by peer reviewed medical literature. Other mandate provisions define "health benefit plan" and "stage four advanced, metastatic cancer."

4. Illinois:

a. Non-Formulary and Step Therapy Exception IL16-3027525 215 ILCS 134/45.1 (effective 1/1/2018)

A step therapy requirement exception request shall be approved if:
- the required prescription drug is contraindicated;
- the patient has tried the required prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or
- the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan.

b. Step Therapy Exception for Stage 4 Advanced, Metastatic Cancer IL18-9299149 215 ILCS 5/356z.29 (effective 1/1/2019)

No individual or group policy of accident and health insurance amended, issued, delivered, or renewed in this State after the effective date of this amendatory Act of the 100th General Assembly that, as a provision of hospital, medical, or surgical services, directly or indirectly covers the treatment of stage 4 advanced, metastatic cancer shall limit or exclude coverage for a drug approved by the United States Food and Drug Administration by mandating that the insured shall first be required to fail to successfully respond to a different drug or prove history of failure of the drug as long as the use of the drug is consistent with best practices for the treatment of stage 4 advanced, metastatic cancer and is supported by peer-reviewed medical literature

c. **Zero Dollar Cost Share for Medically Necessary Abortifacients, Hormone Therapy for Gender Dysphoria and PrEP/PEP** IL23-23712618 EI, ILCS 5/356z.60 (effective 1/1/2024)

- An individual or group policy of accident and health insurance amended, delivered, issued, or renewed in this State on or after January 1, 2024 shall provide coverage

for all abortifacients, hormonal therapy medication, human immunodeficiency virus pre-exposure prophylaxis, and post-exposure prophylaxis drugs approved by the United States Food and Drug Administration, and follow-up services related to that coverage, including, but not limited to, management of side effects, medication self-management or adherence counseling, risk reduction strategies, and mental health counseling. This coverage shall include drugs approved by the United States Food and Drug Administration that are prescribed or ordered for off-label use for the purposes described in this Section.

- The coverage required under subsection (b) is subject to the following conditions:
  - If the United States Food and Drug Administration has approved one or more therapeutic equivalent versions of an abortifacient drug, a policy is not required to include all such therapeutic equivalent versions in its formulary so long as at least one is included and covered without cost sharing and in accordance with this Section.
  - If an individual's attending provider recommends a particular drug approved by the United States Food and Drug Administration based on a determination of medical necessity with respect to that individual, the plan or issuer must defer to the determination of the attending provider and must cover that service or item without cost sharing.
  - If a drug is not covered, plans and issuers must have an easily accessible, transparent, and sufficiently expedient process that is not unduly burdensome on the individual or a provider or other individual acting as a patient's authorized representative to ensure coverage without cost sharing.

The conditions listed under this subsection (c) also apply to drugs prescribed for off-label use as abortifacients.

d. Medically Necessary Treatment for Menopause IL 2023000 H 5295 (effective 1/1/2026)

A group or individual policy of accident and health insurance or a managed care plan shall provide coverage for medically necessary hormonal and non-hormonal therapy to treat menopausal symptoms if the therapy is recommended by a qualified health care provider who is licensed, accredited, or certified under Illinois law and the therapy has been proven safe and effective in peer-reviewed scientific studies. Coverage for therapy to treat menopausal symptoms shall include all federal Food and Drug Administration-approved modalities of hormonal and nonhormonal administration, including, but not limited to, oral, transdermal, topical, and vaginal rings.

5. Louisiana:

a. Step Therapy Exception for Stage 4 Advanced, Metastatic Cancer LA19-13246769 EI La. R.S. 22:1053 (effective 6/5/2019)

No health coverage plan shall use step therapy or fail first protocols as the basis to restrict any prescription benefit for the treatment of stage-four advanced, metastatic cancer or associated conditions if at least one of the following criteria is met:

- The prescribed drug or drug regimen has the United States Food and Drug Administration approved indication.
- The prescribed drug or drug regimen has the National Comprehensive Cancer Network Drugs and Biologic Compendium indication.
- The prescribed drug or drug regimen is supported by peer-reviewed, evidenced-based medical literature.

The provisions this Section shall not apply if the preferred drug or drug regimen is considered clinically equivalent for therapy, contains the identical active ingredient or ingredients, and is proven to have the same efficacy. For purposes of this Subsection, different salts proven to have the same efficacy shall not be considered as different active ingredients.

b. Exception for Cancer Treatment Targeting A Specific Genetic Mutation, LA 2022000 S 146 EI La. Stat. 22:§1054.1 (A) (effective 8/1/22)

No health coverage plan delivered or issued for delivery in this state shall deny coverage for the treatment of metastatic or unresectable tumors or other advanced cancers with a medically necessary drug prescribed by a physician on the sole basis that the drug is not indicated for the specific tumor type or location in the body of the patient's cancer if the drug is approved by the United States Food and Drug Administration for the treatment of the specific mutation in a different type of cancer. Insurers shall not consider the treatment experimental or outside of their policy scope if the United States Food and Drug Administration has approved the drug for the treatment of cancer with the specific genetic mutation, even if in a different tumor type. This coverage may be denied only if an alternative treatment has proven to be more effective in published randomized clinical trials and is not contraindicated in the patient.

c. Off-Label Use Exception, R.S. 22:1060.8 (effective 1/1/23)

No health coverage plan delivered or issued for delivery in this state shall limit or exclude coverage involving a minor for a drug on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved by the United States Food and Drug Administration and all of the following apply:

- The drug has been approved by the United States Food and Drug Administration.
- The drug is prescribed by a licensed healthcare provider for the treatment of a life threatening, chronic, or seriously debilitating disease or condition in a minor and the drug has been approved by the United States Food and Drug Administration for the same condition or disease in an adult and the drug is medically necessary to treat the disease or condition.
- The drug has been recognized for the treatment of the disease or condition in pediatric application by one of the following:
    - The American Hospital Formulary Service Drug Information
    - The United States Pharmacopeia Dispensing Information, Volume 1, "Drug Information for the Health Care Professional"
    - Recognized in two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed journal.

d. Cancer Prior Authorization Requirements LA23-23518873 R.S. 22:1060.14 (effective 1/1/2024)

No health coverage plan that is renewed, delivered, or issued for delivery in this state that provides coverage for cancer in accordance with the Louisiana Insurance Code shall deny a request for prior authorization or the payment of a claim for any procedure, pharmaceutical, or diagnostic test typically covered under the plan to be provided or performed for the diagnosis and treatment of cancer if the procedure, pharmaceutical, or diagnostic test is recommended by nationally recognized clinical practice guidelines or consensus statements for use in the diagnosis or treatment for the insureds particular type of cancer and clinical state.

e. Step Therapy Exception for Menopause and Perimenopause, LA 2024000 H 392 R.S. 22:988 (effective 8/1/2024)

A health insurance issuer offering health coverage plans in this state shall provide coverage for any medically necessary care or treatment for menopause and perimenopause.

A health insurance issuer shall not require a prior authorization or otherwise be subject to a step-therapy or fail-first policy or protocol for the administration or prescription of any medication administered or prescribed for hormone replacement therapy used to treat symptoms of menopause and perimenopause

f. Urinary and Sexual Dysfunction for Cancer Patients, LA 2024000 H 508 (effective 7/1/2025)

Health benefit plans shall not deny coverage for drugs used to treat urinary and sexual dysfunction as chosen by the patient diagnosed with cancer in consultation with the attending physician. Treatment procedures to be performed following a diagnosis of cancer shall be made solely by the patient in consultation with attending physicians. All levels of medical and surgical treatment found medically necessary shall not be excluded

6. Maryland:

a. Non-Formulary and Step Therapy Exception MD 23-23313747, MD INS Code Ann. §15-141 (effective 1/1/2024)

An entity subject to this section may not impose a Step Therapy or Fail - First Protocol on an insured or enrollee if:

- The Step Therapy Drug has not been approved by the U.S. Food and Drug Administration for the medical condition being treated; or
- A prescriber provides supporting medical information to the entity that a prescription drug covered by the entity:
    - Was ordered by a prescriber for the insured or enrollee within the past 180 days; and
    - Based on the professional judgment of the prescriber, was effective in treating the insured's or enrollee's disease or medical condition.

A step therapy exception request shall be granted if, based on the professional judgment of the prescriber and any information and documentation required when:

- The step therapy drug is contraindicated or will likely cause an adverse reaction to the insured or enrollee;
- The step therapy drug is expected to be ineffective based on the known clinical characteristics of the insured or enrollee and the known characteristics of the prescription drug regimen;
- The insured or enrollee is stable on a prescription drug prescribed for the medical condition under consideration while covered under the policy or contract of the entity or under a previous source of coverage; or
- While covered under the policy or contract of the entity or a previous source of coverage, the insured or enrollee has tried a prescription drug that:
    - Is in the same pharmacologic class or has the same mechanism of action as the step therapy drug; and
    - Was discontinued by the prescriber due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

This subsection may not be construed to prevent:

- An entity subject to this section from requiring an insured or enrollee to try an AB-rated generic equivalent or interchangeable biologic product before providing coverage for the equivalent branded prescription drug; OR
- A health care provider from prescribing a prescription drug that is determined to be medically inappropriate; or
    - Require an entity subject to this section to provide coverage for a prescription drug that is not covered by a policy or contract of the entity

b. Step Therapy Exception for Stage 4 Advanced, Metastatic Cancer, MD17-4512688 MD INS Code §15-142 (effective 10/1/2017)

An entity subject to this section may not impose a step therapy or fail-first protocol on an insured or an enrollee for a prescription drug approved by the U.S. Food and Drug Administration if:

- The prescription drug is used to treat the insured's or enrollee's stage four advanced metastatic cancer; and
- Use of the prescription drug is:
    - Consistent with the U.S. Food and Drug Administration-approved indication or
        - The National Comprehensive Cancer Network Drugs & Biologics Compendium Indication for the treatment of stage four advanced metastatic cancer; and
    - Supported by peer-reviewed medical literature.

c. **Step Therapy Exception for Insulin or Insulin Analogs**, MD 2025000 H 970 (effective 1/1/2026)

An entity subject to this section may not impose a step therapy or fail-first protocol on an insured or an enrollee for a prescription drug approved by the U.S. Food and Drug Administration if the prescription drug is insulin or an insulin analog used to treat the insureds's or enrollees's Type 1, Type 2, or gestational diabetes.

7. Mississippi:

a. Terminal Condition, § 83-9-22
Health coverage plans prohibited from restricting coverage for medically appropriate treatment prescribed by physician based on insured's diagnosis with terminal condition.;

(1); (a) Notwithstanding any other provision of the law to the contrary, no health coverage plan shall restrict coverage for medically appropriate treatment prescribed by a physician and agreed to by a fully informed insured, or if the insured lacks legal capacity to consent by a person who has legal authority to consent on his or her behalf, based on an insured's diagnosis with a terminal condition. Refusing to pay for treatment rendered to an insured near the end of life that is consistent with best practices for treatment of a disease or condition, approved uses of a drug or device, or uses supported by peer reviewed medical literature, is a per se violation of this section;
(b) Violations of this section shall constitute an unfair trade practice and subject the violator to the penalties provided by law;
(c) As used in this section "terminal condition" means any aggressive malignancy, chronic end-stage cardiovascular or cerebral vascular disease, or any other disease, illness or condition which a physician diagnoses as terminal;
(d) As used in this section, a "health coverage plan" shall mean any hospital, health or medical expense insurance policy, hospital or medical service contract, employee welfare benefit plan, contract or agreement with a health maintenance organization or a preferred provider organization, health and accident insurance policy, or any other insurance contract of this type, including a group insurance plan and the State Health and Life Insurance Plan.;
(2); (a) Notwithstanding any other provision of the law to the contrary, no health benefit paid directly or indirectly with state funds, specifically Medicaid, shall restrict coverage for medically appropriate treatment prescribed by a physician and agreed to by a fully informed individual, or if the individual lacks legal capacity to consent by a person who has legal authority to consent on his or her behalf, based on an individual's diagnosis with a terminal condition.;
(b) Refusing to pay for treatment rendered to an individual near the end of life that is consistent with best practices for treatment of a disease or condition, approved uses of a drug or device, or uses supported by peer reviewed medical literature, is a per se violation of this section;
(c) As used in this section "terminal condition" means any aggressive malignancy, chronic end-stage cardiovascular or cerebral vascular disease, or any other disease, illness or condition which a physician diagnoses as terminal.

b. Step Therapy Exception for Advanced, Metastatic Cancer and Associated Conditions MS § 83-9-36, HB 2143 (effective 8/1/2024)

A health benefit plan that provides coverage for advanced, metastatic cancer and associated conditions may not require, before the health benefit plan provides coverage of a

prescription drug approved by the United States Food and Drug Administration, that the enrollee:

(a) Fail to successfully respond to a different drug; or

(b) Prove a history of failure of a different drug.

This section applies only to a drug the use of which is:

(a) Consistent with best practices for the treatment of advanced, metastatic cancer or an associated condition.

(b) Supported by peer-reviewed, evidence-based literature; and

(c) Approved by the United States Food and Drug Administration.

An override of that restriction shall be expeditiously granted by the insurer under the following circumstances:

(a) The prescribing practitioner can demonstrate, based on sound clinical evidence, that the preferred treatment required under step therapy or fail-first protocol has been ineffective in the treatment of the insured's disease or medical condition; or

(b) Based on sound clinical evidence or medical and scientific evidence:

(i) The prescribing practitioner can demonstrate that the preferred treatment required under the step therapy or fail-first protocol is expected or likely to be ineffective based on the known relevant physical or mental characteristics of the insured and known characteristics of the drug regimen; or

(ii) The prescribing practitioner can demonstrate that the preferred treatment required under the step therapy or fail-first protocol will cause or will likely cause an adverse reaction or other physical harm to the insured.

“Associated conditions" means the symptoms or side effects associated with advanced, metastatic cancer or its treatment and which, in the judgment of the health care practitioner, further jeopardizes the health of a patient if left untreated.

“Advanced, metastatic cancer" means cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes, or other areas or parts of the body.

8. New Mexico

a. Medically Necessary Treatment of Autoimmune Disorder, Cancer, Rare Disease and Substance Use Disorder, NM24-25727768 NM INS Code §59A-22B-8 (effective 7/1/2025)

Coverage for medication approved by the federal food and drug administration that is prescribed for the treatment of an autoimmune disorder, cancer, rare disease or condition or a substance use disorder, pursuant to a medical necessity determination made by a health care professional from the same or similar practice specialty that typically manages the medical condition, procedure or treatment under review, shall not be subject to prior authorization, except in cases in which a biosimilar, interchangeable biologic or generic version is available.

A health insurer shall not impose step therapy requirements before authorizing coverage for medication approved by the federal food and drug administration that is prescribed for the treatment of an autoimmune disorder, cancer or a substance use disorder, pursuant to a medical necessity determination, except in cases in which a biosimilar, interchangeable biologic or generic version is available.

A health insurer shall not impose step therapy requirements before authorizing coverage for an off-label medication that is prescribed for the treatment of a rare disease or condition, pursuant to a medical necessity determination made by a health care professional from the same or similar practice specialty that typically manages the medical condition, procedure or treatment under review, except in cases in which a biosimilar, interchangeable biologic or generic version is available.

“Rare disease or condition" means a disease or condition that affects fewer than two hundred thousand people in the United States.

9. New York

a. Non-Formulary and Step Therapy Exception, NY17-3767755 47 NY INS Law §4900 (effective 1/1/2026)

A utilization review agent shall grant a step therapy protocol override determination within seventy-two hours of the receipt of information that includes supporting rationale and documentation from a health care professional which demonstrates that:

- The required prescription drug or drugs is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the insured;
- The required prescription drug or drugs is expected to be ineffective based on the known clinical history and conditions of the insured and the insured's prescription drug regimen;
- The insured has tried the required prescription drug or drugs while under their current or a previous health insurance or health benefit plan, or another prescription drug or drugs in the same pharmacologic class or with

the same mechanism of action and such prescription drug or drugs was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

- The insured is stable on a prescription drug or drugs selected by their health care professional for the medical condition under consideration, provided that this shall not prevent a utilization review agent from requiring an insured to try an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug or drugs; or
- The required prescription drug or drugs is not in the best interest of the insured because it will likely cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care, will likely worsen a comorbid condition of the insured , or will likely decrease the covered individual's ability to achieve or maintain reasonable functional ability in performing daily activities.

Questions and Answers on Step Therapy Legislation (Chapter 512 of the Laws of 2016) May 2, 2017

Q.19 Do the use of prescription drug samples or drugs obtained through coupon cards meet the criteria in Insurance Law § 4903(c1)(4) and Public Health Law § 4903(3a)(d) for the insured to be stable on a prescription drug?

Insurance Law § 4903(c1)(4) and Public Health Law § 4903(3a)(d) require the insured to be stable on a prescription drug or drugs selected by his or her health care professional for the medical condition under consideration. Insureds who undergo a trial period of a prescription drug primarily due to the availability of free or low cost samples or where the prescription drug was not selected by the insured's health care professional specifically for the insured's medical condition, may not have sufficient experience with available therapies for the insured's condition to meet the requirements in these sections of the law, depending upon review of the prescriber's documentation, the insured's documented case history, and whether the health plan's criteria has otherwise been met. See Q.18 with respect to when an insured could be considered stable

10. Ohio:

a. Step Therapy Exception for Stage 4 Advanced, Metastatic Cancer, OH21-16933950, ORC **§ 3902.51** (effective 3/24/2021)

A health benefit plan issued, delivered, or renewed in Ohio on or after 3/24/2021 that directly or indirectly covers the treatment of stage four advanced metastatic cancer is prohibited from making coverage of a drug that is prescribed to treat such cancer or associated conditions dependent upon a covered person demonstrating either of the following:

- Failure to successfully respond to a different drug;
- A history of failing to respond to a different drug or drugs.

This prohibition applies only to uses of such drug or drugs that are consistent with either of the following:

- An indication approved by, or described in, as applicable, either of the following for the treatment of stage four advanced metastatic cancer:
  - The United States Food and Drug Administration;
  - The National Comprehensive Cancer Network drugs and biologics compendium.
- The best practices for the treatment of stage four advanced metastatic cancer, as supported by peer-reviewed medical literature.

A violation of this prohibition is an unfair and deceptive practice in the business of insurance.

11. Oklahoma:

a. Step Therapy Exception for Stage 4 Advanced, Metastatic Cancer, H-2748, OK23-2329415 (effective 11/1/23)

A health benefit plan that provides coverage for advanced metastatic cancer and associated conditions may not require, before providing coverage of an FDA-approved prescription drug, that the enrollee: (1) fails to successfully respond to a different drug; or (2) proves a history of failure of a different drug. This prohibition applies only to a drug, the use of which is: (1) consistent with best practices for the treatment of advanced metastatic cancer or an associated condition; (2) supported by peer-reviewed, evidence-based literature; and (3) approved by the FDA.

b. Authorization Approval Duration for 3 Years for Chronic Conditions, OK25-27770074 OK Stat. Title 36 § 6570.56 (effective 11/1/2025)

A. If a prior authorization is required for a prescription drug for the treatment of a chronic condition of an enrollee, and the enrollee remains on the same health plan, then the prior authorization shall remain valid for three (3) years from the date the health care provider receives the prior authorization approval, unless clinical criteria changes, the enrollee's health plan removes the generic prescription drug from the formulary, or moves the prescription drug to a less preferred tier status on its formulary.

B. This section shall not apply to prior authorizations approved for:

1. A prescription drug that is an opioid or is a controlled substance that is prohibited from being dispensed without a prescription under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C., Section 301 et seq., as amended; or
2. A prescription drug for the treatment of weight loss.

12. Tennessee:

a. Step Therapy Exception for Stage 4 Advanced, Metastatic Cancer and Associated Conditions, TN 2025000 H 858 (effective 1/1/2026)

(1) A health benefit plan that provides coverage for stage 4 advanced metastatic cancer, metastatic blood cancer, and associated conditions shall not require use of a step therapy protocol before the health benefit plan provides coverage of an approved prescription drug to an enrollee who has received a diagnosis of stage 4 advanced metastatic cancer or metastatic blood cancer.

(2) For an approved prescription drug prescribed for an associated condition in this section, the treating healthcare provider shall inform the health benefit plan that the condition is an associated condition of stage 4 advanced metastatic cancer or metastatic blood cancer when requesting authorization.

"Associated conditions" means the symptoms or side effects associated with stage 4 advanced metastatic cancer, metastatic blood cancer, or treatment of such cancers and which, in the judgment of the healthcare provider, further jeopardizes the health of a patient if left untreated.

13. Texas:

a. Step Therapy Exception for Stage 4 Advanced, Metastatic Cancer, TX19-13305672 Tex. Ins. Code §1369.213 (effective 1/1/2020)

A health benefit plan that provides coverage for stage-four advanced, metastatic cancer and associated conditions may not require, before the health benefit plan provides coverage of a prescription drug approved by the United States Food and Drug Administration (FDA), that the enrollee:

- Fail to successfully respond to a different drug; or
- Prove a history of failure of a different drug.

This section applies only to a drug the use of which is:

- Consistent with best practices for the treatment of stage-four advanced, metastatic cancer or an associated condition;
- Supported by peer-reviewed, evidence-based literature; and
- Approved by the United States Food and Drug Administration.

b. Step Therapy Exception for Serious Mental Illness TX23-23491650 §1369.0547 (effective 1/1/2024)

This section applies only to a drug prescribed to an enrollee who is 18 years of age or older to treat a diagnosis of a serious mental illness. A health benefit plan that provides coverage for prescription drugs to treat a serious mental illness may not require, before the health benefit plan provides coverage of a prescription drug approved by the United States Food and Drug Administration, that the enrollee:

- fail to successfully respond to more than one different drug for each drug prescribed, excluding the generic or pharmaceutical equivalent of the prescribed drug; or
- prove a history of failure of more than one different drug for each drug prescribed, excluding the generic or pharmaceutical equivalent of the prescribed drug.

Subject to Section 1369.0546, a health benefit plan issuer may implement a step therapy protocol to require a trial of a generic or pharmaceutical equivalent of a prescribed prescription drug as a condition of continued coverage of the prescribed drug only:

- once in a plan year; and
- if the generic or pharmaceutical equivalent drug is added to the plan's drug formulary.

c. Coverage of Gender Transition Adverse Effects and Reversals, TX 2025000 S 1257 (effective 1/1/2026)

A health benefit plan that provides or has ever provided coverage for an enrollee's gender transition procedure or treatment shall provide coverage:

- all possible adverse consequences related to the enrollee's gender transition procedure or treatment, including any short- or long-term side effects of the procedure or treatment;
- any baseline and follow-up testing or screening necessary to monitor the mental and physical health of the enrollee on at least an annual basis without regard to the sex or gender identity designation in the enrollee's medical record; and
- any procedure, treatment, or therapy necessary to manage, reverse, reconstruct from, or recover from the enrollee's gender transition procedure or treatment.

14. Virginia:

a. Continuity of Care for Treatment of a Mental Disorder, VA21-17387330 VA code §38.2-3407.15:2 (effective 7/1/2021)

Any provider contract between a carrier and a participating health care provider with prescriptive authority, or its contracting agent, shall contain specific provisions that:

• Require that when any carrier has previously approved prior authorization for any drug prescribed for the treatment of a mental disorder listed in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association, no additional prior authorization shall be required by the carrier, provided that (i) the drug is a covered benefit; (ii) the prescription does not exceed the FDA-labeled dosages; (iii) the prescription has been continuously issued for no fewer than three months; and (iv) the prescriber performs an annual review of the patient to evaluate the drug's continued efficacy, changes in the patient's health status, and potential contraindications. Nothing in this subdivision shall prohibit a carrier from requiring prior authorization for any drug that is not listed on its prescription drug formulary at the time the initial prescription for the drug is issued.

b. **Non-Formulary Exception Process**, VA Code Ann. § 38.2-3407.9:01 (effective 8/1/2024)

If an insurer, corporation, or health maintenance organization maintains one or more closed drug formularies, each insurer, corporation, or health maintenance organization shall:

Establish a process to allow an enrollee to obtain, without additional cost-sharing beyond that provided for formulary prescription drugs in the enrollee's covered benefits, a specific, medically necessary nonformulary prescription drug when the enrollee has been receiving the specific nonformulary prescription drug for at least six months previous to the development or revision of the formulary and the prescribing physician has determined that the formulary drug is an inappropriate therapy for the specific patient or that changing drug therapy presents a significant health risk to the specific patient. After reasonable investigation and consultation with the prescribing physician, the insurer, corporation or health maintenance organization shall act on such requests within one business day of receipt of the request. For purposes of this subsection, substituting the generic equivalent drug, which has been approved by the U.S. Food and Drug Administration, for a branded version of such drug shall not constitute a change in drug therapy.

15. Washington

a. Non-Formulary and Step Therapy Exception, WA19-12810894 48.43 RCW (effective 1/1/2021)

An exception request must be granted if the health carrier or prescription drug utilization management entity determines that the evidence submitted by the provider or patient is sufficient to establish that:

- The required prescription drug is contraindicated or will likely cause a clinically predictable adverse reaction by the patient;
- The required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;
- The patient has tried the required prescription drug or another prescription drug in the same pharmacologic class or a drug with the same mechanism of action while under his or her current or a previous health plan, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
- The patient is currently experiencing a positive therapeutic outcome on a prescription drug recommended by the patient's provider for the medical condition under consideration while on his or her current or immediately preceding health plan, and changing to the required prescription drug may cause clinically predictable adverse reactions, or physical or mental harm to, the patient; or
- The required prescription drug is not in the best interest of the patient, based on documentation of medical appropriateness, because the patient's use of the prescription drug is expected to:
    a. Create a barrier to the patient's adherence to or compliance with the patient's plan of care;
    b. Negatively impact a comorbid condition of the patient;
    c. Cause a clinically predictable negative drug interaction; or
    d. Decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities
- This section does not prevent:
    a. A health carrier or prescription drug utilization management entity from requiring a patient to try an AB-rated generic equivalent or a biological product that is an interchangeable biological product prior to providing coverage for the equivalent branded prescription drug;
    b. A health carrier or prescription drug utilization management entity from denying an exception for a drug that has been removed from the market due to safety concerns from the federal food and drug administration; or
    c. A health care provider from prescribing a prescription drug that is determined to be medically appropriate

b. Continuity of Care, WA21-16859749 WAC 284-43-2021 (effective 1/1/2021)

A carrier must not require the enrollee to submit a new exception request for a refill if the enrollee’s prescribing physician or other prescriber continues to prescribe the drug and the drug continues to be approved by the U.S. Food and Drug Administration for treating the enrollee’s disease or medical condition, or if the drug was prescribed as part of the enrollee’s participation in a clinical trial.

- If the substituted drug is for an off-label drug use, a carrier may require the enrollee to

submit a new exception request when a prescription fill and renewal cycle ends.
• A carrier may require an enrollee to try and AB-rated generic equivalent or a biological product that is an interchangeable biological product prior to providing coverage for the equivalent branded prescription drug.
• A carrier must consider exception requests for a U.S. Food and Drug Administration approved drug used for purposes other than what is indicated on the official label if the use is medically acceptable. A carrier must take into consideration major drug compendia, authoritative medical literature, and accepted standards of practice when making its decision.

3 . Revision History

Date	Notes
3/13/2026	Added Authorization Approval Duration for 3 Years for Chronic Conditions to Oklahoma.

Step Therapy Antiparkinson Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-162170
Guideline Name	Step Therapy Antiparkinson Agents
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	2/1/2025
P&T Approval Date:	11/13/2020
P&T Revision Date:	09/15/2021 ; 12/18/2024

1 . Criteria

Product Name:Rasagiline (generic Azilect) [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication, or intolerance to the following:	

• selegiline (generic Eldepryl)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background: Rasagiline (generic Azilect) is an antiparkinson agent indicated for the treatment of Parkinson's disease as monotherapy or as adjunct therapy in patients taking / not taking levodopa, with or without other Parkinson's Disease drugs. Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try selegiline before providing coverage for Rasagiline (generic Azilect). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

3 . References

1. Rasagiline [package insert]. Overland Park, KS: Teva Neuroscience; April 2021.

4 . Revision History

Date	Notes
12/17/2024	Removed documentation requirement of step therapy.

Step Therapy Atypical Antipsychotics

Prior Authorization Guideline

Guideline ID	GL-461344
Guideline Name	Step Therapy Atypical Antipsychotics
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	1/20/2021
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 05/20/2022 ; 05/20/2022 ; 06/21/2023 ; 08/18/2023 ; 10/01/2024 ; 12/18/2024 ; 12/17/2025

1 . Criteria

Product Name:generic asenapine [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication, or intolerance to TWO of the following:	

- olanzapine oral or orally disintegrating tablets
- quetiapine oral immediate release or extended-release tablets
- risperidone oral solution, oral disintegrating, or tablets
- ziprasidone oral capsules
- aripiprazole immediate release tablets
- lurasidone tablets

OR

2 - Treatment was initiated at a recent behavioral inpatient admission and the member is currently stable on therapy

OR

3 - The member is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and currently stabilized on therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:generic asenapine [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Step Therapy

Approval Criteria

1 - Documentation of positive clinical response

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background: Asenapine (generic Saphris) is an atypical antipsychotic indicated for the treatment of Schizophrenia in adults; Bipolar I disorder as acute monotherapy treatment of manic or mixed episodes in adults and pediatric patients 10 to 17 years of age, adjunctive treatment to lithium or valproate in adults, and maintenance monotherapy treatment in adults. [1,2] Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try generic atypical antipsychotic alternative(s) prior to receiving coverage for asenapine (generic Saphris). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

3 . References

1. Saphris [package insert]. AbbVie Inc.; North Chicago, IL. January 2025.
2. Asenapine [package insert]. Peapack, NJ: Greenstone, LLC.; February 2017.

4 . Revision History

Date	Notes
12/8/2025	Annual review with no changes to coverage criteria. Updated references.

Step Therapy Duobrii



Prior Authorization Guideline

Guideline ID	GL-155446
Guideline Name	Step Therapy Duobrii
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2025
P&T Approval Date:	10/1/2024
P&T Revision Date:	

1 . Criteria

Product Name:Duobrii [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - 1. History of failure, contraindication or intolerance to ONE of the following:

- Calcipotriene cream 0.005%

• Calcipotriene-betamethasone dipropionate ointment 0.005-0.064% (generic Taclonex)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background: Duobrii lotion is a combination of halobetasol propionate and tazarotene indicated for the topical treatment of plaque psoriasis in adults. Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try calcipotriene cream or calcipotriene-betamethasone dipropionate ointment before providing coverage for Duobrii. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may apply

3 . References

1. Duobrii [package insert]. Bridgewater, NJ: Bausch Health US, LLC.; January 2020.

4 . Revision History

Date	Notes
9/23/2024	New program

Step Therapy Glaucoma Agents

Prior Authorization Guideline

Guideline ID	GL-224192
Guideline Name	Step Therapy Glaucoma Agents
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	10/18/2020
P&T Revision Date:	03/17/2021 ; 09/15/2021 ; 03/16/2022 ; 07/19/2023 ; 3/19/2025

1 . Indications

Drug Name: Tafluprost (generic Zioptan)
Open-angle glaucoma/ocular hypertension Tafluprost (generic Zioptan) is an ophthalmic prostaglandin analog therapy for the treatment of open-angle glaucoma/ocular hypertension.

2 . Criteria

Product Name:generic tafluprost [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria **1** - History of failure, contraindication, or intolerance to one of the following: • latanoprost (generic Xalatan) • travoprost (generic Travatan Z)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Tafluprost (generic Zioptan) is an ophthalmic prostaglandin analog therapy for the treatment of open-angle glaucoma/ocular hypertension. Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try one alternative Glaucoma Agent – latanoprost (generic Xalatan) or travoprost (generic Travatan Z) – prior to receiving coverage for tafluprost (generic Zioptan). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. American Academy of Ophthalmology. Preferred Practice Pattern: Primary Open-Angle Glaucoma. September 2020.
2. Zioptan [package insert]. Waltham, MA: Thea Pharma Inc; May 2023.
3. Travatan Z [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. January 2024.

5 . Revision History

Date	Notes
3/21/2025	Annual review, updated references.

Step Therapy Inhaled Corticosteriod

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436464
Guideline Name	Step Therapy Inhaled Corticosteriod
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	10/1/2024
P&T Revision Date:	11/21/2025

1 . Criteria

Product Name:Alvesco [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of failure, contraindication or intolerance to ALL of the following:

- Qvar RediHaler (beclomethasone dipropionate)
- Arnuity Ellipta (fluticasone furoate)

• Asmanex HFA or Asmanex Twisthaler (mometasone furoate)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background: Alvesco is an inhaled corticosteroid indicated for maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 12 years of age and older. Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Qvar RediHaler, Arnuity Ellipta and either Asmanex HFA or Asmanex Twisthaler before providing coverage for Alvesco. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may apply

3 . References

1. Alvesco [package insert]. Zug, Switzerland: Covis Pharma US, Inc.; February 2025.

4 . Revision History

Date	Notes
10/30/2025	Annual review with no changes to coverage criteria. Updated referen ce.

Step Therapy Leukotriene Modifiers

Prior Authorization Guideline

Guideline ID	GL-412244
Guideline Name	Step Therapy Leukotriene Modifiers
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	11/13/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 03/16/2022 ; 03/15/2023 ; 04/17/2024 ; 06/18/2025 ; 9/17/2025

1 . Criteria

Product Name:generic zileuton extended-release [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication, or intolerance to ONE of the following: • montelukast tablets or chewable (generic Singulair)	

• zafirlukast (generic Accolate)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background: Zileuton extended-release is a leukotriene modifier indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try one of two alternative leukotriene modifiers - montelukast tablets or chewable (generic Singulair) or zafirlukast (generic Accolate) - prior to receiving coverage for zileuton extended-release (generic Zyflo CR). **Additional Clinical Rules:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class

3 . References

1. Zileuton extended-release [package insert]. East Brunswick, NJ: Rising Pharma Holdings, Inc.; May 2024.

4 . Revision History

Date	Notes
10/7/2025	Combined criteria in alignment with standard step therapy format.

Step Therapy Ophthalmic Anti-allergy Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-461346
Guideline Name	Step Therapy Ophthalmic Anti-allergy Agents
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	12/16/2020
P&T Revision Date:	09/15/2021 ; 11/18/2022 ; 12/18/2024 ; 12/17/2025

1 . Criteria

Product Name:Epinastine Ophthalmic Solution [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication, or intolerance to azelastine ophthalmic solution.	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

2 . Background

Benefit/Coverage/Program Information
Background: Epinastine is an ophthalmic anti-allergy agent indicated for the prevention of itching of the eye associated with allergic conjunctivitis. Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try one alternative ophthalmic anti-allergy alternative – azelastine – prior to receiving coverage for epinastine. **Additional Clinical Programs:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limits may also be in place.

3 . References

1. Epinastine Ophthalmic Solution [package insert]. Hollywood, FL: Somerset Therapeutics, LLC. March 2025.

4 . Revision History

Date	Notes

12/8/2025	Annual review with no changes to coverage criteria. Removed references to Optivar and Elestat brand names since products are obsolete.

Step Therapy Oral NSAIDs

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-436467
Guideline Name	Step Therapy Oral NSAIDs
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	11/13/2020
P&T Revision Date:	06/16/2021 ; 09/15/2021 ; 06/15/2022 ; 10/18/2023 ; 10/16/2024 ; 10/15/2025

1 . Criteria

Product Name:generic ketoprofen, generic ketoprofen extended-release [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication, or intolerance to THREE of the following solid oral formulary products:	

• diclofenac IR or ER • flurbiprofen • ibuprofen (prescription strength) • naproxen (prescription strength) • indomethacin or indomethacin ER • meloxicam • nabumetone • piroxicam • sulindac	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background: Ketoprofen is a non-steroidal anti-inflammatory (NSAID) for the management of the signs and symptoms of rheumatoid arthritis and osteoarthritis, for the management of pain, and for treatment of primary dysmenorrhea. Ketoprofen extended-release is indicated for the management of the signs and symptoms of rheumatoid arthritis and osteoarthritis. Extended-release ketoprofen is not indicated for acute pain. Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try three alternative solid oral NSAIDs – diclofenac, flurbiprofen, prescription strength ibuprofen, prescription strength naproxen, indomethacin, meloxicam, nabumetone, piroxicam, or sulindac – prior to receiving coverage for ketoprofen or ketoprofen extended-release. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may also be in place.

3 . References

1. Ketoprofen [package insert]. Ripley, MS: Misemer Pharmaceutical, Inc. September 2022.
2. Ketoprofen extended-release [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; July 2024.

4 . Revision History

Date	Notes
10/30/2025	Updated products

Step Therapy Otic Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-461347
Guideline Name	Step Therapy Otic Agents
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	11/13/2020
P&T Revision Date:	03/17/2021 ; 09/15/2021 ; 11/18/2022 ; 11/17/2023 ; 12/18/2024 ; 12/17/2025

1 . Criteria

Product Name:Ciprofloxacin/dexamethasone otic (generic Ciprodex) [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication, or intolerance to ONE of the following: • Generic ofloxacin otic or generic ophthalmic formulation administered in the ear	

• Generic ciprofloxacin otic or generic ophthalmic formulation administered in the ear	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

2 . Background

Benefit/Coverage/Program Information
Background: Ciprofloxacin/dexamethasone (generic Ciprodex) is an otic agent indicated for the treatment of acute otitis externa and acute otitis media due to susceptible organisms. Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try one alternative fluoroquinolone otic or ophthalmic agent administered in the ear prior to receiving coverage for ciprofloxacin/dexamethasone (generic Ciprodex). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

3 . References

1. Ciprofloxacin and dexamethasone [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals, LLC. October 2022.

4 . Revision History

Date	Notes
12/8/2025	Annual review with no changes to coverage criteria. Updated backgr ound.

Step Therapy Overactive Bladder Agents

Prior Authorization Guideline

Guideline ID	GL-412208
Guideline Name	Step Therapy Overactive Bladder Agents
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	11/13/2020
P&T Revision Date:	09/15/2021 ; 11/18/2022 ; 11/17/2023 ; 10/01/2024 ; 10/01/2024 ; 10/15/2025

1 . Criteria

Product Name:generic darifenacin ER, generic fesoterodine ER, or generic trospium ER [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication, or intolerance to oxybutynin (generic Ditropan) or oxybutynin ER (generic Ditropan XL).	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background: Darifenacin ER is indicated for the treatment of an overactive bladder (OAB) with symptoms of urinary frequency, urinary urgency, or urge-related urinary incontinence. Fesoterodine fumarate ER is indicated for overactive bladder in adults with symptoms of urge urinary incontinence, urgency, and frequency. It is also indicated for neurogenic detrusor overactivity (NDO) in pediatric patients 6 years of age and older with a body weight greater than 25 kg Trospium chloride ER is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency. Oxybutynin is indicated for the treatment of OAB with symptoms of urinary frequency, urinary urgency, or urinary incontinence due to involuntary detrusor muscle contractions (includes neurogenic bladder), and for the relief of symptoms of bladder instability associated with voiding in patients with uninhibited neurogenic or reflex neurogenic bladder (i.e., urgency, frequency, urinary leakage, urge incontinence, dysuria). Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try oxybutynin (generic Ditropan) prior to receiving coverage for darifenacin. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

3 . References

1. Ditropan XL [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2021.

2. Darifenacin [package insert]. Florham Park, NJ: Xiromed, LLC; April 2021.
3. Oxybutynin chloride syrup [package insert]. Philadelphia, PA: Lannett Company, Inc.; February 2020.
4. Oxybutynin chloride tablet [package insert]. Princeton, NJ: Eywa Pharma Inc.; July 2019.
5. Toviaz [package insert]. New York, NY: Pfizer Inc.; February 2024.
6. Trospium ER [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; August 2014.

4 . Revision History

Date	Notes
10/6/2025	Annual review with no changes to coverage criteria.

Step Therapy Savella

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412247
Guideline Name	Step Therapy Savella
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	10/1/2024
P&T Revision Date:	9/17/2025

1 . Criteria

Product Name:Savella, Savella titration PAK [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of failure, contraindication, or intolerance to ALL of the following:

- duloxetine capsules (generic Cymbalta)
- gabapentin capsules, tablets, or oral solution (generic Neurontin)

• pregabalin capsules (generic Lyrica)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background: Savella is an oral serotonin norepinephrine reuptake inhibitor (SNRI) antidepressant indicated for the treatment of fibromyalgia in adults 18 years of age and older. Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try three oral agents before providing coverage for Savella. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3 . References

1. Savella [package insert]. North Chicago, IL: AbbVie Inc; May 2024.

4 . Revision History

Date	Notes

10/7/2025	Annual review, clarified dosage form for duloxetine for consistency a mong step therapy options.

Step Therapy Sedative Hypnotic Agents

Prior Authorization Guideline

Guideline ID	GL-139061
Guideline Name	Step Therapy Sedative Hypnotic Agents
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	3/1/2024
P&T Approval Date:	11/13/2020
P&T Revision Date:	09/15/2021 ; 05/20/2022 ; 07/19/2023 ; 1/17/2024

1 . Criteria

Product Name:Belsomra [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of trial and failure, contraindication, or intolerance to TWO of the following sedative-hypnotic alternatives:

- Zolpidem immediate release tablets (generic Ambien)

• Zaleplon (generic Sonata) • Eszopiclone (generic Lunesta)	
Notes	[a]State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ramelteon (generic Rozerem) [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - ONE of the following criteria: **1.1** History of trial and failure, contraindication, or intolerance to TWO of the following sedative-hypnotic alternatives: • Zolpidem immediate release oral tablets (generic Ambien) • Zaleplon (generic Sonata) • Eszopiclone (generic Lunesta) **OR** **1.2** History of or potential for a substance abuse disorder	
Notes	[a]State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background:

Ramelteon (generic Rozerem) is a sedative hypnotic agent indicated for the treatment of sleep-onset insomnia. Belsomra (suvorexant) is a sedative hypnotic agent indicated for treatment of both sleep-onset and sleep-maintenance insomnia.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try alternative sedative hypnotic agents prior to receiving coverage for Ramelteon (generic Rozerem) or Belsomra (suvorexant).

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

3 . References

1. Belsomra [package insert]. Whitehouse Station, NJ: Merck & Co; March 2023
2. Rozerem [package insert]. Deerfield, IL: Takeda Global; January 2023.

4 . Revision History

Date	Notes
1/16/2024	Updated references.

Prior Authorization Guideline

Guideline ID	GL-436469
Guideline Name	Step Therapy Serotonin (5-HT) Receptor Agonists
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	11/13/2020
P&T Revision Date:	03/17/2021 ; 09/15/2021 ; 11/18/2022 ; 10/01/2024 ; 11/21/2025

1 . Criteria

Product Name:generic almotriptan, eletriptan (generic Relpax), frovatriptan (generic Frova), sumatriptan-naproxen (generic Treximet), and zolmitriptan (generic Zomig)	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication, or intolerance to ALL of the following: • naratriptan (generic Amerge)	

• rizatriptan (generic Maxalt/Maxalt MLT) • sumatriptan (generic Imitrex) tablets or nasal spray	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information

Background:

FDA Approved Indications:

a. **Frovatriptan (generic Frova), eletriptan (generic Relpax), zolmitriptan tablet (generic Zomig), zolmitriptan orally disintegrating tablet:**

- Migraine Headaches: Indicated for the acute treatment of migraine with or without aura in adults. Not intended for the prophylactic therapy of migraine attacks or for the treatment of cluster headache.

b. **almotriptan:**

- Migraine Headaches for adults: Approved for the acute treatment of migraine attacks in adults with a history of migraine with or without aura. Not intended for the prophylactic therapy of cluster headache attacks.
- Migraine Headaches for adolescents: Approved for the acute treatment of migraine headache pain in adolescents age 12 to 17 years with a history of migraine with or without aura, and who have migraine attacks usually lasting 4 hours or more. Not intended for the prophylactic therapy of cluster headache attacks.

c. **Sumatriptan/naproxen (generic Treximet), zolmitriptan nasal spray (generic Zomig)**

- Migraine Headaches: Indicated for the acute treatment of migraine attacks with or without aura in adults and pediatric patients 12 years of age and older. Not intended for the prophylactic therapy of migraine attacks or for the treatment of cluster headache.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes.

Additional Clinical Programs:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3 . References

1. Zomig [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals; March 2022.
2. Zomig Nasal Spray [package insert]. Bridgewater NJ: Amneal Pharmaceuticals LLC; May 2019.
3. Almotriptan [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; May 2017.
4. Frova [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc.; August 2018.
5. Relpax [package insert. New York, NY: Pfizer, Inc.; January 2024.
6. Treximet [package insert]. Brentwood, TN: Currax Pharmaceuticals LLC; November 2024.

4 . Revision History

Date	Notes
10/30/2025	Annual review with no changes to coverage criteria. Updated references.

Step Therapy SNRIs

Prior Authorization Guideline

Guideline ID	GL-399248
Guideline Name	Step Therapy SNRIs
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	11/13/2020
P&T Revision Date:	06/16/2021 ; 08/19/2022 ; 03/15/2023 ; 11/17/2023 ; 10/16/2024 ; 12/18/2024 ; 9/25/2025

1 . Criteria

Product Name:Fetzima [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - ONE of the following:	

1.1 History of failure, contraindication, or intolerance to at least THREE of the following generic formulations:

- bupropion (non-smoking deterrent)
- citalopram
- duloxetine
- escitalopram
- fluoxetine
- fluvoxamine immediate release
- paroxetine
- sertraline tablets
- venlafaxine IR tablets
- venlafaxine ER capsules
- desvenlafaxine (generic Pristiq only)

OR

1.2 The requested medication was initiated during a recent inpatient mental health hospitalization, and the member is stabilized on the requested medication

OR

1.3 Member is new to the plan and currently stabilized on the requested medication (as evidenced by coverage effective date of less than or equal to 120 days)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information
Background: Fetzima (levomilnacipran) is a serotonin norepinephrine reuptake inhibitor [SNRI] indicated for major depressive disorder [MDD].

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a trial of at least three generic formulary medications before providing coverage for Fetzima.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also be in place.

3 . References

1. Fetzima [Package Insert]. St. Louis, MO: Forest Pharmaceuticals, Inc.; April 2024.
2. American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder, third edition. Oct. 2010.

4 . Revision History

Date	Notes
9/18/2025	Annual review, clarified background section.

Step Therapy Topical Steroids

Prior Authorization Guideline

Guideline ID	GL-399297
Guideline Name	Step Therapy Topical Steroids
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	2/19/2021
P&T Revision Date:	06/16/2021 ; 09/15/2021 ; 06/15/2022 ; 08/18/2023 ; 10/18/2023 ; 10/01/2024 ; 9/25/2025

1 . Criteria

Product Name:generic flurandrenolide 0.05% lotion [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication, or intolerance to TWO generic alternative medications in the lower-mid potency class (Class 5 and 6):	

- betamethasone dipropionate lotion 0.05%
- betamethasone valerate lotion 0.1%
- desonide cream 0.05%
- desonide lotion 0.05%
- desonide ointment 0.05%
- fluticasone propionate cream 0.05%
- hydrocortisone valerate 0.2% cream
- triamcinolone acetonide cream 0.025%
- triamcinolone acetonide 0.1% lotion
- triamcinolone acetonide 0.025% ointment

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:generic amcinonide cream 0.1%, generic amcinonide lotion 0.1%,generic clocortolone pivalate 0.1% cream, and diflorasone cream 0.05% [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of failure, contraindication, or intolerance to ONE generic alternative medication in the medium potency class (Class 4):

- betamethasone diproprionate cream 0.05%
- desoximetasone cream, gel, ointment 0.05%
- fluocinolone acetonide 0.025% ointment
- fluocinonide emulsified base cream 0.05%
- hydrocortisone valerate 0.2% ointment
- mometasone furoate cream 0.1%
- mometasone furoate solution 0.1%
- triamcinolone acetonide cream 0.1%
- triamcinolone acetonide ointment 0.1%

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:generic amcinonide ointment 0.1% [a]	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of failure, contraindication, or intolerance to TWO alternative medications in the high potency class (Class 2):

- betamethasone dipropionate ointment 0.05%
- betamethasone dipropionate augmented cream 0.05%
- desoximetasone spray 0.25%
- desoximetasone cream, ointment 0.25%
- fluocinonide cream, gel, ointment, solution 0.05%

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2 . Background

Benefit/Coverage/Program Information

Background:

Topical steroids are commonly prescribed for the treatment of rash, eczema, and dermatitis. Topical steroids have anti-inflammatory properties, and are classified into different potency classes based on their vasoconstriction abilities. A vasoconstriction bioassay provides potency measurements that correlate with clinical potency. There are numerous topical steroid products.

Class 1: Super Potent	Class 5: Lower Mid-Strength
Class 2: Potent	Class 6: Mild
Class 3: Upper Mid-Strength	Class 7: Least Potent

Class 4: Mid-Strength	

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try one or two lower cost alternative topical steroids before providing coverage for higher cost topical steroids.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

3 . References

1. Psoriasis.org. 2019. Topical steroid potency chart - National Psoriasis Foundation. [online] Available at: https://www.psoriasis.org/potency-chart/ [Accessed: May 5, 2022].
2. Uptodate.com. 2024. Topical corticosteroids: Use and adverse effects. [online] Available at: https://www.uptodate.com/contents/topical-corticosteroids-use-and-adverse-effects?csi=d791a823-1d28-44eb-aafb-79f08a6eed30&source=contentShare
3. Elmets, C. A., Korman, N. J., Prater, E. F., Wong, E. B., Rupani, R. N., Kivelevitch, D., ... & Menter, A. (2021). Joint AAD–NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. Journal of the American Academy of Dermatology, 84(2), 432-470.

4 . Revision History

Date	Notes
9/23/2025	Updated step therapy criteria for 2026 implementation. Removed pre dnicarbate from list of alts in the lower-mid potency section now that i t is obsolete. Added amcinonide cream, lotion 0.1% to list of target dr ugs in the medium-potency section. Added amcinonide ointment 0.1 % as a target drug to high potency section and removed Apexicon E cream 0.5% as a step option.

Stivarga

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-284187
Guideline Name	Stivarga
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	06/16/2021 ; 09/15/2021 ; 06/15/2022 ; 10/19/2022 ; 06/21/2023 ; 08/18/2023 ; 06/17/2024 ; 10/01/2024 ; 6/18/2025

1 . Indications

Drug Name: Stivarga (regorafenib)
Colorectal cancer (CRC) Indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild type, an anti-EGFR therapy. **Gastrointestinal stromal tumor (GIST)** Indicated for the treatment of locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate (Gleevec) and sunitinib malate (generic Sutent). **Hepatocellular carcinoma (HCC)** Indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib tosylate (generic Nexavar).

2 . Criteria

Product Name:Stivarga [a]	
Diagnosis	Colorectal Cancer (CRC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic colorectal cancer

AND

2 - History of failure, contraindication, or intolerance to treatment with ALL of the following:^

- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy
- Anti-VEGF based chemotherapy

AND

3 - ONE of the following:

3.1 Tumor is RAS mutant-type

OR

3.2 BOTH of the following:

- Tumor is RAS wild-type

• History of failure, contraindication, or intolerance to anti-EGFR therapy^ [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling and/or treatment guidelines.

Product Name:Stivarga [a]	
Diagnosis	Colorectal Cancer (CRC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Stivarga therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of soft tissue sarcoma	

AND

2 - ONE of the following:

- Extremity/superficial trunk or head/neck that is non-adipocytic with advanced/metastatic disease with disseminated metastases
- Retroperitoneal/intra-abdominal that is non-adipocytic with recurrent unresectable or stage IV disease
- Advanced/metastatic pleomorphic rhabdomyosarcoma
- Angiosarcoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Disease is ONE of the following:

- Gross residual (R2 resection)
- Unresectable primary
- Tumor rupture
- Recurrent/metastatic

AND

3 - ONE of the following:

3.1 SDH-deficient GIST

OR

3.2 History of progression to BOTH of the following^:

3.2.1 Imatinib mesylate (generic Gleevec)

AND

3.2.2 ONE of the following:

- Sunitinib malate (generic Sutent)
- Qinlock (ripretinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

	^ Tried/failed alternative(s) are supported by FDA labeling and/or treat ment guidelines

Product Name:Stivarga [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Stivarga therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Stivarga [a]	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic cholangiocarcinoma
- Intrahepatic cholangiocarcinoma

AND

1.1.2 Disease is ONE of the following:

- Unresectable
- Gross residual (R2)
- Metastatic

OR

1.2 BOTH of the following

- Diagnosis of hepatocellular carcinoma
- Used as subsequent-line therapy for disease progression

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	Bone Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following bone cancer:

- Dedifferentiated chondrosarcoma
- Ewing Sarcoma
- High grade undifferentiated pleomorphic sarcoma (UPS)
- Mesenchymal chondrosarcoma
- Osteosarcoma
- Other primary round cell tumors of the bone (e.g., CIC::DUX4, BCOR::CCNB3)

AND

2 - Used as second-line therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	Glioblastoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of recurrent or progressive glioblastoma	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	Glioblastoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Stivarga therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - Disease is ONE of the following:

- Advanced
- Recurrent/metastatic
- Inoperable

AND

3 - Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Stivarga will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Stivarga [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Stivarga therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Additional Clinical Rules: • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place. **Background:** Stivarga (regorafenib) is a kinase inhibitor indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild type, an anti-EGFR therapy; locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate (generic Gleevec) and sunitinib malate (generic Sutent); hepatocellular carcinoma (HCC) who have been previously treated with sorafenib tosylate (generic Nexavar). [1] The National Cancer Comprehensive Network (NCCN) also recommends additional use of Stivarga in colon cancer, rectal cancer, soft tissue sarcoma, hepatocellular carcinoma, biliary tract cancer, bone cancer, gastrointestinal stromal tumor (GIST), and glioblastoma. [2]

4 . References

1. Stivarga [package insert]. Whippany, NJ: Bayer Healthcare Pharmaceuticals, Inc. February 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content. Accessed April 28, 2025.

5 . Revision History

Date	Notes
5/28/2025	Annual review. Added new indication and coverage criteria for uterine sarcoma. Updated coverage criteria for colorectal cancer, gastrointestinal stromal tumors, and bone cancer based on NCCN. Updated references.

Strensiq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412193
Guideline Name	Strensiq
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	11/13/2020
P&T Revision Date:	05/21/2021 ; 06/16/2021 ; 06/15/2022 ; 06/21/2023 ; 10/18/2023 ; 10/16/2024 ; 10/15/2025

1 . Indications

Drug Name: Strensiq (asfotase alfa)
Perinatal/infantile and juvenile-onset hypophosphatasia (HPP) Indicated for the treatment of patients with perinatal/infantile and juvenile-onset hypophosphatasia (HPP).

2 . Criteria

Product Name:Strensiq [a]	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia

AND

2 - Submission of medical records documenting confirmation of diagnosis by ALL of the following:

2.1 Presence of clinical signs and symptoms of hypophosphatasia (e.g., skeletal abnormalities, respiratory insufficiency, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, short stature, rickets, fractures)

AND

2.2 Onset of disease < 18 years of age [If member is ≥ 18 years of age at time of request, documentation of disease onset before age of 18 must be provided (e.g., member began experiencing symptoms at age 8)]

AND

2.3 ONE of the following:

2.3.1 ALL of the following:

- Persistent serum alkaline phosphatase (ALP) levels below the age- and gender-specific reference range (i.e., present in at least two measurements)
- Elevated tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])
- Radiographic imaging demonstrating skeletal abnormalities (e.g., craniosynostosis, rickets, non-traumatic fractures)

OR

2.3.2 Presence of known pathological mutation in the ALPL gene as detected by ALPL molecular genetic testing*

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone disorders

AND

4 - ONE of the following:

4.1 BOTH of the following:

- Diagnosis of perinatal/infantile-onset hypophosphatasia
- Request does not exceed a maximum supply limit of 9 mg/kg/week

OR

4.2 Both of the following:

- Diagnosis of juvenile-onset hypophosphatasia
- Request does not exceed a maximum supply limit of 6 mg/kg/week

AND

5 - ONE of the following:

5.1 Patient is prescribed Strensiq 18 mg/0.45 mL, Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

5.2 BOTH of the following:

- Patient is prescribed Strensiq 80 mg/0.8 mL vial

• Patient's weight is greater than or equal to 40 kg	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Results of prior genetic testing can be submitted as confirmation of diagnosis of HPP, however please note that the provider should confirm coverage status of any new genetic testing under the patient's United Healthcare plan prior to ordering.

Product Name:Strensiq [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Strensiq therapy (e.g., improvement in clinical symptoms, improvement in Radiographic Global Impression of Change)

AND

2 - Prescribed by ONE of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone diseases

AND

3 - ONE of the following:

3.1 BOTH of the following:

- Diagnosis of perinatal/infantile-onset hypophosphatasia
- Request does not exceed a maximum supply limit of 9 mg/kg/week

OR

3.2 BOTH of the following:

- Diagnosis of juvenile-onset hypophosphatasia
- Request does not exceed a maximum supply limit of 6 mg/kg/week

AND

4 - ONE of the following:

4.1 Patient is prescribed Strensiq 18 mg/0.45 mL, Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

4.2 BOTH of the following:

- Patient is prescribed Strensiq 80 mg/0.8 mL vials
- Patient's weight is greater than or equal to 40 kg

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Strensiq is a tissue nonspecific alkaline phosphatase indicated for the treatment of patients with perinatal/infantile and juvenile-onset hypophosphatasia (HPP). [1] **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Strensiq [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; July 2024.
2. Khan AA, Brandi ML, Rush ET, et al. Hypophosphatasia diagnosis: current state of the art and proposed diagnostic criteria for children and adults. Osteoporos Int. 2024;35(3):431-438.
3. Cárdenas-Aguilera JG, González-López V, Zarante-Bahamón AM, et al. Diagnosis, treatment, and follow-up of patients with hypophosphatasia. Endocrine. 2025;87(2):400-419. Clinical Practice Guidelines for Hypophosphatasia* - PMC (nih.gov)

5 . Revision History

Date	Notes
10/6/2025	Annual review. Updated initial and reauthorization criteria. Updated r eferences.

Stromectol

Prior Authorization Guideline

Guideline ID	GL-555220
Guideline Name	Stromectol
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	9/22/2021
P&T Revision Date:	08/19/2022 ; 12/14/2022 ; 01/17/2024 ; 03/19/2025 ; 3/18/2026

1 . Indications

Drug Name: Stromectol (ivermectin) tablets
Parasitic Infections Indicated for the treatment of parasitic infections including strongyloidiasis and onchocerciasis. Ivermectin may also be used for other compendia supported parasitic infections including but not limited to scabies, hookworm disease, and ascariasis.

2 . Criteria

Product Name:Brand Stromectol, generic ivermectin tablets [a]	
Approval Length	1 Month
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following*:

- Onchocerciasis due to nematode parasite
- Pediculosis
- Strongyloidiasis
- Ascariasis
- Scabies (including crusted scabies)
- Cutaneous larva migrans (hook worm disease)
- Enterobiasis
- Filariasis
- Trichuriasis
- Gnathostomiasis

Notes	*Requests for COVID treatment and/or prophylaxis are to be denied. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Stromectol (ivermectin) is indicated for the treatment of parasitic infections including strongyloidiasis and onchocerciasis. It may also be used for other compendia supported parasitic infections including but not limited to scabies, hookworm disease, and ascariasis. Most infections are treated with a single weight-based dose.

Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place

4 . References

1. U.S. Food and Drug Administration. Ivermectin and COVID-19. Updated April 5, 2024. Accessed February 5, 2026.
2. Stromectol [package insert]. Rahway, NJ: Merck Sharp & Dohme, LLC.; September 2024.
3. Clinical Pharmacology [database online]. Ivermectin. Tampa, FL: Gold Standard, Inc.; 2022. Updated February 10, 2025.

5 . Revision History

Date	Notes
3/18/2026	Annual review with no changes to coverage criteria. Updated references.

Sublingual Immunotherapy (SLIT)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-555219
Guideline Name	Sublingual Immunotherapy (SLIT)
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	10/1/2024
P&T Revision Date:	3/18/2026

1 . Indications

Drug Name: Grastek (Timothy grass pollen allergen extract) and Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens allergen extract)
Grass pollen-induced allergic rhinitis Indicated for patients with grass pollen-induced allergic rhinitis
Drug Name: Ragwitek (short ragweed pollen allergen extract)
Ragweed pollen-induced allergic rhinitis Indicated for ragweed pollen-induced allergic rhinitis
Drug Name: Odactra (Dermatophagoides farinae/Dermatophagoides pteronyssinus allergen extract)
House dust mite (HDM)-induced allergic rhinitis. Indicated for house dust mite (HDM)-induced allergic rhinitis.

2 . Criteria

Product Name:Grastek [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

AND

2 - Diagnosis confirmed by ONE of the following:

- Positive skin test to Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)
- in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the grass pollen season

AND

4 - History of failure, contraindication, or intolerance to TWO of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]

- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

5 - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Oralair)

AND

6 - Patient does not have unstable and/or uncontrolled asthma

AND

7 - Prescribed by or in consultation with a specialist in allergy and immunology

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Grastek [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Grastek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Oralair [a]

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

AND

2 - Diagnosis confirmed by ONE of the following:

- Positive skin test to any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]
- in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]

AND

3 - Treatment is started or will be started at least 4 months before the beginning of the grass pollen season

AND

4 - History of failure, contraindication, or intolerance to TWO of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]
- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

5 - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Grastek)

AND

6 - Patient does not have unstable and/or uncontrolled asthma

AND

7 - Prescribed by or in consultation with a specialist in allergy and immunology

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Oralair [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Oralair therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ragwitek [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe short ragweed pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

AND

2 - Diagnosis confirmed by ONE of the following:

- Positive skin test to short ragweed pollen
- in vitro testing for pollen-specific IgE antibodies for short ragweed pollen

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the short ragweed pollen season

AND

4 - History of failure, contraindication, or intolerance to TWO of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]
- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

5 - Patient does not have unstable and/or uncontrolled asthma

AND

6 - Prescribed by or in consultation with a specialist in allergy and immunology

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Ragwitek [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ragwitek therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Odactra [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of house dust mite (HDM)-induced allergic rhinitis

AND

2 - Diagnosis confirmed by ONE of the following:

- Positive skin test to licensed house dust mite allergen extracts
- in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites

AND

3 - History of failure, contraindication, or intolerance to TWO of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]
- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

4 - Patient does not have unstable and/or uncontrolled asthma

AND

5 - Prescribed by or in consultation with a specialist in allergy and immunology

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Odactra [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Odactra therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: The sublingual immunotherapy (SLIT) medications are indicated for patients who have symptoms of allergic rhinitis with natural exposure to allergens and who demonstrate specific IgE antibodies to the relevant allergen. Grastek (Timothy grass pollen allergen extract) and Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens allergen extract) are indicated for patients with grass pollen-induced allergic rhinitis, Ragwitek (short ragweed pollen allergen extract) is indicated for ragweed pollen-induced allergic rhinitis and Odactra (*Dermatophagoides farinae/Dermatophagoides pteronyssinus* allergen extract), is indicated for house dust mite (HDM)-induced allergic rhinitis. Candidates for allergen immunotherapy are patients whose symptoms are not adequately controlled by medications, and avoidance measures have been ineffective. In addition, patients experiencing unacceptable adverse effects of medications or who wish to reduce the long-term use of medications may also be candidates for immunotherapy. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits and/or Notification may be in place.

4 . References

1. Grastek® [package insert]. Blagrove Swindon Wiltshire, UK: Catalent Pharma Solutions Limited; September 2022.
2. Oralair® [package insert]. Lenoir, NC: Greer Laboratories, Inc.: September 2022.
3. Ragwitek® [package insert]. Blagrove Swindon, Wiltshire, UK: Catalent Pharma Solutions Limited; September 2022.
4. Odactra® [package insert]. Blagrove Swindon, Wiltshire, UK: Catalent Pharma Solutions Limited: February 2025.
5. Cox, L, Nelson, H, Lockey, R, et al. Allergen immunotherapy: A practice parameter third update. American Academy of Allergy, Asthma & Immunology. December 2010.
6. Treatment of seasonal allergic rhinitis: An evidence-based focused 2017 guideline update. Dykewicz MS, Wallace DV, Baroody F, et.al. Ann Allergy Asthma Immunol. 2017 Dec;119(6):489-511.e41

7. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. Greenhawt M, Oppenheimer J, Nelson M, et.al. Ann Allergy Asthma Immunol. 2017 Mar;118(3):276-82.e2.

5 . Revision History

Date	Notes
3/18/2026	Annual review with no changes to coverage criteria. Updated referen ces.

Sucraid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-500242
Guideline Name	Sucraid
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 01/19/2022 ; 01/18/2023 ; 01/17/2024 ; 04/17/2024 ; 01/15/2025 ; 1/21/2026

1 . Indications

Drug Name: Sucraid (sacrosidase)
Sucrase deficiency Indicated for the treatment of sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

2 . Criteria

Product Name:Sucraid [a]	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting a diagnosis of congenital sucrase-isomaltase deficiency (CSID)

AND

2 - Submission of medical records documenting a diagnosis has been confirmed by ONE of the following:

2.1 Endoscopic biopsy of the small bowel indicating ALL of the following:

2.1.1 Normal small bowel morphology

AND

2.1.2 Absent or markedly reduced sucrase activity

AND

2.1.3 Isomaltase activity varying from 0 to full activity

AND

2.1.4 Reduced maltase activity

AND

2.1.5 ONE of the following:

2.1.5.1 Normal lactase activity

OR

2.1.5.2 BOTH of the following:

- Reduced lactase
- Sucrase:lactase ratio of < 1.0

OR

2.2 Molecular genetic testing of the sucrase-isomaltase (SI) gene indicating a pathogenic isomaltase gene variant

OR

2.3 Carbon-13 sucrose breath test (13C SBT) indicating a cumulative [13C] CO2 exhalation over 90 minutes below 10th percentile (i.e.,

AND

3 - Prescribed by or in consultation with a gastroenterologist or rare disease specialist

AND

4 - Will be used with a sucrose-free, low starch diet

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Sucraid [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response Sucraid therapy [e.g., reduced symptoms (e.g., abdominal pain, bloating, gas, vomiting), reduced number of stools per day, reduced number of symptomatic days]

AND

2 - Prescribed by or in consultation with a gastroenterologist or rare disease specialist

AND

3 - Will be used with a sucrose-free, low starch diet

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Sucraid (sacrosidase) is an oral enzyme replacement therapy indicated for the treatment of sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID). The effects of Sucraid have not been evaluated in patients with secondary (acquired) sucrase deficiency.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4 . References

1. Sucraid [package insert]. Vero Beach, FL: QOL Medical, LLC. August 2024.
2. Danialifar TF, Chumpitazi BP, Mehta DI, Di Lorenzo C. Genetic and acquired sucrase-isomaltase deficiency: A clinical review. J Pediatr Gastroenterol Nutr. 2024;78(4):774-782.
3. Congenital sucrase-isomaltase deficiency. U.S. Nation Library of Medicine. October 2019.
4. Puntis JW, Zamvar V. Congenital sucrase-isomaltase deficiency: diagnostic challenges and response to enzyme replacement therapy. Arch Dis Child. September 2015.
5. Treem WR. Clinical aspects and treatment of congenital sucrase-isomaltase deficiency. J Ped Gastro Nutr. 55 (Sup 2 Nov): S7-S13. November 2012.
6. Treem WR, McAdams L, Stanford L, Kastoff G, Justinich C, Hyams J. Sacrosidase therapy for congenital sucrase-isomaltase deficiency. J Pediatr Gastroenterol Nutr. 1999 Feb;28(2):137-42.
7. Robayo-Torres CC, Opekun AR, Quezada-Calvillo R, Villa X, Smith EO, Navarrete M, Baker SS, Nichols BL. 13C-breath tests for sucrose digestion in congenital sucrase isomaltase-deficient and sacrosidase-supplemented patients. J Pediatr Gastroenterol Nutr. 2009 Apr;48(4):412-8.

5 . Revision History

Date	Notes
1/20/2026	Annual review with no changes to coverage criteria.

Sunosi

Prior Authorization Guideline

Guideline ID	GL-399250
Guideline Name	Sunosi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	2/17/2023
P&T Revision Date:	08/18/2023 ; 11/17/2023 ; 09/18/2024 ; 9/25/2025

1 . Indications

Drug Name: Sunosi (solriamfetol)
Narcolepsy or Obstructive Sleep Apnea Indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

2 . Criteria

Product Name:Sunosi [a]	
Diagnosis	Narcolepsy
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

2 - Symptoms of excessive daytime sleepiness (including but not limited to daily periods of irrepressible need to sleep or daytime lapses into sleep) are present

AND

3 - History of failure, contraindication, or intolerance of BOTH the following:

3.1 ONE of the following:

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant

AND

3.2 ONE of the following:

- modafinil (generic Provigil)
- armodafinil (generic Nuvigil)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Sunosi [a]	
Diagnosis	Narcolepsy
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Sunosi [a]	
Diagnosis	Obstructive Sleep Apnea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of obstructive sleep apnea defined by ONE of the following:

1.1 Fifteen or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

OR

1.2 BOTH of the following:

1.2.1 Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

1.2.2 One or more of the following sign/symptoms are present:

- Daytime sleepiness
- Nonrestorative sleep
- Fatigue
- Insomnia
- Waking up with breath holding, gasping, or choking
- Habitual snoring noted by bed partner or other observer
- Observed apnea

AND

2 - BOTH of the following:

2.1 Standard treatments for the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP]) have been used for one month or longer

AND

2.2 Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

AND

3 - History of failure, contraindication, or intolerance to ONE of the following:

- armodafinil (generic Nuvigil)
- modafinil (generic Provigil)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Sunosi [a]	
Diagnosis	Obstructive Sleep Apnea
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy **AND** **2** - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g., CPAP, BiPAP)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Sunosi is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

Limitations of Use: Sunosi is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating Sunosi for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi. Sunosi is not a substitute for these modalities.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Sunosi [package insert]. New York, NY: Axsome Therapeutics, Inc.; June 2023.
2. American Academy of Sleep Medicine. International Classification of Sleep Disorders: Diagnostic and Coding Manual. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
3. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American 4. Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881–1893.
4. Practice Guidelines: Obstructive Sleep Apnea and Chronic Insomnia Disorder : Updated Guidelines from the VA/DoD. Ann Intern Med. March 3, 2020; 172(5):325-336.
5. Malhorta A, Kundel V, et al. Obstructive sleep apnea: Overview of management in adults. In: UpToDate, Coop N, Finlay G, UpToDate, Waltham, MA, 2025

5 . Revision History

Date	Notes
9/18/2025	Annual review. Updated references.

Sutent

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-555221
Guideline Name	Sutent
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	03/17/2021 ; 09/15/2021 ; 03/16/2022 ; 08/19/2022 ; 03/15/2023 ; 03/20/2024 ; 03/19/2025 ; 3/18/2026

1 . Indications

Drug Name: Sutent (sunitinib malate)
Gastrointestinal stromal tumor (GIST) Indicated for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to Gleevec (imatinib mesylate). **Renal cell carcinoma (RCC)** Indicated for the treatment of advanced renal cell carcinoma (RCC). **Recurrent RCC** Indicated for the treatment of adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy. **Pancreatic neuroendocrine tumors (pNET)** Indicated for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease. **Off Label Uses: Other Uses:** The National Cancer Comprehensive Network (NCCN)

recommends use of Sutent for medullary, follicular, oncocytic, or papillary thyroid carcinoma; chordoma; meningiomas; thymic carcinoma; and treatment of myeloid/lymphoid neoplasms with eosinophilia and FMS-like tyrosine kinase 3 (FLT3) rearrangement. NCCN also approves the use of Sutent for other soft tissue sarcomas: alveolar soft part sarcoma (ASPS), angiosarcoma, solitary fibrous tumor/ hemangiopericytoma, and extraskeletal myxoid chondrosarcoma.

2 . Criteria

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - ONE of the following:

2.1 History of disease progression on, contraindication, or intolerance to one of the following^:

- imatinib (generic Gleevec)
- Stivarga (regorafenib)
- Standard dose Qinlock (ripretinib)

OR

2.2 SDH-deficient GIST

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NC CN guidelines

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Sutent therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of renal cell carcinoma (RCC) **AND** **2** - ONE of the following: **2.1** Disease has relapsed	

OR **2.2** Disease is advanced **OR** **2.3** BOTH of the following • Used in adjuvant setting • Patient has a high risk of recurrence following nephrectomy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Sutent therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of progressive pancreatic neuroendocrine tumors (pNET)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sutent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Alveolar soft part sarcoma (ASPS)
- Angiosarcoma
- Solitary fibrous tumor/hemangiopericytoma
- Extraskeletal myxoid chondrosarcoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sutent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Oncocytic cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 Disease is refractory to radioactive iodine treatment

OR

1.2 ALL of the following:

1.2.1 Diagnosis of medullary thyroid carcinoma

AND

1.2.2 ONE of the following:

- Patient has progressive disease

- Patient has symptomatic metastatic disease

AND

1.2.3 One of the following^:

- Clinical trials or preferred systemic therapy options are not available or appropriate [e.g., Caprelsa (vandetanib), Cometriq (cabozantinib)]
- There is progression on preferred systemic therapy options [e.g., Caprelsa (vandetanib), Cometriq (cabozantinib)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sutent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of recurrent chordoma	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Sutent therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of surgically inaccessible meningiomas	

AND

2 - ONE of the following:

- Disease is recurrent
- Disease is progressive

AND

3 - Further radiation is not possible

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sutent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymic carcinoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sutent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND **2** - Patient has a FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic or blast phase

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sutent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Sutent will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Sutent, generic sunitinib [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Sutent therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Sutent (sunitinib malate) is a tyrosine kinase inhibitor indicated for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to Gleevec (imatinib mesylate); treatment of advanced renal cell carcinoma (RCC); adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy; and treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease. The National Cancer Comprehensive Network (NCCN) recommends use of Sutent for medullary, follicular, oncocytic, or papillary thyroid carcinoma; chordoma; meningiomas; thymic carcinoma; and treatment of myeloid/lymphoid neoplasms with eosinophilia and FMS-like tyrosine kinase 3 (FLT3) rearrangement. [2] NCCN also approves the use of Sutent for

other soft tissue sarcomas: alveolar soft part sarcoma (ASPS), angiosarcoma, solitary fibrous tumor/hemangiopericytoma, and extraskeletal myxoid chondrosarcoma.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Sutent [package insert]. New York, NY: Pfizer Lab; September 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed January 30, 2025

5 . Revision History

Date	Notes
3/18/2026	Annual review with no changes to coverage criteria. Updated references.

Syprine

Prior Authorization Guideline

Guideline ID	GL-291196
Guideline Name	Syprine
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	06/15/2022 ; 08/19/2022 ; 06/21/2023 ; 11/17/2023 ; 07/17/2024 ; 6/18/2025

1 . Indications

Drug Name: Syprine (trientine)
Wilson's disease Indicated for the treatment of patients with Wilson's disease who are intolerant of penicillamine.

2 . Criteria

Product Name:Brand Syprine, generic trientine [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration) **AND** **2** - History of intolerance, failure or contraindication to penicillamine^	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or treatment guidelines

Product Name:Brand Syprine, generic trientine [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Syprine (trientine hydrochloride) and trientine hydrochloride 500mg are indicated for the treatment of patients with Wilson's disease who are intolerant of penicillamine. Syprine and trientine hydrochloride cannot be considered interchangeable with penicillamine. Syprine and trientine hydrochloride should be used when continued treatment with penicillamine is no longer possible because of intolerable or life endangering side effects. [1]

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Syprine [package insert]. Bridgewater, NJ: Bausch Health US, LLC. September 2020.
2. Trientine hydrochloride [package insert]. Parsippany, NJ: Teva Pharmaceuticals; January 2022.

5 . Revision History

Date	Notes
6/9/2025	Annual review with no changes to criteria. Updated formatting.

Tafinlar

Prior Authorization Guideline

Guideline ID	GL-270220
Guideline Name	Tafinlar
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	03/16/2022 ; 08/19/2022 ; 05/25/2023 ; 06/21/2023 ; 05/17/2024 ; 5/16/2025

1 . Indications

Drug Name: Tafinlar (dabrafenib)
Melanoma Indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation. Tafinlar is also indicated, in combination with trametinib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, and the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations and involvement of lymph node(s), following complete resection. **Non-small cell lung cancer** Indicated, in combination with trametinib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation. **Anaplastic thyroid cancer** Indicated, in combination with trametinib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.

Solid Tumors Indicated for the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.

Low-Grade Glioma Indicated, in combination with Mekinist, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

Other Uses: The National Cancer Comprehensive Network (NCCN) also approves the use of Tafinlar in combination with Mekinist for the adjuvant treatment of ATC with BRAF V600E mutations following resection; and as monotherapy for the treatment of follicular, oncocytic, and papillary thyroid carcinomas with a BRAF mutation; in combination with Mekinist for the treatment for recurrent, advanced, or metastatic NSCLC in patients with BRAF V600E mutation, or as single agent if the combination of Tafinlar and Mekinist is not tolerated; in the treatment of glioblastomas and other high-grade gliomas; in the treatment of central nervous system (CNS) cancer in patients with melanoma; ovarian cancer/fallopian tube cancer/primary peritoneal cancer with persistent disease or recurrence in BRAF V600E positive tumors; pancreatic and ampullary adenocarcinomas if BRAF V600E mutation positive; and certain BRAF V600E mutation positive histiocytic neoplasms and hepatobiliary cancers; hairy cell leukemia; salivary gland tumor; and gastrointestinal stromal tumor.

2 . Criteria

Product Name:Tafinlar [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Unresectable melanoma

OR

1.2 Metastatic melanoma

OR

1.3 BOTH of the following:

- Prescribed as adjuvant therapy for melanoma involving the lymph node(s)
- Used in combination with Mekinist (trametinib)

AND

2 - Cancer is positive for BRAF V600 mutation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

- Patient has metastatic brain lesions
- Tafinlar is active against primary tumor (melanoma)

OR

1.2 Patient has a glioma

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - Used in combination with Mekinist (trametinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Tafinlar therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - ONE of the following:

- Used in combination with Mekinist (trametinib)

• Used as a single agent if the combination of Mekinist and Tafinlar is not tolerated	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Tafinlar therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ALL of the following: **1.1** Diagnosis of anaplastic thyroid cancer (ATC)	

AND

1.2 Cancer is positive for BRAF V600E mutation

AND

1.3 Used in combination with Mekinist (trametinib)

AND

1.4 ONE of the following:

1.4.1 Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

OR

1.4.2 Prescribed as adjuvant therapy following resection

OR

2 - ALL of the following:

2.1 ONE of the following diagnoses:

- Follicular Carcinoma
- Oncocytic Carcinoma
- Papillary Carcinoma

AND

2.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

2.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

2.4 Disease is refractory to radioactive iodine treatment

AND

2.5 Cancer is positive for BRAF V600 mutation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Tafinlar [a]	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic Cholangiocarcinoma
- Intrahepatic Cholangiocarcinoma

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E mutation

AND

5 - Used in combination with Mekinist (trametinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Tafinlar [a]	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Tafinlar therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Tafinlar [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of ONE of the following: • Langerhans Cell Histiocytosis • Erdheim-Chester Disease **AND** **2** - Cancer is positive for BRAF V600E mutation	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Tafinlar therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Presence of solid tumor **AND** **2** - Used as subsequent treatment after progression on or after systemic treatment	

AND **3** - Disease is unresectable or metastatic **AND** **4** - Cancer is positive for BRAF V600E mutation **AND** **5** - Used in combination with Mekinist (trametinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Tafinlar therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial Ovarian Cancer
- Fallopian Tube Cancer
- Primary Peritoneal Cancer

AND

2 - ONE of the following:

- Persistent disease
- Recurrence in BRAF V600E positive tumors
- Recurrence of low-grade serous carcinoma.

AND

3 - Used in combination with Mekinist (trametinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Pancreatic Cancer / Ampullary Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Pancreatic adenocarcinoma
- Ampullary adenocarcinoma

AND

2 - Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

AND

3 - Cancer is positive for BRAF V600E mutation

AND **4** - Used in combination with Mekinist (trametinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Pancreatic Cancer / Ampullary Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

AND **2** - Used in combination with Mekinist (trametinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of salivary gland tumor

AND

2 - Disease is ONE of the following:

- Recurrent and unresectable
- Metastatic

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Mekinist (trametinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRAF V600E-mutated GIST

AND

2 - Disease is ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Progressive
- Recurrent
- Metastatic

AND

3 - Used in combination with Mekinist (trametinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tafinlar will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tafinlar [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tafinlar therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Tafinlar® (dabrafenib) is a kinase inhibitor indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors.[1]

Tafinlar, in combination with Mekinist® (trametinib), is indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutations as detected by an FDA-approved test and for the adjuvant treatment of melanoma with BRAF V600E or BRAF V600K mutations, as detected by an FDA approved test, involving the lymph node(s), following complete resection. Tafinlar, in combination with Mekinist, is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test, for the treatment of locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options, and for the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. The latter indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Tafinlar, in combination with Mekinist, is also indicated for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

The National Comprehensive Cancer Network (NCCN) also recommends use of Tafinlar in combination with Mekinist for the adjuvant treatment of ATC with BRAF V600E mutations following resection; and as monotherapy for the treatment of follicular, oncocytic, and papillary thyroid carcinomas with a BRAF mutation; in combination with Mekinist for the treatment for recurrent, advanced, or metastatic NSCLC in patients with BRAF V600E

mutation, or as single agent if the combination of Tafinlar and Mekinist is not tolerated; in the treatment of glioblastomas and other high-grade gliomas; in the treatment of central nervous system (CNS) cancer in patients with melanoma; ovarian cancer/fallopian tube cancer/primary peritoneal cancer with persistent disease or recurrence in BRAF V600E positive tumors; pancreatic and ampullary adenocarcinomas if BRAF V600E mutation positive; and certain BRAF V600E mutation positive histiocytic neoplasms and hepatobiliary cancers; hairy cell leukemia; salivary gland tumor; and gastrointestinal stromal tumor.

Information on FDA-approved tests for the detection of BRAF V600 mutations in melanoma may be found at: http://www.fda.gov/CompanionDiagnostics

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Tafinlar [package insert]. Research Triangle Park, NC: GlaxoSmithKline; April 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 10, 2025.

5 . Revision History

Date	Notes
5/19/2025	Annual review. Updated background and references.

Tagrisso

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-291199
Guideline Name	Tagrisso
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	5/16/2025
P&T Revision Date:	6/18/2025

1 . Indications

Drug Name: Tagrisso (osimertinib)
Adjuvant Treatment of EGFR Mutation-Positive Non-Small Cell Lung Cancer (NSCLC) Indicated as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test **Locally Advanced, Unresectable (Stage III) EGFR Mutation-Positive NSCLC** Indicated for the treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test **First-line Treatment of EGFR Mutation-Positive Metastatic NSCLC** Indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

First-line Treatment of EGFR Mutation-Positive Locally Advanced or Metastatic NSCLC In combination with pemetrexed and platinum-based chemotherapy is indicated for the first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test **Previously Treated EGFR T790M Mutation-Positive Metastatic NSCLC** Indicated for the treatment of adult patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy

2 . Criteria

Product Name:Tagrisso [a]	
Diagnosis	Central Nervous System (CNS) Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of brain metastases from EGFR mutation-positive NSCLC **OR** **2** - Diagnosis of leptomeningeal metastases from EGFR mutation-positive NSCLC	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tagrisso [a]	
Diagnosis	Central Nervous System (CNS) Cancer
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tagrisso therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tagrisso [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is positive for at least ONE of the following EGFR mutations:

- Exon 19
- Exon 21 L858R
- S768I
- L861Q
- G719X
- T790M

AND

3 - ONE of the following:

3.1 ALL of the following:

- Disease is stage IB, II, IIIA, or IIIB (T3, N2)
- Patient has undergone complete resection
- Patient has received previous adjuvant chemotherapy or ineligible to receive platinum-based chemotherapy

OR

3.2 ALL of the following:

- Disease is stage II-III
- Disease is locally advanced or unresectable
- No disease progression during or following concurrent or sequential chemoradiation

OR

3.3 Disease is recurrent, advanced, or metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tagrisso [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tagrisso therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tagrisso [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Tagrisso will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tagrisso [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Tagrisso therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Tagrisso (osimertinib) is a kinase inhibitor indicated for first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, and patients with metastatic EGFR T790M mutation-positive NSCLC, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy. Tagrisso is also indicated for adjuvant therapy after tumor resection in adults with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, and for the treatment of adult patients with locally advanced, unresectable (stage III) non-small cell lung cancer (NSCLC) whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations. The National Cancer Comprehensive Network (NCCN) recommends the use of Tagrisso for the treatment for limited and extensive brain metastases in EGFR mutation-positive NSCLC. NCCN also recommends Tagrisso for use in leptomeningeal metastases from NSCLC that is EGFR mutation-positive.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Tagrisso [package insert]. AstraZeneca Pharmaceuticals LP: Wilmington, DE; September 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed September 21, 20243.

5 . Revision History

Date	Notes

6/9/2025	Updated misspelled EGFR mutation type in non-small cell lung canc er.

Takhzyro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-552195
Guideline Name	Takhzyro
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/18/2023
P&T Revision Date:	03/20/2024 ; 3/18/2026

1 . Indications

Drug Name: Takhzyro
Hereditary angioedema (HAE) Takhzyro is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 2 years and older.

2 . Criteria

Product Name:Takhzyro [a]	
Approval Length	^See Note
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - Prescribed for prophylaxis of HAE attacks

AND

3 - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Andembry, Cinryze, Dawnzera, Haegarda, Orladeyo)

AND

4 - Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Takhzyro

AND

5 - Submission of medical records documenting a history of failure, contraindication, or intolerance to Haegarda (C1 esterase inhibitor, human)

AND

6 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Approval durations: 1) Adult and pediatric patients 12 years of age and older: Authorization of Takhzyro 300mg given every 2 weeks will be issued for 8 months. 2) Pediatric patients 6 to less than 12 years of age: Authorization of Takhzyro 150 mg given every 2 weeks will be issued for 8 months. 3) Pediatric patients less than 6 years of age: Authorization of Takhzyro 150 mg given every 4 weeks will be issued for 12 months.

Product Name:Takhzyro [a]	
Approval Length	^See Note
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response while on Takhzyro therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Ekterly, Firazyr, icatibant, Kalbitor, Ruconest) as determined by claims information, while on Takhzyro therapy

AND

3 - Prescribed by ONE of the following:

- Immunologist
- Allergist

AND

4 - Prescribed for prophylaxis against HAE attacks

AND

5 - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Andembry, Cinryze, Dawnzera, Haegarda, Orladeyo)

AND

6 - ONE of the following:

6.1 Patient is less than 6 years of age

OR

6.2 Documentation of the number of acute HAE attacks in the previous 6 months, while on Takhzyro therapy indicates ONE of the following,

6.2.1 Patient experienced no (zero) acute HAE attacks in the previous 6 months:

OR

6.2.2 Patient experienced one or more acute HAE attacks in the previous 6 months:

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Approval durations: 1) Pediatric patients less than 6 years of age: Authorization of Takhzyro 150 mg given every 4 weeks for 12 months. 2) No (zero) acute HAE attacks in the previous 6 months while on Takhzyro therapy: Adult and pediatric patients 12 years of age and older: Authorization of Takhzyro 300mg given every 4 weeks for 12 months* 3) No (zero) acute HAE attacks in the previous 6 months while on Takhzyro therapy: Pediatric patients 6 to less than 12 years of age: Authorization of Takhzyro 150 mg given every 4 weeks for 12 months* 4) One or more acute HAE attacks in the previous 6 months while on Takhzyro therapy: Adult and pediatric patients 12 years of age and older: Authorization of Takhzyro 300 mg given every 2 weeks for 6 months 5) One or more acute HAE attacks in the previous 6 months while on Takhzyro therapy: Pediatric patients 6 to less than 12 years of age: Authorization of Takhzyro 150 mg given every 2 weeks for 6 months. *Patients experiencing unexpected breakthrough HAE attacks once switched to every 4 week dosing will require additional review to allow for every 2- week dosing.

3 . Background

Benefit/Coverage/Program Information
Background: Takhzyro is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 2 years and older.[1] **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Takhzyro [package insert]. Lexington, MA: Dyax Corp; February 2023.
2. Riedl MA, Bernstein JA, Craig T, et al. An open-label study to evaluate the long-term safety and efficacy of lanadelumab for prevention of attacks in hereditary angioedema: design of the HELP study extension. Clin Transl Allergy. 2017 Oct 6;7:36.
3. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2023.
4. Busse, P., Christiansen, S., Riedl, M., et. al. “US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema.” The Journal of Allergy and Clinical Immunology. 2020 September 05.
5. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2021 revision and update. Allergy. 2022;77(7):1961-1990. doi:10.1111/all.15214

5 . Revision History

Date	Notes
3/17/2026	Annual review. Updated list of examples of prophylactic and acute H AE treatments. Updated criteria by removing requirement to docume nt frequency of HAE attacks. Updated references.

Taltz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523277
Guideline Name	Taltz
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	10/1/2024
P&T Revision Date:	12/18/2024 ; 01/15/2025 ; 2/20/2026

1 . Indications

Drug Name: Taltz (ixekizumab)
Plaque Psoriasis (PsO) Indicated for the treatment of moderate to severe plaque psoriasis in patients aged 6 years or older who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis. **Non-radiographic Axial Spondyloarthritis** Indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation.

2 . Criteria

Product Name:Taltz [a]	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic moderate to severe plaque psoriasis

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 Greater than or equal to 3 % body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

2.1.2 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

2.1.3 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless

contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Siliq (brodalumab), Sotyktu (deucravacitinib), Tremfya (guselkumab), ustekinumab]

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to ONE of the following preferred products (document drug, date, and duration of trial):

- One of the preferred adalimumab products [b]
- Skyrizi (risankizumab)
- One of the preferred ustekinumab products [c]

OR

3.2 BOTH of the following:

- Patient is currently on Taltz therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from Lilly Support ServicesTM for Taltz (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Taltz*

AND

4 - Patient is not receiving Taltz in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Cimzia (certolizumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Siliq (brodalumab), Sotyktu (deucravacitinib), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. [c] For a list of preferred ustekinumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from Lilly Support Services for Taltz SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Taltz [a]	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Siliq (brodalumab), Sotyktu (deucravacitinib), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Taltz [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - ONE of the following:

- History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)
- Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab, Xeljanz/Xeljanz XR (tofacitinib)]

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to ONE of the following preferred products (document drug, date, and duration of trial):

- One of the preferred adalimumab products [b]
- Simponi (golimumab)
- Skyrizi (risankizumab)

- One of the preferred ustekinumab products [c]

OR

3.2 BOTH of the following:

- Patient is currently on Taltz therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from Lilly Support Services for Taltz (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Taltz*

AND

4 - Patient is not receiving Taltz in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab, Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication

AND

5 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. [c] For a list of preferred ustekinumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from Lilly Support Services for Taltz SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Taltz [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab, Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Taltz [a]	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - ONE of the following:

- History of failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)
- Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to ONE of the following preferred products (document drug, date, and duration of trial):

- One of the preferred adalimumab products [b]
- Simponi (golimumab)

OR

3.2 BOTH of the following:

- Patient is currently on Taltz therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from Lilly Support Services for Taltz (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Taltz*

AND

4 - Patient is not receiving Taltz in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from Lilly Support Services for Taltz SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Taltz [a]	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizu- mab- bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Taltz [a]	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - ONE of the following:

- History of failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)
- Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g. Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Rinvoq (upadacitinib)]

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to Rinvoq (upadacitinib) (document date and duration of trial)

OR

3.2 BOTH of the following:

- Patient is currently on Taltz therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from Lilly Support Services for Taltz (e.g., sample card

which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Taltz*

AND

4 - Patient is not receiving Taltz in combination with another systemic targeted immunomodulator [e.g. Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Rinvoq (upadacitinib)] for treatment of the same indication

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from Lilly Support Services for Taltz SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Taltz [a]	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with another systemic targeted immunomodulator [e.g. Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Rinvoq (upadacitinib)] for treatment of the same indication	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Taltz (ixekizumab) is a humanized interleukin-17A antagonist indicated for the treatment of moderate to severe plaque psoriasis in patients aged 6 years or older who are candidates for systemic therapy or phototherapy. It is also indicated for the treatment of adult patients with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, or active ankylosing spondylitis.[1] **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; August 2024.
2. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, J Eur Acad Derm Venereol 2015;29:2277-94.
3. Gossec L, et al; European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update, Ann Rheum Dis 2016;75:499-510.
4. Ward MM, Deodhar A, Dubreuil M, et al. 2019 update of the american college of rheumatology/spondylitis association of america/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and

nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019; Aug 22. doi: 10.1002/art.41042.
5. Menter A, Strober BE, Kaplan DH et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019:80:1029-72.
6. Fraenkel L, Bathon JM, et al; 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2021 Jul;73(7):924-939.
7. Singh, JA, Guyatt, G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2019; 71(1): 5-32.

5 . Revision History

Date	Notes
2/23/2026	Annual review. Updated examples with no change to clinical intent. U pdated references.

Talzenna

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-355233
Guideline Name	Talzenna
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	10/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 12/15/2021 ; 12/14/2022 ; 08/18/2023 ; 08/16/2024 ; 8/22/2025

1 . Indications

Drug Name: Talzenna (talazoparib)
BRCA-mutated (gBRCAm) HER2-negative Locally Advanced or Metastatic Breast Cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. Appropriate patients for therapy are selected based on an FDA-approved companion diagnostic for Talzenna. [1] **HRR Gene-mutated mCRPC** Indicated in combination with Xtandi (enzalutamide) for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC). **Other Uses:** The National Comprehensive Cancer Network (NCCN) also supports use of Talzenna in any locally advanced metastatic breast cancer subtype associated with a germline BRCA1 or BRCA2 mutation.

2 . Criteria

Product Name:Talzenna [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of breast cancer **AND** **2** - Disease is one of the following: • Locally advanced • Metastatic **AND** **3** - Presence of a germline BRCA-mutation	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Talzenna [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Talzenna therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Talzenna [a]	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer

AND

2 - Presence of homologous recombination repair (HRR) gene mutations

AND

3 - Used in combination with Xtandi (enzalutamide)

AND

4 - One of the following:

- Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

• Patient has had bilateral orchiectomy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Talzenna [a]	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Talzenna therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Talzenna [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Talzenna will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Talzenna [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Talzenna therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Talzenna (talazoparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as a single agent for the treatment of adult patients with deleterious or suspected deleterious germline BRCA mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. Appropriate patients for therapy are selected based on an FDA-approved companion diagnostic for Talzenna. [1] Talzenna is also indicated in combination with Xtandi (enzalutamide) for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC). The National Comprehensive Cancer Network (NCCN) also supports use of Talzenna in any locally advanced metastatic breast cancer subtype associated with a germline BRCA1 or BRCA2 mutation.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.

4 . References

1. Talzenna [package insert]. New York, NY: Pfizer Labs, June 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 1, 2025.

5 . Revision History

Date	Notes
8/5/2025	Annual review. Updated background and references.

Tarpeyo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-552220
Guideline Name	Tarpeyo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	2/18/2022
P&T Revision Date:	04/20/2022 ; 07/20/2022 ; 07/19/2023 ; 02/16/2024 ; 02/20/2025 ; 02/20/2026 ; 3/18/2026

1 . Indications

Drug Name: Tarpeyo (budesonide delayed-release capsules)
Primary immunoglobulin A nephropathy (IgAN) Indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease

2 . Criteria

Product Name:Tarpeyo [a]	
Approval Length	9 month(s)

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

AND

2 - Patient is at risk for disease progression

AND

3 - Used to reduce the loss of kidney function

AND

4 - Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m2

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following:

- maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

5.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs

AND **6** - Prescribed by or in consultation with a nephrologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Tarpeyo (budesonide delayed-release capsule) is indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class • Supply limits may be in place.

4 . References

1. Tarpeyo [package insert]. Stockholm, Sweedem: Calliditas Therapeutics AB; June 2024.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. (2025). KDIGO 2025 clinical practice guideline for the management of IgA nephropathy (IgAN) and IgA vasculitis (IgAV). KDIGO. https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2025-IgAN-IgAV-Guideline.pdf

5 . Revision History

Date	Notes
3/17/2026	Removed corticosteroid step and updated references.

Testosterone

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-432226
Guideline Name	Testosterone
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	
P&T Revision Date:	11/21/2025

1 . Indications

Drug Name: Androgel Pump (1.62%), Testim, Vogelxo, Natesto, Fortesta, Jatenzo, Kyzatrex, Tlando, Undecatrex, testosterone 30 mg/act soln, Xyosted, Depo-Testosterone, testosterone enanthate inj.
Hypogonadism (congenital or acquired) or hypogonadrotropic hypogonadism Testosterone products are approved by the Food and Drug Administration (FDA) for testosterone replacement therapy in males with primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). Primary hypogonadism originates from a deficiency or disorder in the testicles. Secondary hypogonadism indicates a problem in the hypothalamus or the pituitary gland. Testosterone use has been strongly linked to improvements in muscle mass, bone density, and libido.

2 . Criteria

Product Name:Testosterone 30mg/act solution, generic testosterone gel 1% and 1.62%, Brand Testim, Brand Vogelxo, Brand Androgel, Brand Fortesta, generic testosterone gel, Natesto, Brand Depo-Testosterone, generic testosterone cypionate, generic testosterone enanthate, Kyzatrex, Tlando, Jatenzo, Undecatrex, Xyosted [a]	
Diagnosis	Hypogonadism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient has a history of ONE of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

AND

1.2 Patient was male at birth

OR

2 - ALL of the following:

2.1 ONE of the following:

2.1.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (less than 10.4 nmol/L) or less than the reference range for the lab, taken at separate times (This may require treatment to be temporarily held. Document lab value and date for both levels)

OR

2.1.2 BOTH of the following:

- Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)
- One pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (<5 ng/dL or < 0.17 nmol/L) or less than the reference range for the lab (This may require treatment to be temporarily held. Document lab value and date)

AND

2.2 Patient is NOT taking any of the following:

- One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
- Aromatase inhibitor (e.g., Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

AND

2.3 Patient was male at birth

AND

2.4 Diagnosis of hypogonadism

AND

2.5 ONE of the following:

- Significant reduction in weight (less than 90% ideal body weight) (e.g., AIDS wasting syndrome)
- Osteopenia
- Osteoporosis
- Decreased bone density
- Decreased libido
- Organic cause of testosterone deficiency (e.g., injury, tumor, infection, or genetic defects)

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Testosterone 30mg/act solution, generic testosterone gel 1% and 1.62%, Brand Testim, Brand Vogelxo, Brand Androgel, Brand Fortesta, generic testosterone gel, Natesto, Brand Depo-Testosterone, generic testosterone cypionate, generic testosterone enanthate, Kyzatrex, Tlando, Jatenzo, Undecatrex, Xyosted [a]	
Diagnosis	Gender Dysphoria [b][c]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Using hormones to change physical characteristics

AND

2 - The covered person must be diagnosed with gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

AND

3 - Patient is NOT taking any of the following:

- One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
- Aromatase inhibitor (e.g., Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply. [b] Gender Dysphoria/Gender affirming treatment is not a coverable b enefit in the following markets: AL, AZ, FL, GA, IN, IA, KS, LA, MS, M O, NE, NC, NM, OH, OK, SC, TN, TX, WY [c] In TX, if an enrollee has ever been provided coverage for a gender

	transition procedure or treatment then coverage shall be provided for all possible adverse consequences or side effects related to that treat ment or procedure and for any procedure, treatment, or therapy neces sary to manage, reverse, reconstruct from, or recover from the proced ure or treatment.

Product Name:Testosterone 30mg/act solution, generic testosterone gel 1% and 1.62%, Brand Testim, Brand Vogelxo, Brand Androgel, Brand Fortesta, generic testosterone gel, Natesto, Brand Depo-Testosterone, generic testosterone cypionate, generic testosterone enanthate, Kyzatrex, Tlando, Jatenzo, Undecatrex, Xyosted [a]	
Diagnosis	Non-Gender Dysphoria (includes hypogonadism) and Gender Dysphoria [b][c]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a history of ONE of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (eg, congenital anorchia, Klinefelter's syndrome)

OR

2 - BOTH of the following:

2.1 ONE of the following:

2.1.1 Follow-up total serum testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document value and date)

OR

2.1.2 Follow-up total serum testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

OR

2.1.3 BOTH of the following:

2.1.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

2.1.3.2 ONE of the following:

- Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document lab value and date)
- Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

AND

2.2 Patient is NOT taking any of the following:

- One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
- Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] Gender Dysphoria/Gender affirming treatment is not a coverable benefit in the following markets: AL, AZ, FL, GA, IN, IA, KS, LA, MS, MO, NE, NC, NM, OH, OK, SC, TN, TX, WY [c] In TX, if an enrollee has ever been provided coverage for a gender transition procedure or treatment then coverage shall be provided for all possible adverse consequences or side effects related to that treatment or procedure and for any procedure, treatment, or therapy necessary to manage, reverse, reconstruct from, or recover from the procedure or treatment.

3 . Background

Benefit/Coverage/Program Information
Background: Testosterone products are approved by the Food and Drug Administration (FDA) for testosterone replacement therapy in males with primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). Primary hypogonadism originates from a deficiency or disorder in the testicles. Secondary hypogonadism indicates a problem in the hypothalamus or the pituitary gland. Testosterone use has been strongly linked to improvements in muscle mass, bone density, and libido. The purpose of this program is to provide coverage for androgens and anabolic steroid therapy for the treatment of conditions for which they have shown to be effective and are within the scope of the plan's pharmacy benefit. Coverage for the enhancement of athletic performance or body building will not be provided. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. The World Professional Association for Transgender Health (WPATH), Standards of Care for the Health of, Transgender and Gender Diverse People, 8th Version, Sept 15, 2022
2. Androgel [package insert]. Bridgewater, NJ: Ascend Therapeutics U.S., LLC; July 2025.
3. Fortesta [package insert]. Malvern, PA: Endo Pharmaceuticals Inc; June 2020.
4. Testim [package insert]. Malvern, PA: Endo Pharmaceuticals Inc; July 2025.
5. Natesto [package insert]. Englewood, CO: Aytu BioScience, Inc; July 2025.
6. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; April 2020.

7. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2017; 102:3869.
8. Shalender Bhasin, Juan P Brito, Glenn R Cunningham, Frances J Hayes, Howard N Hodis, Alvin M Matsumoto, Peter J Snyder, Ronald S Swerdloff, Frederick C Wu, Maria A Yialamas, Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 103, Issue 5, May 2018, Pages 1715–1744, https://doi.org/10.1210/jc.2018-00229
9. Mulhall JP, Trost LW, Brannigan RE et al: Evaluation and management of testosterone deficiency: AUA guideline. J Urol 2018; 200: 423.
10. Xyosted [package insert]. Ewing, NJ: Antares Pharma, Inc; July 2025.
11. Jatenzo [package insert]. Fort Collins, CO: Tolmar, Inc; September 2025.
12. Tlando [package insert]. Salt Lake City, UT: Lipocine Enhancing Health; March 2022.
13. Kyzatrex [package insert]. Raleigh, NC: Marius Pharmaceuticals; August 2025.
14. Depo-testosterone [package insert]. New York, NY: Pharmacia & Upjohn Co; August 2020.
15. Testosterone enanthate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc. January 2021.
16. Undecatrex [package insert]. San Antonio, TX: Trifluent Pharma, LLC. September 2022.

5 . Revision History

Date	Notes
10/28/2025	Updated product list to remove obsolete Androgel 1% and 1.62% (br and), Androgel Pump 1%, and Androderm. Added generic testostero ne gel 1% and 1.62% and testosterone gel pump 1%. Added operatio nal note to identify states which do not cover Gender Dysphoria and exception for Texas. Added requirement male at birth to orchiectomy, panhypopituitarism and genetic disorders requirement section.

Tezspire

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-458252
Guideline Name	Tezspire
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	7/19/2023
P&T Revision Date:	08/18/2023 ; 07/17/2024 ; 07/16/2025 ; 12/17/2025

Note:

This program applies to the prefilled pen for self-administration

1 . Indications

Drug Name: Tezspire (tezepelumab)
Severe Asthma Indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)** Indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

2 . Criteria

Product Name:Tezspire auto-inj prefilled pen [a]	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - ALL of the following:

1.1 Patient has been established on therapy with Tezspire under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

AND

1.2 Documentation of positive clinical response to Tezspire therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

AND

1.3 Tezspire is being used in combination with an inhaled corticosteroid (ICS)-containing controller medication [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

AND

1.4 Patient is not receiving Tezspire in combination with ANY of the following for the treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE-therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

AND

1.5 Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

OR

2 - ALL of the following:

2.1 Diagnosis of severe asthma

AND

2.2 Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:

- Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
- Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
- Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
- Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
- Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

2.3 Tezspire will be used in combination with ONE of the following:

2.3.1 ONE maximally-dosed (appropriately adjusted for age) combination inhaled

corticosteroid (ICS)/long-acting beta2 agonist (LABA) product [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

2.3.2 Combination therapy including BOTH of the following:

- ONE high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]
- ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist - montelukast (Singulair); theophylline]

AND

2.4 ONE of the following:

2.4.1 BOTH of the following:

- Tezspire will be used to treat eosinophilic asthma
- History of failure, contraindication, or intolerance to a 4-month trial of Dupixent (dupilumab)

OR

2.4.2 BOTH of the following:

- Tezspire will be used to treat persistent allergic asthma
- History of failure, contraindication, or intolerance to a 4-month trial of Xolair (omalizumab)

OR

2.4.3 BOTH of the following:

- Tezspire will be used to treat oral corticosteroid dependent asthma
- History of failure, contraindication, or intolerance to a 4-month trial of Dupixent (dupilumab)

OR

2.4.4 Patient's asthma is not of the eosinophilic, allergic, or oral corticosteroid dependent phenotype

AND

2.5 Patient is not receiving Tezspire in combination with ANY of the following for the treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

AND

2.6 Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tezspire auto-inj prefilled pen [a]	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Tezspire therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

AND

2 - Tezspire is being used in combination with an ICS-containing controller medication [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

AND

3 - Patient is not receiving Tezspire in combination with ANY of the following for the treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tezspire auto-inj prefilled pen [a]	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - ALL of the following:

1.1 Patient has been established on therapy with Tezspire under an active UnitedHealthcare medical benefit prior authorization for the treatment of chronic rhinosinusitis with nasal polyps

AND

1.2 Documentation of positive clinical response to Tezspire therapy

AND

1.3 Patient continues to receive Tezspire as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

1.4 Patient is not receiving Tezspire in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE-therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

AND

1.5 Prescribed by ONE of the following:

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

OR

2 - ALL of the following:

2.1 Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) defined by ALL of the following:

2.1.1 TWO OR MORE of the following symptoms for longer than 12 weeks duration:

- Nasal mucopurulent discharge
- Nasal obstruction, blockage, or congestion
- Facial pain, pressure, and/or fullness
- Reduction or loss of sense of smell

AND

2.1.2 ONE of the following findings using nasal endoscopy and/or sinus computed tomography (CT):

- Purulent mucus or edema in the middle meatus or ethmoid regions
- Polyps in the nasal cavity or the middle meatus
- Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

AND

2.1.3 ONE of the following:

- Patient has required prior sinus surgery
- Patient has previously required surgical removal of bilateral nasal polyps

AND

2.1.4 ONE of the following:

2.1.4.1 Patient has required prior sinus surgery

OR

2.1.4.2 Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for CRSwNP in the previous 2 years

OR

2.1.4.3 Patient has been unable to obtain symptom relief after trial of TWO of the following classes of agents:

- Nasal saline irrigations
- Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)
- Antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)

AND

2.2 Patient will receive Tezspire as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

2.3 History of failure, contraindication, or intolerance to BOTH of the following products (document date and duration of trial):

- Dupixent (dupilumab)
- Xolair (omalizumab)

AND

2.4 Patient is not receiving Tezspire in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE-therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

AND

2.5 Prescribed by ONE of the following:

- Allergist
- Immunologist

• Otolaryngologist • Pulmonologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tezspire auto-inj prefilled pen [a]	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Tezspire therapy

OR

2 - Patient will continue to receive Tezspire as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

3 - Patient is not receiving Tezspire in combination with ANY of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background Tezspire (tezepelumab) is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma and for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP). *Limitations of use:* Tezspire is not indicated for relief of acute bronchospasm of status asthmaticus. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Global Initiative for Asthma. Difficult-To-Treat & Severe Asthma in adolescent and adult patients. Diagnosis and Management, 2024. Available at http://www.ginasthma.org. Accessed May 29, 2025.
2. Tran TN, Zeiger RS, Peters SP, et al. Overlap of atopic, eosinophilic, and TH2-high asthma phenotypes in a general population with current asthma. Ann Allergy Asthma Immunol. 2016;116(1):37-42. doi:10.1016/j.anai.2015.10.027.
3. Corren J, Ziegler SF. TSLP: from allergy to cancer. Nat Immunol. 2019;20(12):1603-1609. doi:10.1038/s41590-019-0524-9.
4. Tezspire™ [package insert]. Thousand Oakes, CA: Amgen Inc.; October 2025.
5. Institute for Clinical and Economic Review (ICER). Tezepelumab for Severe Asthma. November 4, 2021. Available at ICER | Working Towards Fair Pricing, Fair Access, & Future Innovation. Accessed May 29, 2024

6. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J. 2020 Jan 2;55(1):1900588. doi: 10.1183/13993003.00588-2019. PMID: 31558662

5 . Revision History

Date	Notes
12/3/2025	Added criteria for new indication of chronic rhinosinusitis with nasal p olyps. Updated background and references.

Thalomid

Prior Authorization Guideline

Guideline ID	GL-254195
Guideline Name	Thalomid
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	05/21/2021 ; 09/15/2021 ; 05/20/2022 ; 05/25/2023 ; 05/17/2024 ; 5/16/2025

1 . Indications

Drug Name: Thalomid (thalidomide)
Erythema nodosum leprosum (ENL) Indicated for the acute treatment of cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). It is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. It is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. **Multiple myeloma** Indicated for treatment of newly diagnosed multiple myeloma in combination with dexamethasone.

2 . Criteria

Product Name:Thalomid [a]	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple myeloma	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Thalomid [a]	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Thalomid therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Thalomid [a]	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL)

AND

2 - ONE of the following:

- Used for acute treatment
- Used as maintenance therapy for prevention and suppression of cutaneous manifestations of ENL recurrence

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Thalomid [a]	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Thalomid [a]	
Diagnosis	Castleman Disease

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Castleman's Disease (CD)

AND

2 - ONE of the following:

2.1 NOT used as first line therapy

OR

2.2 ALL of the following:

- Therapy is for active idiopathic multicentric CD with no evidence of organ failure
- Used in combination with cyclophosphamide and prednisone
- Patient is human immunodeficiency virus (HIV)-negative
- Patient is human herpesvirus-8 (HHV8)-negative

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Thalomid [a]	
Diagnosis	Castleman Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Thalomid therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Thalomid [a]	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of HIV-negative Kaposi Sarcoma

OR

1.2 BOTH of the following:

- Diagnosis of AIDS-related Kaposi Sarcoma
- Patient is currently being treated with antiretroviral therapy (ART)

AND

2 - NOT used as first line therapy

AND

3 - Patient has immune reconstitution inflammatory syndrome (IRIS)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Thalomid [a]	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Thalomid therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Thalomid [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Langerhans cell histiocytosis **OR** **2** - Diagnosis of Rosai-Dorfman Disease	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Thalomid [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Thalomid therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Thalomid [a]	
Diagnosis	Pediatric Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pediatric medulloblastoma **AND** **2** - Disease is recurrent or progressive	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Thalomid [a]	
Diagnosis	Pediatric Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Thalomid therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Thalomid [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Thalomid will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Thalomid [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Thalomid therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Thalomid (thalidomide) is a synthetic glutamic acid derivative indicated for the treatment of patients with newly diagnosed multiple myeloma (MM) in combination with dexamethasone. It is also indicated for the acute treatment of cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL) and as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. It is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

The National Cancer Comprehensive Network (NCCN) also recommends the use of Thalomid for treatment of histiocytic neoplasms – Langerhans cell histiocytosis and Rosai-Dorman disease, Castleman's disease, pediatric medulloblastoma, and kaposi sarcoma.

Because of the risk of serious malformations if given during pregnancy, the manufacturer has an extensive risk management program requiring registration by patients, prescribers and dispensing pharmacies. Additional information about the Thalomid Risk Evaluation and Mitigation Strategy (REMS) [Thalomid REMS®] program may be found at http://www.thalidomiderems.com/.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4 . References

1. Thalomid [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; December 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 10, 2025.
3. Thalomid REMS®. Available at http://www.thalomidrems.com/. Accessed April 10, 2025

5 . Revision History

Date	Notes
5/7/2025	Annual review. Added criteria for pediatric central nervous system ca ncers based on NCCN recommendations. Updated background and r eferences.

Therapeutic Duplication

Prior Authorization Guideline

Guideline ID	GL-155312
Guideline Name	Therapeutic Duplication
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2024
P&T Approval Date:	9/18/2024
P&T Revision Date:	

1 . Criteria

Product Name:Therapeutic Duplication Criteria	
Approval Length	2 Week(s)
Guideline Type	Administrative

Approval Criteria

1 - The requested medication will be used exclusively, and the previously prescribed medication will be discontinued

OR

2 - Special circumstances exist that necessitate the need for duplicate therapy such as a nationally recognized drug shortage (document special circumstances)

2 . Background

Benefit/Coverage/Program Information

Background:

A concurrent DUR (cDUR) program screens all retail and mail service prescription claims at the point of service before the drug is dispensed. The cDUR system screens each prescription against the member's prescription drug history. The system evaluates drug prescribing and utilization, including therapeutic duplication, as well as drug interactions to improve quality and cost effectiveness of dispensed medications by helping to ensure that adjudicated and covered prescriptions are clinically appropriate. The program includes communication avenues through claims edits and messaging to the dispensing pharmacy at point-of-service.

The following situations would result in application of the therapeutic duplication edit:

- The requested medication has been utilized concurrently with a different drug in the same therapeutic class per recent prescription claims history.
- The requested medication has been utilized concurrently in a different dosage of the same medication per recent prescription claims history.
- The requested medication has been utilized concurrently with a different drug in a different therapeutic class per recent prescription claims history, when the two medications share the same clinical indication but lack support for concomitant use from evidence-based medicine.

Drug Classes Subject to a Therapeutic Duplication Edit:

A. Drug Classes Subject to Therapeutic Duplication Edit (Reject 88):

- Both brand and generic versions of medications are subject to edit

B. Diabetes Agents:

- GLP-1 Receptor Agonists

Additional Clinical Rules:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3 . Revision History

Date	Notes
9/19/2024	New program

Therdose Administrative



Prior Authorization Guideline

Guideline ID	GL-157012
Guideline Name	Therdose Administrative
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2025
P&T Approval Date:	1/20/2021
P&T Revision Date:	10/20/2021

1 . Criteria

Product Name:Cumulative doses of acetaminophen exceeding 4 grams per day	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The cumulative* total daily dose of acetaminophen is supported by one of the following references:

- American Hospital Formulary Service Drug Information

• Micromedex DRUGDEX Information System • National Comprehensive Cancer Network (NCCN) • Clinical pharmacology • Wolters Kluwer Lexi-Drugs • United States Pharmacopoeia-National Formulary (USP-NF) • Drug Facts and Comparisons	
Notes	*For any given member, all medications containing acetaminophen wil l accumulate to the total daily dose. For members who need one time overrides for acetaminophen exceeding 4 grams per day due to admin istrative reasons such as vacation supplies, drug changes, dosage ch anges, etc., please refer the prescriber/member to the Help Desk by i ncluding the following verbiage in closure letters: If you exceed the ma ximum FDA approved dosing of 4 grams of acetaminophen per day b ecause you need extra medication due to reasons such as going on a vacation, replacement for a stolen medication, your doctor changed to another medication that has acetaminophen, or your doctor changed the dosing on your medication that resulted in acetaminophen exceedi ng 4 grams per day, please have your pharmacy contact the OptumR x Pharmacy Helpdesk at the time they are filling your prescription for a one-time override.

2 . Background

Benefit/Coverage/Program Information
Background: A hard safety edit assesses the total cumulative daily dose of acetaminophen based on FDA approved maximum dosing of 4 grams. The edit is triggered if total daily dose exceeds the FDA-defined maximum daily dose. This program is administered for members who have triggered the hard safety edit.

3 . Revision History

Date	Notes
10/3/2024	Annual Review. Clerical change to Background section. No changes to criteria.

Tivicay State Mandate Non-Formulary

Prior Authorization Guideline

Guideline ID	GL-133862
Guideline Name	Tivicay State Mandate Non-Formulary
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Tivicay, Tivicay PD [a]	
Diagnosis	Treatment of HIV Infection
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - For the treatment of HIV infection

AND

2 - The patient must try and fail, or have specific medical reason(s) why the number of alternatives* specified by the Non-Formulary Alternatives Table is not appropriate (see technician note in Background for NF Alts Table URL)

Notes	[a] Formulary: 2024 UnitedHealthcare Government Programs Exchange Formulary. If approved, the non-formulary drug will be covered at tier 5 for 6-tiered formularies, at tier 4 for 5-tiered formularies, or tier 3 for 4-tiered formularies. *If an alternative is the generic equivalent of the non-formulary target drug, then it must be one of the required alternatives the patient must try and fail or have a specific medical reason why the alternative is not appropriate.

Product Name:Tivicay 50 mg [a]	
Diagnosis	HIV Post-Exposure Prophylaxis (PEP) [off-label]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Request is for 50 mg (milligrams) strength

AND

2 - Used for HIV-1 post-exposure prophylaxis (PEP)

AND

3 - One of the following:

3.1 Prescribed by a qualified Colorado-licensed pharmacist

OR

3.2 The patient must try and fail, or have specific medical reason(s) why the number of alternatives* specified by the Non-Formulary Alternatives Table is not appropriate (see technician note in Background for NF Alts Table URL)

Notes	[a] Formulary: 2024 UnitedHealthcare Government Programs Exchange Formulary. If approved, the non-formulary drug will be covered at tier 5 for 6-tiered formularies, at tier 4 for 5-tiered formularies, or tier 3 for 4-tiered formularies. *If an alternative is the generic equivalent of the non-formulary target drug, then it must be one of the required alternatives the patient must try and fail or have a specific medical reason why the alternative is not appropriate.

2 . Background

Benefit/Coverage/Program Information
Background: The Colorado State Board of Pharmacy Statewide Protocol for HIV PrEP and post-exposure prophylaxis (PEP) prohibits health plans from requiring prior authorization or step therapy when prescribed by a qualified Colorado-licensed pharmacist. **Formulary Note:** Termination date of authorizations approved pursuant to this guideline is 12 months from date of approval **Technician Note:** Non-Formulary Alternatives Table link: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x01200027C80175A8369D44AC45A99A99328B80&View=%7B4B6D25AD%2D6A95%2D496D%2D9937%2D65CECD43AFE7%7D&viewid=c2ad0afa%2D814c%2D499e%2Dbf25%2D3411fac9171f&id=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FUHCGP%20Exchange%2FNF%20Alt%20Tables **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program

and/or therapeutic class. • Supply limits may be in place

3 . References

1. Tivicay [package insert]. Durham, NC: GlaxosmithKline; October 2022.
2. Tivicay. AHFS Drug Information. http://online.lexi.com/lco/action/home. Accessed July 2023.

4 . Revision History

Date	Notes
9/27/2023	New guideline.

Tobacco Cessation Health Care Reform Zero Dollar Cost Share Review

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-437194
Guideline Name	Tobacco Cessation Health Care Reform Zero Dollar Cost Share Review
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	2/19/2021
P&T Revision Date:	09/15/2021 ; 08/19/2022 ; 04/17/2024 ; 03/19/2025 ; 11/21/2025

1 . Criteria

Product Name:Apo-varenicline*, Brand Chantix, generic varenicline, Nicotrol inhaler, or Nicotrol NS [a]	
Approval Length	Authorization will be issued for zero copay with deductible bypass for 12-month period
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is 18 years of age or older	

AND

2 - Treatment is being requested for tobacco cessation

AND

3 - History of failure, contraindication, or intolerance to ONE of the following:

- Nicotine replacement patches OTC (e.g. Nicoderm CQ-OTC)
- Nicotine gum OTC (e.g. Nicorette gum- OTC)
- Nicotine lozenge or mini-lozenge OTC (e.g. Nicorette lozenge-OTC)

AND

4 - History of failure, contraindication, or intolerance to bupropion

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *For members in Illinois, members do not need to meet the age check or try/fail the listed alternatives.

2 . Background

Benefit/Coverage/Program Information
Background: Tobacco cessation therapies are more likely to succeed for patients who are motivated to stop tobacco use and who are given additional advice and support. Patients should be provided with appropriate educational materials and counseling to support the quit attempt. The patient should set a quit date. This program is designed to meet Health Care Reform requirements for tobacco cessation coverage at zero dollar cost share.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

3 . References

1. Nicotrol NS [package insert]. New York, NY: Pharmacia and Upjohn: June 2024.
2. Nicotrol Inhaler [package insert]. New York, NY: Pharmacia and Upjohn; August 2024.
3. Bupropion Hydrochloride SR [package insert]. Parsippany, NJ: Teva Pharmaceuticals; March 2023.
4. Varenicline [package insert]. Indianapolis, IN: Major Pharmaceuticals; August 2023.
5. Chantix [package insert]. New York, NY: Pfizer Inc.; June 2025.
6. US Department of Health and Human Services. Clinical practice guideline for treating tobacco use and dependence: 2008 Update. Washington, DC: US Department of Health and Human Services;.Am J Prev Med 2008;35(2)

4 . Revision History

Date	Notes
11/12/2025	Chantix brand name added to policy as it is back on market.

Tobramycin inhalation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399259
Guideline Name	Tobramycin inhalation
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 02/18/2022 ; 09/20/2023 ; 01/17/2024 ; 08/16/2024 ; 09/18/2024 ; 9/25/2025

1 . Indications

Drug Name: TOBI (tobramycin), TOBI Podhaler (tobramycin inhalation capsules) 28 mg, Bethkis (tobramycin solution for inhalation) 300 mg/4ml, Kitabis Pak (tobramycin solution for inhalation) 300 mg/5 ml
Management of cystic fibrosis An aminoglycoside antibacterial indicated for the management of CF patients with Pseudomonas aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with a forced expiratory volume in less than one second (FEV1) less than 25% or greater than 75% predicted, or patients colonized with Burkholderia cepacia. [1,2]

2 . Criteria

Product Name:Brand TOBI, Brand Bethkis, generic tobramycin, TOBI Podhaler, Kitabis Pak, tobramycin solution for inhalation [a]	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF) **OR** **2** - BOTH of the following: **2.1** Diagnosis of noncystic fibrosis bronchiectasis **AND** **2.2** ONE of the following: • Three or more exacerbations per year • Two or more exacerbations requiring hospitalization per year	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3 . Background

Benefit/Coverage/Program Information
Background: TOBI is an aminoglycoside antibacterial indicated for the management of cystic fibrosis (CF) patients with *P. aeruginosa*. Safety and efficacy have not been demonstrated in patients

under the age of 6 years, patients with FEV_1 <25% or >75% predicted, or patients colonized with *B. cepacia.* After 28 days of therapy, patients should stop tobramycin inhalation therapy for the next 28 days, and then resume therapy for the next 28 day on and 28 day off cycle. [1,2]

Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. TOBI Inhalation Solution [package insert]. East Hanover, NJ: Mylan Pharmaceuticals; February 2023.
2. Tobramycin Inhalation Solution [package insert]. Sellersville, PA.: Teva Pharmaceuticals USA; December 2024.
3. Polverino E, Goeminne PC, McDonnell MJ, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. Eur Respir J. 2017;50(3):1700629. Published 2017 Sep 9. doi:10.1183/13993003.00629-2017
4. Spencer S, Felix LM, Milan SJ, et al. Oral versus inhaled antibiotics for bronchiectasis. Cochrane Database Syst Rev. 2018;3(3):CD012579. Published 2018 Mar 27. doi:10.1002/14651858.CD012579.pub2
5. Chang AB, Bell SC, Byrnes CA, et al. Thoracic Society of Australia and New Zealand (TSANZ) position statement on chronic suppurative lung disease and bronchiectasis in children, adolescents and adults in Australia and New Zealand. Respirology. 2023;28(4):339-349. doi:10.1111/resp.14479
6. Laska IF, Crichton ML, Shoemark A, Chalmers JD. The efficacy and safety of inhaled antibiotics for the treatment of bronchiectasis in adults: a systematic review and meta-analysis. Lancet Respir Med. 2019;7(10):855-869. doi:10.1016/S2213-2600(19)30185-7
7. TOBI Podhaler [package insert]. San Carlos, CA: Mylan Pharmaceuticals; February 2023.
8. Bethkis [package insert]. Woodstock, Illinois: Chesi USA, Inc; February 2023.
9. Kitabis Pak [package insert]. Woodstock, Illinois: Woodstock Sterile Solutions, LLC; April 2023.

5 . Revision History

Date	Notes

9/18/2025	Annual review. No changes to coverage criteria. Updated references.

Tocilizumab

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-552223
Guideline Name	Tocilizumab
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	01/21/2021 ; 04/21/2021 ; 06/16/2021 ; 09/15/2021 ; 04/20/2022 ; 09/21/2022 ; 01/18/2023 ; 05/25/2023 ; 09/20/2023 ; 10/01/2024 ; 12/18/2024 ; 12/17/2025 ; 03/18/2026

1 . Indications

Drug Name: Tocilizumab [Actemra (tocilizumab), Avtozma (tocilizumab-anoh), and Tyenne (tocilizumab-aazg)]
Rheumatoid Arthritis Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). **Giant Cell Arteritis** Indicated for giant cell arteritis in adult patients. **Polyarticular Juvenile Idiopathic Arthritis** Indicated for the treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older. **Active Systemic Juvenile Idiopathic Arthritis** Indicated for the treatment of active systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older.

Systemic Sclerosis-Associated Interstitial Lung Disease Indicated for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

2 . Criteria

Product Name:Tocilizumab [a]	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of giant cell arteritis **AND** **2** - Patient is not receiving tocilizumab in combination with another systemic targeted immunomodulator for treatment of the same indication. **AND** **3** - Prescribed by or in consultation with a rheumatologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tocilizumab [a]	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to tocilizumab therapy

AND

2 - Patient is not receiving tocilizumab in combination with another systemic targeted immunomodulator for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tocilizumab [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - ONE of the following:

2.1 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)^

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)].

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to TWO of the following preferred products (Document drug, date, and duration of trial):

- One of the formulary adalimumab products [b]
- Simponi (golimumab)
- Olumiant (baricitinib)
- Rinvoq (upadacitinib)
- Xeljanz/Xeljanz XR (tofacitinib)

OR

3.2 BOTH of the following:

3.2.1 Patient is currently on tocilizumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

AND

3.2.2 Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of tocilizumab*

AND

4 - Patient is not receiving tocilizumab in combination with another systemic targeted

immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication. **AND** **5** - Prescribed by or in consultation with a rheumatologist	
Notes	*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the manufacturer sponsored program shall be required to meet initial authorization criteria as if patient were new to therapy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of formulary adalimumab products please reference drug coverage tools. ^ Tried/Failed alternative(s) are supported by FDA labeling

Product Name:Tocilizumab [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to tocilizumab therapy **AND** **2** - Patient is not receiving tocilizumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Tocilizumab [a]	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

2 - Patient is not receiving tocilizumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to one of the formulary adalimumab products [b] (Document date and duration of trial)

OR

3.2 BOTH of the following:

- Patient is currently on tocilizumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program

(e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of tocilizumab*

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program shall be required to meet initial authorization criteria as if patient were new to therapy. [b] For a list of formulary adalimumab products please reference drug coverage tools.

Product Name:Tocilizumab [a]	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to tocilizumab therapy

AND

2 - Patient is not receiving tocilizumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Tocilizumab [a]	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of active systemic juvenile idiopathic arthritis **AND** **2** - Patient is not receiving tocilizumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication. **AND** **3** - Prescribed by or in consultation with a rheumatologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Tocilizumab [a]	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to tocilizumab therapy

AND

2 - Patient is not receiving tocilizumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tocilizumab [a]	
Diagnosis	Systemic sclerosis-associated interstitial lung disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by ALL of the following criteria:[4]

1.1 ONE of the following:

1.1.1 Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

OR

1.1.2 At least TWO of the following:

- Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
- Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
- Telangiectasia
- Abnormal nailfold capillaries
- Pulmonary arterial hypertension
- Raynaud's phenomenon
- SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

AND

1.2 Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on HRCT, involving at least 10% of the lungs

AND

2 - Patient is not receiving tocilizumab in combination with another systemic targeted immunomodulator for treatment of the same indication.

AND

3 - Prescribed by or in consultation with a pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tocilizumab [a]	
Diagnosis	Systemic sclerosis-associated interstitial lung disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to tocilizumab therapy **AND** **2** - Patient is not receiving tocilizumab in combination with another systemic targeted immunomodulator for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Tocilizumab [Actemra (tocilizumab) Avtozma (tocilizumab-anoh), and Tyenne (tocilizumab-aazg)] is an interleukin-6 (IL-6) receptor antagonist, available in both an intravenous and a subcutaneous formulation.

Subcutaneous formulations of tocilizumab are indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). It is also indicated for giant cell arteritis in adult patients, the treatment of active polyarticular juvenile idiopathic arthritis (PJIA) and active systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older, and for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; August 2025.
2. Avtozma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; July 2025.
3. Tyenne [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; February 2025
4. Pavy S. Constantin A, Pham T, et al. Methotrexate therapy for rheumatoid arthritis: clinical practice guidelines based on published evidence and expert opinions. Joint Bone Spine 2006;73(4):388-95.
5. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2016;68(1):1-26.
6. van den Hoogen F, Khanna D, Fransen J, et al. 2013 Classification criteria for systemic sclerosis: an American College of Rheumatology/European League against Rheumatism collaborative initiative. Ann Rheum Dis 2013;72:1747-1755.

5 . Revision History

Date	Notes
3/17/2026	Renamed program to Tocilizumab. Added Avtozma (tocilizumab-anoh) to the program. Updated Actemra and Tyenne to Tocilizumab throug hout the program.

Tonmya

Prior Authorization Guideline

Guideline ID	GL-461304
Guideline Name	Tonmya
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	12/17/2025
P&T Revision Date:	

1 . Indications

Drug Name: Tonmya (cyclobenzaprine sublingual tablet)
Fibromyalgia Indicated for treatment of fibromyalgia in adults.

2 . Criteria

Product Name:Tonmya [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of fibromyalgia

AND

2 - Fibromyalgia diagnosed based on ALL of the following American College of Rheumatology criteria:

2.1 Generalized pain, defined as pain in at least 4 of 5 regions, is present

AND

2.2 Symptoms have been present at a similar level for at least 3 months

AND

2.3 Diagnosis of fibromyalgia is valid irrespective of other diagnoses.

AND

2.4 Diagnosis of fibromyalgia does not exclude the presence of other clinically important illnesses

AND

2.5 ONE of the following:

- Widespread pain index (WPI) ≥ 7 and symptom severity scale (SSS) score ≥ 5
- WPI of 4–6 and SSS score ≥ 9

AND

3 - Patient has implemented ALL of the following nonpharmacologic measures for the treatment of fibromyalgia

- Patient education (e.g., sleep hygiene)
- Physical activity and exercise
- Cognitive therapy (e.g., meditation and relaxation, cognitive-behavioral therapy, mindfulness-based stress reduction)

AND

4 - Submission of medical records (e.g. chart notes) documenting a failure or intolerance to cyclobenzaprine (generic Flexeril) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction)

AND

5 - History of failure, contraindication, or intolerance to TWO of the following:

- amitriptyline (generic Elavil)
- duloxetine (generic Cymbalta)
- gabapentin (generic Neurontin)
- pregabalin (generic Lyrica)
- Savella

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tonmya [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of a reduction in pain intensity with Tonmya use

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Tonmya (cyclobenzaprine sublingual tablet) is indicated for treatment of fibromyalgia in adults. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Tonmya [package insert]. Chatham, NJ: Tonix Medicines, Inc; ;
2. Clauw, D. J. (2025). Fibromyalgia: Treatment in adults. In J. E. Ware & D. M. Drossman (Eds.), UpToDate. Wolters Kluwer. Retrieved November 6, 2025, from https://www.uptodate.com
3. Wolfe, F., Clauw, D. J., Fitzcharles, M.-A., et. al (2016). 2016 revisions to the 2010/2011 fibromyalgia diagnostic criteria. Seminars in Arthritis and Rheumatism, 46(3), 319–329.

5 . Revision History

Date	Notes
12/3/2025	New program.

Topical Retinoids

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399261
Guideline Name	Topical Retinoids
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	09/15/2021 ; 04/20/2022 ; 10/19/2022 ; 10/18/2023 ; 10/16/2024 ; 06/18/2025 ; 9/25/2025

1 . Indications

Drug Name: Topical retinoid products
Cosmetic and medical conditions Indicated for cosmetic and medical conditions (e.g. acne vulgaris, psoriasis, precancerous skin lesions).

2 . Criteria

Product Name:Adapalene solution, adapalene pads, Aklief, Altreno, Arazlo, Brand Atralin, Avita, Fabior, Brand Retin-A, Brand Retin-A Micro, Tazorac, tarzarotene, generic tretinoin, generic tretinoin microsphere [a]	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - The member has a non-cosmetic medical condition (e.g., acne vulgaris, psoriasis, precancerous skin lesions, other conditions listed in Background Section)** (provide diagnosis)

Notes	** See table in Background section. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: Treatment for cosmetic purposes (i.e., photoaging, wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling, sun damage) is a benefit exclusion

Product Name:Brand Differin, generic adapalene [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The member has a non-cosmetic medical condition (e.g. acne vulgaris)

AND

2 - Medication is not being requested solely for cosmetic purposes (e.g., photoaging, wrinkling, hyperpigmentation, sun damage, melasma)

AND

3 - History of failure, contraindication, or intolerance to a trial of Tretinoin cream.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Differin, generic adapalene [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Non-cosmetic medical conditions:

Acanthosis nigricans	Keratoderma
Acne	Keratoderma palmaris et plantaris
Acne keloidalis nuchae	Keratosis rubra figurata
Acne rosacea	Kyrle’s disease
Acne vulgaris	Lamellar ichthyosis
Actinic cheilitis	Leukoplakia
Actinic dermatitis	Lichen planus

Actinic keratosis	Mal de Meleda
Basal cell carcinoma	Malignancy
Bowen's disease	Mendes da Costa syndrome
Cystic acne	Molluscum contagiosum
Darier's disease	Non-bullous congenital ichthyosis
Darier-White Disease	Papillon-Lefevre syndrome
Dermal mucinosis	Porokeratosis
Discoid lupus erythematosus	Pseudofollicular barbae
Epidermoid cysts	Pseudoacanthosis nigricans
Epidermolytic hyperkeratosis	Psoriasis
Erythrokeratoderma variabilis	Psoriasis erythrodermic, palmoplantar
Favre Raucochet disease	Psoriasis pustular
Flat warts	Psoriatic arthritis
Folliculitis	Rosacea
Fox Fordyce disease	Sebaceous cysts
Grover's disease	Senile keratosis
Hidradenitis suppurativa	Solar keratosis
Hyperkeratosis	Squamous cell carcinoma
Hyperkeratosis follicularis	Systematized epidermal nevus
Hyperkeratotic eczema	Transient acantholytic dermatosis
Ichthyoses	Tylotic eczema
Ichthyosis vulgaris	X-linked ichthyosis
Keloid scar	Verucca planae

Keratoacanthoma	Von Zumbusch pustular
Keratosis follicularis	Warts
	Wound healing (mild)

Background:

Topical retinoid products are indicated for cosmetic and medical conditions (e.g. acne vulgaris, psoriasis, precancerous skin lesions). Prior Authorization is in place to verify the use is for the diagnosis of a medical condition.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Atralin [package insert] Bridgewater, NJ: Bausch Health US, LLC; February 2024.
2. Avita cream [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2018.
3. Differin gel [package insert]. Fort Worth, TX: Galderma Laboratories LP; August 2022.
4. Differin lotion [package insert]. Fort Worth, TX: Galderma Laboratories LP; April 2022.
5. Differin cream [package insert]. Fort Worth, TX: Galderma Laboratories LP; October 2022.
6. Retin-A [package insert]. Bridgewater, NJ: Bausch Health US, LLC.; March 2024.
7. Retin-A Micro [package insert]. Bridgewater, NJ: Bausch Health US, LLC.; October 2023.
8. Tazorac cream [package insert]. Exton, PA: Almirall, LLC; August 2019.
9. Tazorac gel [package insert]. Exton, PA: Almirall, LLC; August 2019.
10. Fabior [package insert] Raleigh, NC: Mayne Pharma; February 2023.
11. Altreno [package insert]. Bridgewater, NJ: Bausch Health US, LLC; March 2020.
12. Aklief [package insert]. Fort Worth, TX; Galderma Laboratories LP; October 2023.
13. Arazlo [package insert]. Bridgewater, NJ: Bausch Health US. LLC; August 2023.

5 . Revision History

Date	Notes
9/18/2025	Added Tazarotene foam

Tremfya

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-493420
Guideline Name	Tremfya
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	1/21/2026
P&T Revision Date:	

Note:

*This program applies to the subcutaneous formulation of Tremfya.

1 . Indications

Drug Name: Tremfya (guselkumab)
Plaque Psoriasis Indicated for the treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with moderate-to-severe plaque psoriasis and who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis** Indicated for the treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with active psoriatic arthritis. **Ulcerative Colitis** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

Crohn's Disease Indicated for the treatment of adult patients with moderately to severely active Crohn's disease.

2 . Criteria

Product Name:Tremfya [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

2.1.2 History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

- Anthralin
- Coal tar

AND

2.1.3 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), ustekinumab].

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to TWO of the following preferred products (document drug, date, and duration of trial):

- One of the preferred adalimumab products [b]
- Cimzia (certolizumab pegol)
- Skyrizi (risankisumab)
- Taltz (ixekizumab)
- One of the preferred ustekinumab products [c]

OR

3.2 BOTH of the following:

- Patient is currently on Tremfya therapy for moderate to severe plaque psoriasis as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has not received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a Janssen sponsored program (e.g., sample

card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Tremfya*

AND

4 - Patient is NOT receiving Tremfya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), ustekinumab] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with a dermatologist.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. [c] For a list of preferred ustekinumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a Janssen sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Tremfya [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Tremfya therapy

AND

2 - Patient is not receiving Tremfya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), ustekinumab] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Tremfya [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - ONE of the following:

- History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)
- Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab]

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to two of the following preferred products (document drug, date, and duration of trial):

- One of the preferred adalimumab products [b]
- Cimzia (certolizumab pegol)
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Skyrizi (risankizumab)
- Taltz (ixekizumab)
- One of the preferred ustekinumab products [c]
- Xeljanz/Xeljanz XR (tofacitinib)

OR

3.2 BOTH of the following:

- Patient is currently on Tremfya therapy for active psoriatic arthritis as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a Janssen sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Tremfya*

AND

4 - Patient is not receiving Cimzia in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with one of the following:

- Rheumatologist

• Dermatologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. [c] For a list of preferred ustekinumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a Janssen sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Tremfya [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to Tremfya therapy **AND** **2** - Patient is not receiving Tremfya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tremfya [a]

Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

- Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)
- Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (document drug, date, and duration of trial) [e.g., adalimumab, Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)]

AND

2.1.2 History of failure, contraindication, or intolerance to TWO of the following preferred products (document drug, date of trial, and/or contraindication)

- One of the preferred adalimumab products [b]
- Rinvoq
- Simponi
- Skyrizi
- One of the preferred ustekinumab products [c]
- Xeljanz

OR

2.2 Patient has been established on therapy with Tremfya under an active UnitedHealthcare medical benefit prior authorization for moderately to severely active ulcerative colitis

OR

2.3 BOTH of the following:

- Patient is currently on Tremfya therapy for moderately to severely active ulcerative colitis as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a Janssen sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Tremfya*

AND

3 - Patient is not receiving Tremfya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication.

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. [c] For a list of preferred ustekinumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a Janssen sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Tremfya [a]

Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Tremfya therapy

AND

2 - Patient is not receiving Tremfya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tremfya [a]	
Diagnosis	Crohn’s Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn’s disease

AND

2 - ONE of the following:

2.1 Patient has been established on therapy with Tremfya under an active UnitedHealthcare medical benefit prior authorization for moderately to severely active Crohn's disease

OR

2.2 BOTH of the following:

2.2.1 ONE of the following:

2.2.1.1 History of failure to one of the following conventional therapies at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

OR

2.2.1.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of Crohn's disease as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab]

AND

2.2.2 History of failure, contraindication, or intolerance to two of the following preferred products (document drug, date of trial, and/or contraindication)

- One of the preferred adalimumab products [b]
- Cimzia (certolizumab pegol)
- Rinvoq (upadacitinib)
- Skyrizi (risankizumab)
- One of the preferred ustekinumab products [c]

OR

2.3 BOTH of the following:

- Patient is currently on Tremfya therapy for moderately to severely active Crohn's disease as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a Janssen sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Tremfya*

AND

3 - Patient is not receiving Tremfya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab] for treatment of the same indication.

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. [c] For a list of preferred ustekinumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a Janssen sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

Product Name:Tremfya [a]	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria **1** - Documentation of positive clinical response to Tremfya therapy **AND** **2** - Patient is not receiving Tremfya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Tremfya (guselkumab) is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults and moderately to severely active Crohn's disease in adults. Tremfya is also indicated for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 6 years of age or older weighing at least 40 kg who are candidates for systemic therapy or phototherapy and active psoriatic arthritis in adults and pediatric patients 6 years of age or older weighing at least 40 kg. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limit may be in place**.**

4 . References

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2025.

5 . Revision History

Date	Notes
1/13/2026	New program.

Truqap

Prior Authorization Guideline

Guideline ID	GL-500243
Guideline Name	Truqap
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	9/25/2025
P&T Revision Date:	1/21/2026

1 . Indications

Drug Name: Truqap (capivasertib)
Breast Cancer Indicated, in combination with fulvestrant, for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

2 . Criteria

Product Name:Truqap [a]

Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - ONE of the following:

- Locally advanced
- Recurrent unresectable (local or regional)
- Metastatic

AND

3 - Disease is hormone receptor (HR)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of one or more PIK3CA/AKT1/PTEN-alterations

AND

6 - ONE of the following:

- Has progressed on at least one endocrine-based regimen in the metastatic setting (e.g., anastrozole, letrozole, exemestane, tamoxifen)
- Recurrence on or within 12 months of completing adjuvant therapy

AND

7 - Used in combination with fulvestrant

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Truqap [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Truqap therapy

AND

2 - Used in combination with fulvestrant

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Truqap [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Truqap will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Truqap [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Truqap therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Truqap (capivasertib) is a kinase inhibitor indicated, in combination with fulvestrant, for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic

breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4 . References

1. Truqap [package insert]. Wilmington, DE: Astra Zeneca; November 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed November 26, 2025.

5 . Revision History

Date	Notes
1/20/2026	Annual review with no changes to coverage criteria. Updated references.

Tryngolza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523212
Guideline Name	Tryngolza
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	2/20/2025
P&T Revision Date:	2/20/2026

1 . Indications

Drug Name: Tryngolza (olezarsen)
Familial chylomicronemia syndrome Indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

2 . Criteria

Product Name:Tryngolza [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of familial chylomicronemia syndrome (FCS) (i.e., monogenic chylomicronemia, type 1 hyperlipoproteinemia)

AND

1.2 Diagnosis has been confirmed by BOTH of the following:

1.2.1 ONE of the following:

- Genetic confirmation of FCS (e.g., homozygous, compound heterozygous, or double heterozygote for loss-of-function or otherwise inactivating mutations in genes affecting lipoprotein lipase activity including LPL, GPIHBP1, APOA5, APOC2, or LMF1)
- North American FCS (NAFCS) Score ≥ 45

AND

1.2.2 Untreated fasting triglyceride levels greater than or equal to 880 mg/dL

AND

2 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Gastroenterologist
- Lipid specialist (lipidologist)

AND

3 - Not used in combination with Redemplo (plozasiran)

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Tryngolza [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Tryngolza therapy (e.g., reduction in triglycerides, reduction in episodes of acute pancreatitis)

AND

2 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Gastroenterologist
- Lipid specialist (lipidologist)

AND

3 - Not used in combination with Redemplo (plozasiran)

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information

Background:

Tryngolza (olezarsen) is an APOC-III-directed antisense oligonucleotide (ASO) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Tryngolza [package insert]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; September 2025.
2. Stroes ESG, Alexander VJ, Karwatowska-Prokopczuk E, et al. Olezarsen, Acute Pancreatitis, and Familial Chylomicronemia Syndrome. N Engl J Med. 2024;390(19):1781-1792. doi:10.1056/NEJMoa2400201
3. Davidson M, Stevenson M, Hsieh A, et al. The burden of familial chylomicronemia syndrome: Results from the global IN-FOCUS study. J Clin Lipidol. 2018;12(4):898-907.e2. doi:10.1016/j.jacl.2018.04.009
4. Baass A, Paquette M, Bernard S, Hegele RA. Familial chylomicronemia syndrome: an under-recognized cause of severe hypertriglyceridaemia. J Intern Med. 2020;287(4):340-348. doi:10.1111/joim.13016
5. Hegele RA, Ahmad Z, Ashraf A, et al. Development and validation of clinical criteria to identify familial chylomicronemia syndrome (FCS) in North America. J Clin Lipidol. Published online November 12, 2024. doi:10.1016/j.jacl.2024.09.008
6. Javed F, Hegele RA, Garg A, et al. Familial chylomicronemia syndrome: An expert clinical review from the National Lipid Association. J Clin Lipidol. 2025;19(3):382-403. doi:10.1016/j.jacl.2025.03.013
7. Saadatagah S, Larouche M, Naderian M, et al. Recognition and management of persistent chylomicronemia: A Joint Expert Clinical Consensus by the National Lipid Association and the American Society for Preventive Cardiology. J Clin Lipidol. 2025;19(4):723-736. doi:10.1016/j.jacl.2025.03.012

5 . Revision History

Date	Notes
2/13/2026	Annual review. Simplified generic confirmation criteria. Added combin ation use criteria. Updated references.

Tryvio

Prior Authorization Guideline

Guideline ID	GL-523282
Guideline Name	Tryvio
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	6/17/2024
P&T Revision Date:	02/20/2025 ; 2/20/2026

1 . Indications

Drug Name: Tryvio (aprocitentan)
Hypertension Indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs.

2 . Criteria

Product Name:Tryvio [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of resistant hypertension

AND

2 - ONE of the following:

- Systolic blood pressure greater than or equal to 130 mm Hg on two consecutive measurements despite maximally tolerated antihypertensive treatment
- Diastolic blood pressure greater than or equal to 80 mm Hg on two consecutive measurements despite maximally tolerated antihypertensive treatment

AND

3 - Patient has been previously treated with all of the following antihypertensive classes for an adequate duration (minimum 4 weeks each) at a maximally tolerated dose:

- Maximally tolerated blocker of the renin-angiotensin system [angiotensin-converting enzyme (ACE) inhibitor (e.g., enalapril, lisinopril) or angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)]
- Maximally tolerated calcium channel blocker (e.g., amlodipine, diltiazem, verapamil)
- Maximally tolerated diuretics (e.g., hydrochlorothiazide)
- Maximally tolerated mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)]

AND

4 - Provider attests other causes of hypertension have been excluded (e.g., secondary causes [e.g., primary hyperaldosteronism], white coat effect, medication nonadherence)

AND

5 - Used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

AND **6** - Tryvio will be used in combination with at least 3 antihypertensive medications from different classes at maximally tolerated doses **AND** **7** - Prescribed by or in consultation with a specialist experienced in the treatment of resistant hypertension (e.g., cardiologist, nephrologist)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tryvio [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria **1** - Documentation the patient is receiving clinical benefit to Tryvio therapy **AND** **2** - Tryvio will be used in combination with at least 3 antihypertensive medications from different classes at maximally tolerated doses

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Tryvio (aprocitentan) is an endothelin receptor antagonist indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs. Resistant hypertension (RH) is defined as above-goal elevated blood pressure (BP) in a patient despite the concurrent use of 3 antihypertensive drug classes, commonly including a long-acting calcium channel blocker, a blocker of the renin-angiotensin system (angiotensin-converting enzyme inhibitor or angiotensin receptor blocker), and a diuretic. The antihypertensive drugs should be administered at maximum or maximally tolerated daily doses. [1] **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Tryvio [package insert]. Radnor, PA: Idorsia Pharmaceuticals US Inc; April 2024.
2. Carey, RM, Calhoun, DA, Bakris, GL, et. al. Resistant Hypertension: Detection, Evaluation, and Management: A Scientific Statement From the American Heart Association. Hypertension. 2018: 72(5); e53-e90.

5 . Revision History

Date	Notes
2/23/2026	Annual review. Updated background.

Tukysa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-555225
Guideline Name	Tukysa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	9/15/2021
P&T Revision Date:	08/19/2022 ; 11/18/2022 ; 03/15/2023 ; 03/20/2024 ; 03/19/2025 ; 3/18/2026

1 . Indications

Drug Name: Tukysa
HER2-positive breast cancer Indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. **Colorectal Cancer** Indicated in combination with trastuzumab for the treatment of adult patients with RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. **Other Uses:** The National Cancer Comprehensive Network (NCCN) recommends the use of Tukysa for the treatment of central nervous system cancers (limited and extensive brain metastases) when used in combination with capecitabine and trastuzumab in patients with HER2 positive breast cancer if previously treated with one or more anti-HER2-based

regimens. The NCCN also recommends the use of Tukysa in combination with trastuzumab for the treatment of advanced or metastatic colorectal cancer (HER2-amplified and RAS and BRAF wild-type) if intensive therapy not recommended as well as in combination with trastuzumab as subsequent therapy for HER2-positive unresectable, resected gross residual (R2), or metastatic biliary tract cancers.

2 . Criteria

Product Name:Tukysa [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is ONE of the following:

- Advanced unresectable
- Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Patient has been previously treated with an anti-HER2-based regimen in the metastatic

setting (e.g., trastuzumab [Kanjinti, Ogivri, Trazimera], pertuzumab [Perjeta], ado-trastuzumab emtansine [Kadcyla]) **AND** **5** - Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera) and capecitabine (Xeloda)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tukysa [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tukysa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tukysa [a]	
Diagnosis	CNS Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of brain metastases

AND

2 - Patient has HER2 positive breast cancer

AND

3 - Patient has been previously treated with an anti-HER2-based regimen (e.g., trastuzumab [Kanjinti, Ogivri, Trazimera], pertuzumab [Perjeta], ado-trastuzumab emtansine [Kadcyla])

AND

4 - Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera) and capecitabine (Xeloda)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tukysa [a]	
Diagnosis	CNS Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tukysa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tukysa [a]	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable, advanced, or metastatic colorectal cancer (HER2-amplified and RAS and BRAF wild-type)

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

3 - One of the following:

3.1 Patient has previously been treated with ONE of the following regimens:

- Fluoropyrimidine-based chemotherapy
- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy

OR

3.2 Patient is not appropriate for intensive therapy

AND

4 - Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tukysa [a]	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Tukysa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tukysa [a]	
Diagnosis	Biliary Tract Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gallbladder Cancer
- Intrahepatic cholangiocarcinoma
- Extrahepatic cholangiocarcinoma

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

3 - Disease is one of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic

AND

4 - Patient has received at least one prior systemic therapy

AND

5 - Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tukysa [a]	
Diagnosis	Biliary Tract Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tukysa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tukysa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Tukysa will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Tukysa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Tukysa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Tukysa (tucatinib) is a kinase inhibitor indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. Tukysa is also indicated in combination with trastuzumab for the treatment of adult patients with RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

The National Cancer Comprehensive Network (NCCN) recommends the use of Tukysa for the treatment of central nervous system cancers (limited and extensive brain metastases) when used in combination with capecitabine and trastuzumab in patients with HER2 positive breast cancer if previously treated with one or more anti-HER2-based regimens. The NCCN also recommends the use of Tukysa in combination with trastuzumab for the treatment of advanced or metastatic colorectal cancer (HER2-amplified and RAS and BRAF wild-type) if intensive therapy not recommended as well as in combination with trastuzumab as subsequent therapy for HER2-positive unresectable, resected gross residual (R2), or metastatic biliary tract cancers.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Tukysa [package insert]. Bothell, WA: Seattle Genetics, Inc.; January 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed February 12, 2025.

5 . Revision History

Date	Notes
3/18/2026	Annual review. Changed wording for CNS cancers.

Turalio

Prior Authorization Guideline

Guideline ID	GL-412210
Guideline Name	Turalio
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 10/20/2021 ; 08/19/2022 ; 11/18/2022 ; 11/18/2022 ; 10/18/2023 ; 10/16/2024 ; 10/15/2025

1 . Indications

Drug Name: Turalio (pexidartinib)
Tenosynovial giant cell tumor Indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

2 . Criteria

Product Name:Turalio [a]

Diagnosis	Tenosynovial Giant Cell Tumor/ Pigmented Villonodular Synovitis (PVNS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of tenosynovial giant cell tumor (TGCT) / pigmented villonodular synovitis (PVNS)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Turalio [a]	
Diagnosis	Tenosynovial Giant Cell Tumor/ Pigmented Villonodular Synovitis (PVNS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Turalio therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Turalio [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease
- Rosai-Dorfman Disease

AND

2 - Colony stimulating factor 1 receptor (CSF1R) mutation positive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Turalio [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Turalio therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Turalio [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Turalio will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Turalio [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Turalio therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background:

Turalio (pexidartinib) is a kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

The National Cancer Comprehensive Network (NCCN) also recommends Turalio as single-agent therapy for the treatment of TGCT/ pigmented villonodular synovitis (PVNS) in patients without respect to morbidity and surgery eligibility. NCCN also recommends Turalio for colony stimulating factor 1 receptor (CSF1R) mutation positive histiocytic neoplasms.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Turalio [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc. January 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/ Accessed September 3, 2025.

5 . Revision History

Date	Notes
10/6/2025	Annual review with no changes to coverage criteria. Updated references.

Tykerb



Prior Authorization Guideline

Guideline ID	GL-444192
Guideline Name	Tykerb
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	10/20/2021
P&T Revision Date:	10/19/2022 ; 10/18/2023 ; 10/16/2024 ; 10/15/2025

1 . Indications

Drug Name: Tykerb (lapatinib)
Metastatic breast cancer Indicated for use in combination with Femara (letrozole) for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the human epidermal growth factor receptor 2 (HER2) receptor for whom hormonal therapy is indicated **Advanced or metastatic breast cancer** Indicated in combination with Xeloda (capecitabine) for treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy, including an anthracycline, a taxane, and the HER2 receptor antagonist Herceptin (trastuzumab). Patients should have disease progression on Herceptin prior to initiation of treatment with Tykerb in combination with Xeloda.

2 . Criteria

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is human epidermal growth factor receptor 2-positive (HER2+)

AND

3 - ONE of the following:

3.1 ALL of the following:

- Disease is recurrent unresectable (local or regional) or stage IV breast cancer
- Disease is hormone receptor positive
- Used in combination with an aromatase inhibitor [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]

OR

3.2 BOTH of the following:

3.2.1 ONE of the following:

- Disease is recurrent unresectable (local or regional) or stage IV breast cancer
- Breast cancer is unresponsive to preoperative systemic therapy

AND

3.2.2 Used as fourth line therapy and beyond in combination with ONE of the following:

- Herceptin (trastuzumab)
- Xeloda (capecitabine)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tykerb therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of brain metastases in HER2-positive breast cancer
- Used in combination with Xeloda (capecitabine)

OR

2 - ALL of the following:

2.1 Diagnosis of progressive or recurrent intracranial or spinal ependymoma (excluding subependymoma)

AND

2.2 Patient has received previous radiation therapy

AND

2.3 ONE of the following:

- Patient has received gross total or subtotal resection with negative cerebrospinal fluid (CSF) cytology
- Patient has received subtotal resection and evidence of metastasis (brain, spine, or CSF)
- Patient has unresectable disease

AND

2.4 Used in combination with Temodar (temozolomide)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tykerb therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent conventional or chondroid chordoma

AND

2 - Diagnosis is EGFR-positive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tykerb therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colon cancer

AND

2 - Disease is ALL of the following:

- HER2-amplified
- RAS wild-type
- BRAF wild-type

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 ONE of the following:

3.1.1.1 Disease is proficient mismatch repair/microsatellite-stable (pMMR/MSS)

OR

3.1.1.2 BOTH of the following:

3.1.1.2.1 Disease is positive for ONE of the following:

- Deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H)
- Polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [tumor mutation burden (TMB) > 50 mut/Mb]

AND

3.1.1.2.2 Ineligible for, progressed on, or contraindication to checkpoint inhibitor immunotherapy [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Jemperli (dostarlimab-gxly)]

AND

3.1.2 ONE of the following:

3.1.2.1 BOTH of the following:

- Used as initial therapy for unresectable metachronous metastases
- Previous therapy with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months

OR

3.1.2.2 Intensive chemotherapy is not recommended

OR

3.1.2.3 Used as second-line and subsequent therapy for progression of advanced or metastatic disease

OR

3.2 BOTH of the following:

3.2.1 Used in combination with hepatic artery infusion

AND

3.2.2 ONE of the following:

- Used for resectable synchronous liver metastases and undergoing synchronous or staged colectomy with liver resection
- Used for resectable metachronous metastases and undergoing resection

AND

4 - Used in combination with trastuzumab

AND

5 - Patient has not previously been treated with a HER2 inhibitor [e.g., trastuzumab, Perjeta (pertuzumab), Nerlynx (neratinib)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Tykerb therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of rectal cancer

AND

2 - Disease is ALL of the following:

- HER2-amplified
- RAS wild-type
- BRAF wild-type

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 ONE of the following:

3.1.1.1 Disease is proficient mismatch repair/microsatellite-stable (pMMR/MSS)

OR

3.1.1.2 BOTH of the following:

3.1.1.2.1 Disease is positive for ONE of the following:

- Deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H)
- Polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [tumor mutation burden (TMB) > 50 mut/Mb]

AND

3.1.1.2.2 Ineligible for, progressed on, or has a contraindication to checkpoint inhibitor immunotherapy [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Jemperli (dostarlimab-gxly)]

AND

3.1.2 ONE of the following:

3.1.2.1 BOTH of the following:

- Used as initial therapy for unresectable metachronous metastases
- Previous therapy with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months

OR

3.1.2.2 Intensive chemotherapy is not recommended

OR

3.1.2.3 Used as second-line and subsequent therapy for progression of advanced or metastatic disease

OR

3.2 BOTH of the following:

3.2.1 Used in combination with hepatic artery infusion

AND

3.2.2 ONE of the following:

- Used for resectable metachronous metastases and undergoing resection
- Used for unresectable metachronous metastases that converted to resectable after initial therapy and undergoing resection

AND

4 - Used in combination with trastuzumab

AND

5 - Patient has not previously been treated with a HER2 inhibitor [e.g., trastuzumab, Perjeta (pertuzumab), Nerlynx (neratinib)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tykerb therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Tykerb will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Tykerb, generic lapatinib [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Tykerb therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Tykerb (lapatinib) is a kinase inhibitor indicated for use in combination with Femara (letrozole) for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the human epidermal growth factor receptor 2 (HER2) receptor for whom hormonal therapy is indicated. Tykerb is also indicated in combination with Xeloda (capecitabine) for treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy, including an anthracycline, a taxane, and trastuzumab. Patients should have disease progression on trastuzumab prior to initiation of treatment with Tykerb in combination with Xeloda. The National Cancer Comprehensive Network (NCCN) also recommends the use of Tykerb in metastatic central nervous system (CNS) lesions with primary tumor of the breast, intracranial and spinal ependymomas, EGFR-positive chordoma and colon and rectal cancers not previously treated with HER2 inhibitors. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Tykerb [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; March 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed September 8, 2025.

5 . Revision History

Date	Notes
11/7/2025	Updated criteria

Tymlos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412211
Guideline Name	Tymlos
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	1/20/2021
P&T Revision Date:	10/20/2021 ; 11/18/2022 ; 02/17/2023 ; 10/18/2023 ; 11/17/2023 ; 10/16/2024 ; 10/16/2024 ; 10/15/2025

1 . Indications

Drug Name: Tymlos (abaloparatide)
Osteoporosis Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. Tymlos is also indicated to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name:Tymlos [a]

Diagnosis	Osteoporosis
Approval Length	Authorization will be issued for up to 24 months. Duration of coverage will be limited to 24 months of cumulative parathyroid hormone analog therapy (e.g., Teriparatide injection, Forteo, Tymlos) in the member's lifetime.
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

- Patient is female
- Diagnosis of postmenopausal osteoporosis

OR

1.2 BOTH of the following:

- Patient is male
- Diagnosis of osteoporosis

AND

2 - ONE of the following:

- Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%)]
- Patient has a history of failure, intolerance or contraindication to other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate)

AND

3 - Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Tymlos is a human parathyroid hormone analog indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. Tymlos is also indicated to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. [1]

The American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE) recommend the use of abaloparatide in patients unable to use oral therapy and as initial therapy for patients at very high fracture risk defined as the following: patients with a recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%) or other validated fracture risk algorithm to be at very high fracture risk.[2] Additionally, the AACE/ACE and Endocrine Society both recommend to limit treatment with abaloparatide to 2 years. [2-3]

The safety and efficacy of Tymlos have not been evaluated beyond 2 years of treatment. Cumulative use of Tymlos and other parathyroid hormone analogs (e.g., Forteo, teriparatide injection) for more than 2 years during a patient's lifetime is not recommended. [1-3]

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Tymlos [package insert]. Boston, MA: Radius Health, Inc.; March 2025.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists /American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis - 2020 Update. Endocr Pract. 2020;26(Suppl 1):1-46.
3. Shoback D, Rosen CJ, Black DM, Cheung AM, Murad MH, Eastell R. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update. J Clin Endocrinol Metab. 2020 Mar 1;105(3):dgaa048.

5 . Revision History

Date	Notes
10/6/2025	Annual review with no changes to coverage criteria. Updated references.

Ustekinumab

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-555231
Guideline Name	Ustekinumab
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 05/21/2021 ; 12/15/2021 ; 08/19/2022 ; 09/21/2022 ; 03/15/2023 ; 06/17/2024 ; 10/16/2024 ; 01/15/2025 ; 02/20/2025 ; 03/19/2025 ; 05/16/2025 ; 10/15/2025 ; 02/20/2026 ; 3/18/2026

Note:

NOTE: This program applies to the subcutaneous formulations of ustekinumab

1 . Indications

Drug Name: Stelara® (ustekinumab), Imuldosa™ (ustekinumab-srlf), Otulfi™ (ustekinumab-aauz), Pyzchiva™ (ustekinumab-ttwe), Selarsdi™ (ustekinumab-aekn), Starjemza™ (ustekinumab-hmny), Steqeyma (ustekinumab-stba), ustekinumab-aekn (unbranded Selarsdi), ustekinumab-kfce (unbranded Yesintek), ustekinumab-stba (unbranded Steqeyma), ustekinumab-ttwe (unbranded Pyzchiva), Wezlana (ustekinumab-auub), Yesintek™ (ustekinumab-kfce)
Plaque Psoriasis Indicated for the treatment of adult and pediatric patients 6 years of age or older with moderate to severe plaque psoriasis who are candidates for phototherapy or

systemic therapy.

Psoriatic Arthritis Indicated for the treatment of adult and pediatric patients 6 years of age or older with active psoriatic arthritis.

Crohn's Disease Indicated in adult patients with moderately to severely active Crohn's disease.

Ulcerative Colitis Indicated in adults for moderately to severely active ulcerative colitis.

2 . Criteria

Product Name:Ustekinumab 45mg/0.5mL [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

2.1.2 History of failure to ONE of the following topical therapies, unless contraindicated or

clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Coal tar

AND

2.1.3 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab)].

OR

2.3 BOTH of the following:

- Patient is currently on ustekinumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of ustekinumab*

AND

3 - If the request is for a non-formulary ustekinumab product, the patient has a history of failure to all formulary ustekinumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary ustekinumab product (please document reason/special circumstances) [b]

AND **4** - Patient is not receiving ustekinumab in combination with systemic another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab)] for treatment of the same indication. **AND** **5** - Prescribed by or in consultation with a dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred ustekinumab products please reference drug coverage tools. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored Savings program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary ustekinumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary ustekinumab products should be provided at GPI 90250585******.

Product Name:Ustekinumab 90mg/1mL [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - Patient's weight is greater than 100 kg (220 lbs)

AND

3 - ONE of the following:

3.1 ALL of the following:

3.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

3.1.2 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Coal tar

AND

3.1.3 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

3.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g.,

adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab)].

OR

3.3 BOTH of the following:

- Patient is currently on ustekinumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of ustekinumab*

AND

4 - If the request is for a non-formulary ustekinumab product, the patient has a history of failure to all formulary ustekinumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary ustekinumab product (please document reason/special circumstances) [b]

AND

5 - Patient is not receiving ustekinumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab)] for treatment of the same indication.

AND

6 - Prescribed by or in consultation with a dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred ustekinumab products please reference drug coverage tools.

	*Patients requesting initial authorization who were established on ther apy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer spo nsored Savings program SHALL BE REQUIRED to meet initial authori zation criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteri a requirements for treatment with a non-formulary ustekinumab produ ct, but does not meet non-formulary exception criteria, a non-formular y denial should be issued and a 12 month authorization for formulary ustekinumab products should be provided at GPI 90250585******.

Product Name:Ustekinumab 45mg/0.5mL, 90mg/1mL [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to ustekinumab therapy **AND** **2** - Patient is not receiving ustekinumab in combination with systemic another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply. NOTE: If the member meets the medical necessity authorization criteri a requirements for treatment with a non-formulary ustekinumab produ ct, but does not meet non-formulary exception criteria, a non-formular y denial should be issued and a 12 month authorization for formulary ustekinumab products should be provided at GPI 90250585******.

Product Name:Ustekinumab 45mg/0.5mL [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - ONE of the following:

2.1 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Xeljanz/Xeljanz XR (tofacitinib), Tremfya (guselkumab)].

OR

2.3 BOTH of the following:

- Patient is currently on ustekinumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of ustekinumab*

AND

3 - If the request is for a non-formulary ustekinumab product, the patient has a history of failure to all formulary ustekinumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary ustekinumab product (please document reason/special circumstances) [b]

AND

4 - Patient is not receiving ustekinumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Xeljanz/Xeljanz XR (tofacitinib), Tremfya (guselkumab)] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred ustekinumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program shall be required to meet initial authorization criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary ustekinumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary ustekinumab products should be provided at GPI 90250585******.

Product Name:Ustekinumab 90mg/1mL [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Patient's weight is greater than 100 kg (220 lbs)

AND

3 - ONE of the following:

3.1 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

3.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Xeljanz/Xeljanz XR (tofacitinib), Tremfya (guselkumab)].

OR

3.3 BOTH of the following:

- Patient is currently on ustekinumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of ustekinumab*

AND

4 - If the request is for a non-formulary ustekinumab product, the patient has a history of failure to all formulary ustekinumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary ustekinumab product (please document reason/special circumstances) [b]

AND

5 - Patient is not receiving ustekinumab in combination with systemic another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Xeljanz/Xeljanz XR (tofacitinib), Tremfya (guselkumab)] for treatment of the same indication.

AND

6 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred ustekinumab products please reference drug coverage tools. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy.

	NOTE: If the member meets the medical necessity authorization criteri a requirements for treatment with a non-formulary ustekinumab produ ct, but does not meet non-formulary exception criteria, a non-formular y denial should be issued and a 12 month authorization for formulary ustekinumab products should be provided at GPI 90250585******.

Product Name:Ustekinumab 45mg/0.5mL, 90mg/1mL [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to ustekinumab therapy **AND** **2** - Patient is not receiving ustekinumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Xeljanz/Xeljanz XR (tofacitinib), Tremfya (guselkumab)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply. NOTE: If the member meets the medical necessity authorization criteri a requirements for treatment with a non-formulary ustekinumab produ ct, but does not meet non-formulary exception criteria, a non-formular y denial should be issued and a 12 month authorization for formulary ustekinumab products should be provided at GPI 90250585******.

Product Name:Ustekinumab 90mg/1mL [a]	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization for Maintenance Dosing
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - ONE of the following:

2.1 History of failure to ONE of the following conventional therapies at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of Crohn's disease as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab)

OR

2.3 Patient has been established on therapy with ustekinumab under an active UnitedHealthcare medical benefit prior authorization for treatment of moderately to severely active Crohn's disease

OR

2.4 BOTH of the following:

- Patient is currently on ustekinumab therapy for moderately to severely active Crohn's disease as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of ustekinumab*

AND

3 - If the request is for a non-formulary ustekinumab product, the patient has a history of failure to all formulary ustekinumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary ustekinumab product (please document reason/special circumstances) [b]

AND

4 - Patient is not receiving ustekinumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab)] for treatment of the same indication.

AND

5 - Prescribed by or in consultation with a gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred ustekinumab products please reference drug coverage tools. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary ustekinumab product, but does not meet non-formulary exception criteria, a non-formular

	y denial should be issued and a 12 month authorization for formulary ustekinumab products should be provided at GPI 90250585******.

Product Name:Ustekinumab 90mg/1mL [a]	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to ustekinumab therapy **AND** **2** - Patient is not receiving ustekinumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary ustekinumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary ustekinumab products should be provided at GPI 90250585******.

Product Name:Ustekinumab 90mg/1mL [a]	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - ONE of the following:

2.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

OR

2.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Xeljanz/Xeljanz XR (tofacitinib), Tremfya (guselkumab), Zeposia (ozanimod)

OR

2.3 Patient has been established on therapy with ustekinumab under an active UnitedHealthcare medical benefit prior authorization for treatment of moderately to severely active ulcerative colitis

OR

2.4 BOTH of the following:

- Patient is currently on ustekinumab therapy for moderately to severely active ulcerative colitis as documented by claims history or submission of medical records (Document date and duration of therapy)
- Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of ustekinumab*

AND **3** - If the request is for a non-formulary ustekinumab product, the patient has a history of failure to all formulary ustekinumab products unless the prescriber has given a clinical reason or special circumstance why the patient is unable to use a formulary ustekinumab product (please document reason/special circumstances) [b] **AND** **4** - Patient is not receiving ustekinumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Xeljanz/Xeljanz XR (tofacitinib), Tremfya (guselkumab), Zeposia (ozanimod)] for treatment of the same indication. **AND** **5** - Prescribed by or in consultation with a gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred ustekinumab products please reference drug coverage tools. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program SHALL BE REQUIRED to meet initial authorization criteria as if patient were new to therapy. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary ustekinumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary ustekinumab products should be provided at GPI 90250585******.

Product Name:Ustekinumab 90mg/1mL [a]	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to ustekinumab therapy **AND** **2** - Patient is not receiving ustekinumab in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Xeljanz/Xeljanz XR (tofacitinib), Tremfya (guselkumab), Zeposia (ozanimod)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. NOTE: If the member meets the medical necessity authorization criteria requirements for treatment with a non-formulary ustekinumab product, but does not meet non-formulary exception criteria, a non-formulary denial should be issued and a 12 month authorization for formulary ustekinumab products should be provided at GPI 90250585******.

3 . Background

Benefit/Coverage/Program Information
Background: Ustekinumab is a human interleukin-12 and -23 antagonist indicated for the treatment of adult and pediatric patients 6 years of age or older with active psoriatic arthritis and for moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. It is also indicated in adult patients with moderately to severely active Crohn's disease and for moderately to severely active ulcerative colitis. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- The intravenous infusion is typically covered under the medical benefit. Please refer to the UnitedHealthcare Drug Policy for Stelara.

4 . References

1. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; March 2024.
2. Imuldosa [package insert]. Raleigh, NC: Accord BioPharma Inc., October 2024.
3. Otulfi [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC, September 2024.
4. Pyzchiva [package insert]. Princeton, NJ: Sandoz Inc., June 2024.
5. Selarsdi [package insert]. Parsippany, NJ: Teva Pharmaceuticals, October 2024.
6. Starjemza [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; May 2025
7. Steqeyma [package insert]. Jersey City, NJ: CELLTRION USA, Inc., December 2024.
8. Wezlana [package insert]. Horsham, PA: Janssen Biotech Inc., March 2024.
9. Yesintek [package insert]. Cambridge, MA: Biocon Biologics Inc., November 2024.
10. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
11. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.
12. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
13. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.
14. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
15. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.
16. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158(5):1450-61.
17. Lichtenstein GR, Loftus EV, Isaacs KL, et al ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018; 113:481-517.
18. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80:1029-72.

5 . Revision History

Date	Notes
3/18/2026	Updated combination examples and language with no change to clini cal intent. Updated Janssen CarePath Savings program to manufact urer sponsored program.

Vafseo

Prior Authorization Guideline

Guideline ID	GL-390206
Guideline Name	Vafseo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	9/18/2024
P&T Revision Date:	9/25/2025

1 . Indications

Drug Name: Vafseo (vadadustat)
Anemia due to chronic kidney disease Indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months.

2 . Criteria

Product Name:Vafseo [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of anemia due to chronic kidney disease (CKD)

AND

2 - Patient has been receiving dialysis for at least three months

AND

3 - BOTH of the following:

- Ferritin greater than 100 mcg/L
- Transferrin saturation (TSAT) greater than 20%

AND

4 - Hemoglobin level less than 11 g/dL

AND

5 - Trial and failure, contraindication or intolerance to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

AND

6 - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Nephrologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vafseo [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Vafseo therapy (e.g., clinically meaningful increase in hemoglobin level)

AND

2 - Adequate iron stores confirmed by BOTH of the following:

- Ferritin greater than 100 mcg/L
- Transferrin saturation (TSAT) greater than 20%

AND

3 - Hemoglobin level does not exceed 11 g/dL

AND

4 - Patient is not on concurrent treatment with an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

AND

5 - Prescribed by or in consultation with ONE of the following:

• Hematologist • Nephrologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Vafseo (vadadustat) is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months. The treatment of anemia includes intravenous (IV) iron and/or treatment with either an erythropoiesis-stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] or a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF PHI) [e.g., Jesduvroq (daprodustat), Vafseo (vadadustat)]. *Limitations of Use* • Vafseo has not been shown to improve quality of life, fatigue, or patient well-being. • Vafseo is not indicated for use as a substitute for transfusion in patients requiring immediate correction of anemia or in patients with CKD not on dialysis. **Additional Clinical Rules:** • Supply limits may be in place. • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

1. Vafseo [package insert]. Cambridge, MA: Akebia Therapeutics, Inc.; March 2024.
2. Eckardt K, Agarwal R, Aswad A, et al. Safety and efficacy of vadadustat for anemia in patients undergoing dialysis. N Engl J Med. 2021;384(17):1601-1612.
3. Huang Q, Liao Z, Liu X, Xia Y, Wang J. Efficacy and safety of vadadustat compared to darbepoetin alfa on anemia in patients with chronic kidney disease: a meta-analysis. Int Urol Nephrol. 2023 Feb;55(2):325-334. doi: 10.1007/s11255-022-03316-z. Epub 2022 Aug 12. PMID: 35960479.
4. Ketteler M, Block GA, Evenepoel P, Fukagawa M, Herzog CA, McCann L, Moe SM, Shroff R, Tonelli MA, Toussaint ND, Vervloet MG, Leonard MB. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD). Ann Intern Med. 2018 Mar 20;168(6):422-430.

5 . Revision History

Date	Notes
9/9/2025	Annual review. Updated hemoglobin reauthorization criterion.

Valchlor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-447192
Guideline Name	Valchlor
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 10/20/2021 ; 09/21/2022 ; 10/18/2023 ; 10/16/2024 ; 10/16/2024 ; 11/21/2025

1 . Indications

Drug Name: Valchlor gel for topical use (mechlorethamine)
Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma Indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy. **Langerhans Cell Histiocytosis (LCH)** The National Cancer Comprehensive Network (NCCN) recommends use of topical mechlorethamine in Langerhans Cell Histiocytosis (LCH). **Off Label Uses: T-cell leukemia/lymphoma** The National Cancer Comprehensive Network (NCCN) recommends use of topical mechlorethamine in T-cell leukemia/lymphoma. **Primary cutaneous B-cell lymphoma** The National Cancer Comprehensive Network (NCCN) recommends use of topical mechlorethamine in primary cutaneous B-cell lymphoma. **Primary cutaneous CD30+ T-cell lymphoproliferative disorders** The National Cancer

Comprehensive Network (NCCN) recommends use of topical mechlorethamine in primary cutaneous CD30+ T-cell lymphoproliferative disorders.

2 . Criteria

Product Name:Valchlor [a]	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of ONE of the following: • Chronic or smoldering T-cell leukemia/lymphoma • Primary cutaneous marginal zone or follicle center B-cell lymphoma • Lymphomatoid papulosis (LyP) with extensive lesions • Mycosis fungoides (MF)/Sezary syndrome (SS)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Valchlor [a]	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient does not show evidence of progressive disease while on Valchlor

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Valchlor [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Langerhans Cell Histiocytosis (LCH)

AND

2 - Skin disease is unifocal and isolated

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Valchlor [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Valchlor

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Valchlor [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Valchlor will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Valchlor [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Valchlor therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Valchlor gel for topical use (mechlorethamine) is an alkylating drug indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy. The National Cancer Comprehensive Network (NCCN) recommends use of topical mechlorethamine in T-cell leukemia/lymphoma, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders, and Langerhans Cell Histiocytosis (LCH). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program. • Supply limits may be in place.

4 . References

1. Valchlor [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; January 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia. Accessed September 10, 2025.

5 . Revision History

Date	Notes
11/9/2025	Annual review. No changes to coverage criteria. Updated reference.

Vanrafia

Prior Authorization Guideline

Guideline ID	GL-555232
Guideline Name	Vanrafia
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	6/18/2025
P&T Revision Date:	3/18/2026

1 . Indications

Drug Name: Vanrafia (atrasentan)
Reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.

2 . Criteria

Product Name:Vanrafia [a]	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

AND

2 - Patient is at risk of disease progression

AND

3 - Used to slow kidney function decline

AND

4 - Used to reduce proteinuria

AND

5 - Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m2

AND

6 - BOTH of the following:

6.1 Patient is on a maximized stable dose with ONE of the following prior to initiating therapy:

- maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

AND

6.2 Use of endothelin receptor antagonists (ERAs) (e.g., Letairis, Opsumit, Tracleer) will be discontinued prior to initiating treatment

AND

7 - History of failure (after a 30 day trial), contraindication or intolerance to a 30-day trial of a glucocorticoid (e.g., budesonide, methylprednisolone, prednisone)

AND

8 - Prescribed by or in consultation with a nephrologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vanrafia [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response demonstrated by a reduction in proteinuria

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Vanrafia (atrasentan) is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Vanrafia slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial. **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limitations may be in place.

4 . References

1. Vanrafia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2025.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. (2025). KDIGO 2025 clinical practice guideline for the management of IgA nephropathy (IgAN) and IgA vasculitis (IgAV). KDIGO. https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2025-IgAN-IgAV-Guideline.pdf

5 . Revision History

Date	Notes
3/18/2026	Added budesonide as a corticosteroid example. Updated references.

Velsipity

Prior Authorization Guideline

Guideline ID	GL-527199
Guideline Name	Velsipity
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	4/17/2024
P&T Revision Date:	01/15/2025 ; 2/20/2026

1 . Indications

Drug Name: Velsipity (etrasimod)
Ulcerative colitis Indicated for the treatment of moderately to severely active ulcerative colitis in adults

2 . Criteria

Product Name:Velsipity [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis (UC)

AND

2 - ONE of the following:

- Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)
- Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab, Xeljanz (tofacitinib)]

AND

3 - History of failure, contraindication, or intolerance to THREE of the following preferred products (document drug, date, and duration of trial):

- One of the preferred adalimumab products [b]
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz/Xeljanz XR (tofacitinib)
- One of the preferred ustekinumab products [c]

AND

4 - Patient is not receiving Velsipity in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab, Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with a gastroenterologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. [c] For a list of preferred ustekinumab products please reference drug coverage tools.

Product Name:Velsipity [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to Velsipity therapy **AND** **2** - Patient is not receiving Velsipity in combination with another systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab, Xeljanz (tofacitinib)]	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background:

Velsipity (etrasimod) is a sphingosine 1-phosphate receptor modulator indicated for the treatment of moderately to severely active ulcerative colitis in adults.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place

4 . References

1. Velsipity [package insert]. New York, NY: Pfizer Inc.; August 2025.
2. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158(5):1450-61.

5 . Revision History

Date	Notes
2/24/2026	Annual review. Updated examples with no change to clinical intent. U pdated references.

Venclexta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399264
Guideline Name	Venclexta
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/18/2023
P&T Revision Date:	04/17/2024 ; 04/16/2025 ; 9/25/2025

1 . Indications

Drug Name: Venclexta (venetoclax)
Acute Myeloid Leukemia (AML) Indicated in combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)** Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). **National Cancer Comprehensive Network (NCCN)** In addition, the National Cancer Comprehensive Network (NCCN) recommends the use of Venclexta in in acute lymphoblastic leukemia (ALL); in newly diagnosed, relapsed/refractory, and blastic plasmacytoid dendritic cell neoplasm (BPDCN) AML; relapsed/refractory hairy cell leukemia; mantle cell lymphoma as second line or subsequent therapy; in relapsed or progressive multiple myeloma with t(11;14) translocation; for relapsed/refractory systemic light chain amyloidosis with t(11;14)

translocation; in previously treated Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma; in accelerated/blast phase myeloproliferative neoplasm (MPN) with disease progression; and in chronic myelomonocytic leukemia (CMML)); and in higher risk myelodysplastic syndromes.

2 . Criteria

Product Name:Venclexta [a]	
Diagnosis	Acute Lymphoblastic Leukemia (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of relapsed/refractory T-cell acute lymphoblastic leukemia (ALL) **AND** **2** - Venclexta therapy to be given in combination with one of the following: • Decitabine • HyperCVAD • Nelarabine • Mini-hyperCVD	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Acute Lymphoblastic Leukemia (ALL)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Venclexta therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of newly-diagnosed acute myeloid leukemia (AML)

AND

1.2 ONE of the following:

- Used as treatment induction in candidates for intensive induction therapy
- Used as treatment induction in candidates for lower-intensity induction therapy
- Used as follow-up after induction therapy following response to previous lower intensity therapy with the same regimen
- Used as consolidation therapy as continuation of lower-intensity regimen used for induction

AND

1.3 Used in combination with decitabine, azacitidine, or low-dose cytarabine

OR

2 - ALL of the following:

- Diagnosis of relapsed/refractory acute myeloid leukemia (AML)
- Used as a component of repeating the initial successful induction regimen
- Greater than or equal to 12 months since induction regimen if not administered continuously
- Therapy was not stopped due to development of clinical resistance

OR

3 - ALL of the following:

- Diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) - acute myeloid leukemia (AML)
- Considered systemic disease and therapy is given as palliative intent
- Patient has low performance and/or nutritional status (i.e., serum albumin less than 3.2 g/dL; not a candidate for intensive remission therapy or Elzonris)
- Venclexta therapy to be given in combination with azacitidine, decitabine, or low-dose cytarabine

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or treatment guidelines

Product Name:Venclexta [a]	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Venclexta therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Chronic Lymphocytic Leukemia /Small Lymphocytic Lymphoma (CLL/SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Chronic Lymphocytic Leukemia /Small Lymphocytic Lymphoma (CLL/SLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Venclexta therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Venclexta [a]	
Diagnosis	Chronic Myelomonocytic Leukemia (CMML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic myelomonocytic leukemia (CMML) **AND** **2** - Classified as CMML-2 (less than 20% bone marrow blasts or blast equivalents) **AND** **3** - Venclexta therapy to be given in combination with azacitidine or decitabine	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Venclexta [a]	
Diagnosis	Chronic Myelomonocytic Leukemia (CMML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient does not show evidence of progressive disease while on Venclexta therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

AND

2 - Disease is progressive after relapsed/refractory therapy

AND

3 - Disease is resistant to BRAF inhibitor therapy (i.e., Zelboraf, Tafinlar)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Venclexta therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of mantle cell lymphoma (MCL) **AND** **2** - Not used as first line therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Venclexta therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or progressive multiple myeloma which has been previously treated

AND

2 - Patient has t(11;14) translocation

AND

3 - Venclexta therapy to be given in combination with ONE of the following:

- dexamethasone
- dexamethasone and daratumumab
- dexamethasone and either bortezomib, carfilzomib, or ixazomib

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Venclexta therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Myeloproliferative Neoplasms – Accelerated/Blast Phase Myeloproliferative Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of accelerated/blast phase myeloproliferative neoplasm

AND

2 - Used for management of disease progression of myeloproliferative neoplasm

AND

3 - Venclexta therapy to be given in combination with azacitidine or decitabine

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Myeloproliferative Neoplasms – Accelerated/Blast Phase Myeloproliferative Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Venclexta therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of relapsed/refractory systemic light chain amyloidosis **AND** **2** - Patient has t(11;14) translocation	

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Venclexta therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma which has been previously treated	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Venclexta therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Venclexta [a]	
Diagnosis	Myelodysplastic Syndromes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Disease is higher risk (IPSS-R Intermediate, High, or Very High) **AND** **2** - Used as initial treatment **AND** **3** - Used in combination with azacitidine or decitabine	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Venclexta [a]	
Diagnosis	Myelodysplastic Syndromes
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Venclexta	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Venclexta [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Venclexta will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Venclexta [a]	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Venclexta therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Venclexta (venetoclax) is a BCL-2 inhibitor indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Venclexta is also indicated in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. In addition, the National Cancer Comprehensive Network (NCCN) recommends the use of Venclexta in in acute lymphoblastic leukemia (ALL); in newly diagnosed, relapsed/refractory, and blastic plasmacytoid dendritic cell neoplasm (BPDCN) AML; relapsed/refractory hairy cell leukemia; mantle cell lymphoma as second line or subsequent therapy; in relapsed or progressive multiple myeloma with t(11;14) translocation; for relapsed/refractory systemic light chain amyloidosis with t(11;14) translocation; in previously treated Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma; in accelerated/blast phase myeloproliferative neoplasm (MPN) with disease progression; and in chronic myelomonocytic leukemia (CMML); and in higher risk myelodysplastic syndromes. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic clas
- Supply limits may be in place.

4 . References

1. Venclexta [package insert]. North Chicago, IL: AbbVie Inc. June, 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 13, 2025.

5 . Revision History

Date	Notes
9/18/2025	Removed footnote related to FDA labeling/NCCN guideline recommendations.

Verzenio

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-254196
Guideline Name	Verzenio
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	8/18/2023
P&T Revision Date:	05/17/2024 ; 5/16/2025

1 . Indications

Drug Name: Verzenio (abemaciclib)
Breast cancer Indicated in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence; in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer; in combination with fulvestrant for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy; and as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

2 . Criteria

Product Name:Verzenio [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is hormone-receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

4.1 BOTH of the following:

4.1.1 Disease is advanced, recurrent, or metastatic

AND

4.1.2 ONE of the following:

4.1.2.1 Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or Faslodex (fulvestrant)

OR

4.1.2.2 ALL of the following:

- Used as monotherapy
- Patient has disease progression following endocrine therapy
- Patient has already received at least one prior chemotherapy regimen

OR

4.2 ALL of the following:

4.2.1 Disease is early breast cancer at high risk of recurrence defined by one of the following (confirmed preoperatively and/or at surgery):

4.2.1.1 Greater than or equal to 4 positive lymph nodes

OR

4.2.1.2 BOTH of the following:

- 1-3 positive lymph nodes
- Grade 3 disease or tumor size ≥ 5 cm)

AND

4.2.2 Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or tamoxifen

AND

4.2.3 Use has not exceeded two years in duration

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Verzenio [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of advanced, recurrent, or metastatic breast cancer
- Patient does not show evidence of progressive disease while on Verzenio therapy

OR

2 - ALL of the following:

- Diagnosis of early breast cancer at high risk of recurrence
- Patient does not show evidence of progressive disease while on Verzenio therapy
- Use has not exceeded two years in duration

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Verzenio [a]	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or metastatic endometrial cancer

AND **2** - Tumor is estrogen receptor (ER)-positive **AND** **3** - Used in combination with letrozole

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Verzenio [a]	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Verzenio therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Verzenio [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Verzenio will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Verzenio [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Verzenio® (abemaciclib) is a kinase inhibitor indicated in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence; in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with HR-

positive, HER2-negative advanced or metastatic breast cancer; in combination with fulvestrant for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy; and as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

The National Comprehensive Cancer Network (NCCN) recommends the use of Verzenio similarly for men and premenopausal women treated with ovarian ablation/suppression with recurrent or metastatic HR-positive, HER2-negative breast cancer disease, in combination with an aromatase inhibitor or Faslodex (fulvestrant). The use of an aromatase inhibitor in men with breast cancer is ineffective without concomitant suppression of testicular steroidogenesis. The NCCN recommends the use of Verzenio for 2 years as adjuvant therapy in combination with endocrine therapy in patients with HR-positive, HER2-negative, high risk (i.e., ≥4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: Grade 3 disease, tumor size ≥5 cm) disease. The NCCN also recommends Verzenio for estrogen receptor (ER)-positive recurrent or metastatic endometrial carcinoma in combination with letrozole.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Verzenio [package insert]. Indianapolis, IN: Lilly USA, LLC; February 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 10, 2025.

5 . Revision History

Date	Notes

5/7/2025	Annual review. Updated criteria for breast cancer per NCCN recommendations. Updated references.

Viberzi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-237195
Guideline Name	Viberzi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	6/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	03/17/2021 ; 03/16/2022 ; 03/15/2023 ; 03/20/2024 ; 4/16/2025

1 . Indications

Drug Name: Viberzi (eluxadoline)
Irritable bowel syndrome with diarrhea (IBS-D) Indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults

2 . Criteria

Product Name:Viberzi [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) **AND** **2** - History of failure, contraindication or intolerance to a tricyclic antidepressant (e.g., amitriptyline)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

Product Name:Viberzi [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Viberzi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3 . Background

Benefit/Coverage/Program Information
Background

Viberzi (eluxadoline) is a mu-opioid receptor agonist, indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may apply

4 . References

1. Viberzi [package insert]. North Chicago, IL: AbbVie, Inc; July 2024.
2. Lacey, BE, Pimentel, M, Brenner, DM, et. al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. Am J Gastroenterol. 2021; 116 (1): 17-44
3. Lembo, A., Sultan, S, et. al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome with Diarrhea. Gastroenterology. 2022;163:137-151.

5 . Revision History

Date	Notes
4/8/2025	Annual review. Updated references.

Vijoice

Prior Authorization Guideline

Guideline ID	GL-291202
Guideline Name	Vijoice
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	6/15/2022
P&T Revision Date:	06/21/2023 ; 06/17/2024 ; 6/18/2025

1 . Indications

Drug Name: Vijoice (alpelisib)
PIK3CA-Related Overgrowth Spectrum (PROS) Indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy.

2 . Criteria

Product Name:Vijoice [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)

AND

2 - ONE of the following criteria:

2.1 Confirmed presence of a mutation in the PIK3CA gene

OR

2.2 ONE of the following:

2.2.1 TWO or more of the following spectrum features:

- Overgrowth: adipose, muscle, nerve, skeletal
- Vascular malformations: capillary, venous, arteriovenous, lymphatic
- Epidermal nevus

OR

2.2.2 ONE or more of the following isolated features:

- Large isolated lymphatic malformation
- Isolated macrodactyly or overgrown splayed feet/hands with overgrown limbs
- Truncal adipose overgrowth
- Hemimegalencephaly (bilateral) / dysplastic megalencephaly / focal cortical dysplasia
- Epidermal nevus
- Seborrheic keratoses
- Benign lichenoid keratoses

AND

3 - Patient is 2 years of age or older

AND **4** - Patient has severe manifestations of PROS requiring systemic therapy **AND** **5** - Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PROS manifestations

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vijoice [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Vijoice therapy

AND

2 - Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PROS manifestations

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Vijoice (alpelisib) is a kinase inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Vijoice [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.
2. Keppler-Noreuil, K. M., Rios, J. J., Parker, V. E., Semple, R. K., Lindhurst, M. J., Sapp, J. C., Alomari, A., Ezaki, M., Dobyns, W., & Biesecker, L. G. (2015). PIK3CA-related overgrowth spectrum (PROS): diagnostic and testing eligibility criteria, differential diagnosis, and evaluation. American journal of medical genetics. Part A, 167A(2), 287–295. https://doi.org/10.1002/ajmg.a.36836
3. Venot, Q., Blanc, T., Rabia, S. H., Berteloot, L., Ladraa, S., Duong, J. P., Blanc, E., Johnson, S. C., Hoguin, C., Boccara, O., Sarnacki, S., Boddaert, N., Pannier, S., Martinez, F., Magassa, S., Yamaguchi, J., Knebelmann, B., Merville, P., Grenier, N., Joly, D., … Canaud, G. (2018). Targeted therapy in patients with PIK3CA-related overgrowth syndrome. Nature, 558(7711), 540–546. https://doi.org/10.1038/s41586-018-0217-9.

5 . Revision History

Date	Notes
6/9/2025	Annual review without changes to coverage criteria. Updated backgr ound.

Vitrakvi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-500230
Guideline Name	Vitrakvi
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 01/19/2022 ; 09/21/2022 ; 01/18/2023 ; 01/17/2024 ; 01/15/2025 ; 1/21/2026

1 . Indications

Drug Name: Vitrakvi (larotrectinib)
Solid tumors Indicated for the treatment of adult and pediatric patients with solid tumors that: • Have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation • Are metastatic or where surgical resection is likely to result in severe morbidity, and • Have no satisfactory alternative treatments or that have progressed following treatment. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. [1]

2 . Criteria

Product Name:Vitrakvi [a]	
Diagnosis	Ampullary Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ampullary adenocarcinoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - ONE of the following:

- Used for metastatic disease
- Used for disease progression

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Ampullary Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Vitrakvi therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Appendiceal Neoplasms and Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following appendiceal neoplasms and cancers:

- Appendiceal adenocarcinoma
- Goblet cell adenocarcinoma
- Undifferentiated carcinoma not otherwise specified

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]

Diagnosis	Appendiceal Neoplasms and Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Biliary Tract Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of biliary tract cancer (e.g., gallbladder, cholangiocarcinoma)

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Gross Residual (R2)
- Metastatic

• Resectable locoregionally advanced • Unresectable	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Biliary Tract Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Vitrakvi therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of breast cancer **AND**	

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

AND

4 - Disease is ONE of the following:

- Metastatic
- Recurrent unresectable
- Unresponsive to preoperative systemic therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Central Nervous System Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Circumscribed glioma
- Glioblastoma
- High-grade glioma
- Brain metastases

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Metastatic
- Recurrent or progressive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Central Nervous System Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Cervical Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cervical cancer

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]

Diagnosis	Cervical Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Colorectal Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colon or rectal cancer

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Vitrakvi [a]	
Diagnosis	Colorectal Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Vitrakvi therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Vitrakvi [a]	
Diagnosis	Esophageal, Esophagogastric Junction, and Gastric Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of esophageal, esophagogastric junction, or gastric cancer **AND** **2** - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)	

AND

3 - Disease is ONE of the following:

- Metastatic
- Recurrent
- Unresectable locally advanced

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Esophageal, Esophagogastric Junction, and Gastric Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Gastrointestinal Stromal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Used in ONE of the following settings:

- Neoadjuvant therapy to decrease surgical morbidity
- Gross residual disease (R2 resection)
- Unresectable primary disease
- Preoperative/intraoperative tumor rupture
- Recurrent/metastatic disease

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Gastrointestinal Stromal Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Head and Neck Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of salivary gland tumor **AND** **2** - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.) **AND** **3** - Used as second-line or subsequent therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Head and Neck Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is recurrent or metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Hepatocellular Carcinoma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of histiocytic neoplasm

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Metastatic
- Relapsed/refractory

• Symptomatic unresectable or multifocal	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Vitrakvi therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cutaneous melanoma **AND**	

2 - Disease is positive for ONE of the following gene fusions:

- ROS1-gene fusion
- NTRK-gene fusion

AND

3 - Disease is metastatic or unresectable

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuroendocrine tumor

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

AND

4 - Disease is ONE of the following:

- Locoregional unresectable
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Vitrakvi therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Advanced
- Metastatic
- Recurrent

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Vitrakvi therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Occult Primary [Cancer of Unknown Primary (CUP)]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following occult primary cancers:

- Adenocarcinoma
- Carcinoma not otherwise specified
- Squamous cell carcinoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

AND

4 - Used in ONE of the following settings:

- Asymptomatic patients with PS 0 and aggressive disease
- Symptomatic patients with performance status (PS) 1-2

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Occult Primary [Cancer of Unknown Primary (CUP)]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Ovarian/Fallopian Tube/Primary Peritoneal Cancers

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Fallopian tube cancer
- Ovarian cancer
- Primary peritoneal cancer

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - ONE of the following histologies:

- Endometrioid
- Carcinosarcoma (Malignant Mixed Müllerian Tumors)
- Clear cell carcinoma of the ovary
- Mucinous carcinoma
- Serous carcinoma

AND

4 - Disease is persistent or recurrent

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Ovarian/Fallopian Tube/Primary Peritoneal Cancers

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Pancreatic Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic adenocarcinoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Locally advanced
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Pancreatic Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Vitrakvi therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Small Bowel Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of small bowel adenocarcinoma **AND** **2** - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)	

AND **3** - Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Small Bowel Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of soft tissue sarcoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Advanced
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following thyroid cancers:

- Papillary carcinoma
- Follicular carcinoma
- Oncocytic carcinoma
- Anaplastic carcinoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Metastatic
- Persistent
- Unresectable locoregional recurrent

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Uterine Neoplasm
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following uterine neoplasms:

- Endometrial carcinoma
- Uterine Sarcoma

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is ONE of the following:

- Advanced
- Inoperable
- Recurrent
- Metastatic

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Uterine Neoplasm
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Vaginal/Vulvar Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vaginal or vulvar cancer

AND

2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND **3** - Used as second-line or subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	Vaginal/Vulvar Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Vitrakvi will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vitrakvi [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Vitrakvi therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background Vitrakvi® (larotrectinib) is a kinase inhibitor indicated for the treatment of adult and pediatric patients with solid tumors that: • have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, • are metastatic or where surgical resection is likely to result in severe morbidity, and • have no satisfactory alternative treatments or that have progressed following treatment. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[1]

The National Comprehensive Cancer Network (NCCN) also recommends the use of Vitrakvi in solid tumors that are (NTRK) gene fusion positive with differing clinical circumstances.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Vitrakvi [package insert]. Whippany, NJ: Bayer HealthcCare Pharmaceuticals Inc.; April 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed November 18, 2025.

5 . Revision History

Date	Notes
1/17/2026	Annual review. Expanded section on solid tumors to specify each typ e with their own criteria based on FDA label and NCCN guidance.

Vivjoa

Prior Authorization Guideline

Guideline ID	GL-355236
Guideline Name	Vivjoa
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	10/1/2025
P&T Approval Date:	8/19/2022
P&T Revision Date:	08/18/2023 ; 8/22/2025

1 . Indications

Drug Name: Vivjoa (oteseconazole)
Recurrent vulvovaginal candidiasis Indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential.

2 . Criteria

Product Name:Vivjoa [a]	
Approval Length	4 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of recurrent vulvovaginal candidiasis

AND

2 - Patient is not of reproductive potential (i.e., persons who are biological females who are postmenopausal or have another reason for permanent infertility [(e.g., tubal ligation, hysterectomy, salpingo-oophorectomy)]

AND

3 - Both of the following:

- Other causes (including but not limited to bacterial vaginosis or trichomoniasis) have been ruled out
- Failure of a maintenance course of oral fluconazole defined as 100-mg, 150-mg, or 200-mg taken weekly for 6 months.

AND

4 - Prescribed by or in consultation with one of the following:

- Infectious disease physician
- Obstetrician/Gynecologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Vivjoa (oteseconazole) is an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Vivjoa [package insert]. Durham, NC: Mycovia Pharmaceuticals, Inc; April 2024.
2. Centers for Disease Control and Prevention. Sexually Transmitted Infections Treatment Guidelines, 2021. Morbidity and Mortality Weekly Report. 2021;70(No. RR-4).

5 . Revision History

Date	Notes
8/5/2025	Annual review. Updated references.

Votrient

Prior Authorization Guideline

Guideline ID	GL-447194
Guideline Name	Votrient
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	9/15/2021
P&T Revision Date:	09/21/2022 ; 10/19/2022 ; 11/18/2022 ; 08/18/2023 ; 11/17/2023 ; 11/22/2024 ; 11/21/2025

1 . Indications

Drug Name: Votrient (pazopanib)
Renal cell carcinoma Indicated for the treatment of adults with advanced renal cell carcinoma (RCC) in patients who have received prior chemotherapy. **Soft tissue sarcoma** Indicated for the treatment of adults with advanced soft tissue sarcoma (STS) who have received prior chemotherapy.

2 . Criteria

Product Name:Brand Votrient, generic pazopanib [a]

Diagnosis	Renal cell carcinoma (RCC)/Kidney cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of renal cell carcinoma (RCC)

AND

1.2 ONE of the following:

- Disease has relapsed
- Stage IV disease
- Disease is advanced

OR

2 - Diagnosis of von Hippel-Lindau (VHL)-associated renal cell carcinoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Renal cell carcinoma (RCC)/Kidney cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Votrient therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Alveolar soft part sarcoma
- Angiosarcoma
- Dedifferentiated chordoma
- Dedifferentiated liposarcoma with or without concurrent well-differentiated liposarcoma
- Dermatofibrosarcoma Protuberans (DFSP) with Fibrosarcomatous Transformation
- Desmoid tumors (aggressive fibromatosis)
- Epithelioid hemangioendothelioma
- Extraskeletal myxoid chondrosarcoma
- Soft tissue sarcoma of the extremity/superficial trunk or head/neck with disease that is stage IV or recurrent and has disseminated metastases
- Retroperitoneal/Intra-abdominal disease that is unresectable, stage IV, or postoperative treatment for residual disease
- Pleomorphic rhabdomyosarcoma
- Solitary fibrous tumor/hemangiopericytoma

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Votrient therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Papillary carcinoma

AND

1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.4 ONE of the following:

- Disease is refractory to radioactive iodine treatment
- Distant metastatic disease not amenable to radioactive iodine treatment

OR

2 - ALL of the following:

2.1 Diagnosis of oncocytic carcinoma

AND

2.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

2.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

OR

3 - ALL of the following:

3.1 Diagnosis of medullary carcinoma

AND

3.2 ONE of the following:

- Disease is progressive
- Disease is symptomatic with distant metastases

AND

3.3 History of failure, contraindication, or intolerance to ONE of the following^:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Votrient therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - ONE of the following:

- Disease is advanced
- Disease is recurrent/metastatic
- Disease is inoperable

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Votrient therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial Ovarian Cancer
- Fallopian Tube Cancer
- Primary Peritoneal Cancer

AND

2 - ONE of the following:

- Disease is persistent
- Disease is recurrent

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Votrient therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Chondrosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of chondrosarcoma **AND** **2** - Disease is metastatic and widespread

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Chondrosarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Votrient therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of GIST

AND

2 - Disease is residual, unresectable, progressive, or metastatic

AND

3 - ONE of the following:

3.1 Used as first-line therapy in SDH-deficient GIST

OR

3.2 Used after progression on ALL of the following^:

- imatinib (generic Gleevac)

• sunitinib (generic Sutent) • Stivarga (regorafenib) • standard dose Qinlock (ripretinib)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^ Tried/failed alternative(s) are supported by FDA labeling and/or NCCN guidelines.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Votrient therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Merkel Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Merkel Cell Carcinoma	

AND

2 - ONE of the following:

- Anti-PD-L1 or anti-PD-1 therapy is contraindicated
- Disease has progressed on anti-PD-L1 or anti-PD-1 therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	Merkel Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Votrient therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Votrient will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Votrient, generic pazopanib [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Votrient therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Votrient (pazopanib) is a kinase inhibitor indicated for the treatment of advanced renal cell carcinoma and advanced soft tissue sarcoma in patients who have received prior chemotherapy. [1]

Additionally, the National Comprehensive Cancer Network (NCCN) recommends use of Votrient in treatment of medullary, follicular, oncocytic, and papillary thyroid carcinomas; ovarian cancer; additional soft tissue sarcomas, chondrosarcoma, uterine sarcoma, merkel cell carcinoma, and gastrointestinal stromal tumors (GIST).

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Votrient [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed October 13, 2025.

5 . Revision History

Date	Notes
11/9/2025	Annual review. Added additional soft tissue sarcomas to align with NCCN and reformatted soft tissue sarcoma criteria. Updated oncocytic carcinoma criteria to remove radioactive iodine criteria. Removed staging system criteria for Merkel Cell Carcinoma. Updated references.

Vowst

Prior Authorization Guideline

Guideline ID	GL-162220
Guideline Name	Vowst
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2025
P&T Approval Date:	7/19/2023
P&T Revision Date:	12/13/2023 ; 10/01/2024 ; 12/18/2024

1 . Indications

Drug Name: Vowst (fecal microbiota spores, live-brpk)
Clostridioides difficile infection (CDI) Indicated indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI).

2 . Criteria

Product Name:Vowst [a]	
Approval Length	1 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of recurrent Clostridioides difficile infection (rCDI) as defined by BOTH of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for Clostridioides difficile toxin

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has had one or more recurrences of CDI following an initial episode of CDI

AND

4 - Patient has completed at least 10 days of oral vancomycin for rCDI 2 to 4 days prior to initiating Vowst^:

AND

5 - Previous episode of CDI is under control [e.g., less than 3 unformed/loose (i.e., Bristol Stool Scale type 6-7) stools/day for 2 consecutive days]

AND

6 - Patient will drink magnesium citrate on the day before and at least 8 hours prior to taking the first dose of Vowst

AND

7 - Prescribed by or in consultation with ONE of the following: • Gastroenterologist • Infectious disease specialist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/failed alternative(s) are supported by FDA labeling and/or treatment guidelines.

3 . Background

Benefit/Coverage/Program Information
Background Vowst is indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Vowst [package insert]. Cambridge, MA: Seres Therapeutics, Inc.; June 2024.

5 . Revision History

Date	Notes

12/18/2024	Annual review. Updated reference.

Voxzogo

Prior Authorization Guideline

Guideline ID	GL-461348
Guideline Name	Voxzogo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	3/16/2022
P&T Revision Date:	09/21/2022 ; 03/15/2023 ; 12/13/2023 ; 12/18/2024 ; 09/25/2025 ; 12/17/2025

1 . Indications

Drug Name: Voxzogo (vosoritide)
Achondroplasia Indicated to increase linear growth in pediatric patients with achondroplasia with open epiphyses.

2 . Criteria

Product Name:Voxzogo [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Patient is less than 18 years of age

AND

2 - Diagnosis of achondroplasia as confirmed by ONE of the following:

2.1 Submission of medical records documenting BOTH of the following:

- Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis)
- Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest)

OR

2.2 Submission of medical records documenting molecular genetic testing confirmed c.1138G>A or c.1138G>C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene

AND

3 - Patient has open epiphyses

AND

4 - BOTH of the following:

- Patient has not had limb-lengthening surgery in the previous 18 months

- Patient does not plan to have limb-lengthening surgery while on Voxzogo

AND

5 - Prescribed by ONE of the following:

- Clinical geneticist
- Endocrinologist
- A practitioner who has specialized expertise in the management of achondroplasia

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Voxzogo [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Voxzogo therapy (e.g., improvement in annualized growth velocity (AGV) compared to baseline)

AND

2 - Patient has open epiphyses

AND

3 - Patient does not plan to have limb-lengthening surgery while on Voxzogo

AND

4 - Prescribed by or in consultation with ONE of the following: • Clinical geneticist • Endocrinologist • A practitioner who has specialized expertise in the management of achondroplasia	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Voxzogo (vosoritide) is a C type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients with achondroplasia with open epiphyses. This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply Limits may also be in place

4 . References

1. Voxzogo [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; November 2024.
2. Savarirayan R, Tofts L, Irving M, et al. Once-daily, subcutaneous vosoritide therapy in children with achondroplasia: a randomised, double-blind, phase 3, placebo-controlled, multicentre trial. Lancet. 2020;396(10252):684-692.
3. Pauli RM. Achondroplasia: a comprehensive clinical review. Orphanet J Rare Dis 2019;14(1):1-49.
4. Hoover-Fong J, Scott CI, Jones MC; COMMITTEE ON GENETICS. Health Supervision for People With Achondroplasia. Pediatrics. 2020;145(6):e20201010.

5. Savarirayan R, Ireland P, Irving M, et al. International Consensus Statement on the diagnosis, multidisciplinary management and lifelong care of individuals with achondroplasia. Nat Rev Endocrinol. 2022;18(3):173-189.

5 . Revision History

Date	Notes
12/8/2025	Annual review with no changes to coverage criteria. Updated references.

Voydeya

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-272213
Guideline Name	Voydeya
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	5/17/2024
P&T Revision Date:	5/16/2025

1 . Indications

Drug Name: Voydeya (danicopan)
Extravascular hemolysis (EVH) Indicated as add-on therapy to Ultomiris (ravulizumab) or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH).

2 . Criteria

Product Name:Voydeya [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by BOTH of the following: [2,3,4,5]

- Flow cytometry analysis confirming presence of PNH clones
- Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - ALL of the following:

- Patient is currently receiving complement protein C5 inhibitor eculizumab or Ultomiris (ravulizumab)
- Patient is experiencing extravascular hemolysis (EVH) while on complement protein C5 inhibitor eculizumab or Ultomiris (ravulizumab)
- Patient will continue to receive complement protein C5 inhibitor eculizumab or Ultomiris (ravulizumab)

AND

3 - Patient is not receiving Voydeya in combination with a complement protein C3 inhibitor [e.g., Empaveli (Pegcetacoplan)] or a complement factor B inhibitor [e.g., Fabhalta (iptacopan)] used for the treatment of PNH

AND

4 - Prescribed by, or in consultation with ONE of the following:

- Hematologist
- Oncologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Voydeya [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Voydeya therapy [e.g., decrease in extravascular hemolysis (EVH), increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, etc.)]

AND

2 - Patient continues to receive Voydeya in combination with complement protein C5 inhibitor eculizumab or Ultomiris (ravulizumab) for PNH

AND

3 - Patient is not receiving Voydeya in combination with a complement protein C3 inhibitor [e.g., Empaveli (Pegcetacoplan)] or a complement factor B inhibitor [e.g., Fabhalta (iptacopan)] used for the treatment of PNH

AND

4 - Prescribed by, or in consultation with ONE of the following:

- Hematologist
- Oncologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

3 . Background

Benefit/Coverage/Program Information
Background: Voydeya (danicopan) is a complement factor D inhibitor indicated as add-on therapy to Ultomiris (ravulizumab) or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH). [1] **Additional Clinical Programs:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limitations may be in place.

4 . References

1. Vodeya [package insert]. Boston, Massachusetts: Alexion Pharmaceuticals, Inc.; March 2024.
2. Parker C, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood. 2005 Dec 1; 106(12): 3699–3709.
3. Devalet B, Mullier F, Chatelain B, et al. Pathophysiology, diagnosis, and treatment of paroxysmal nocturnal hemoglobinuria: a review. Eur J Haematol. 2015 Sep;95(3):190-8.
4. Sutherland DR, Keeney M, Illingworth A. Practical guidelines for the high-sensitivity detection and monitoring of paroxysmal nocturnal hemoglobinuria clones by flow cytometry. Cytometry B Clin Cytom. 2012 Jul;82(4):195-208.
5. Röth A, Maciejewski J, Nishimura JI, et al. Screening and diagnostic clinical algorithm for paroxysmal nocturnal hemoglobinuria: Expert consensus. Eur J Haematol. 2018 Jul;101(1):3-11.

5 . Revision History

Date	Notes

5/20/2025	Annual review. Updated list of C5 inhibitors by removing trade name of Soliris from eculizumab.

Voyxact

Prior Authorization Guideline

Guideline ID	GL-500231
Guideline Name	Voyxact
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	1/21/2026
P&T Revision Date:	

1 . Indications

Drug Name: Voyxact (sibeprenlimab-szsl)
Immunoglobulin A nephropathy (IgAN) Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression.

2 . Criteria

Product Name:Voyxact [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

AND

2 - Patient is at risk of rapid disease progression

AND

3 - Used to reduce proteinuria

AND

4 - Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m2

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with one of the following:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to ACE inhibitors and ARBs

AND

6 - ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin)]
- Patient has a contraindication or intolerance to SGLT2 inhibitors

AND

7 - History of a failure to 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone), contraindication or intolerance

AND

8 - Prescribed by or in consultation with a nephrologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Voyxact [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response demonstrated by a reduction in proteinuria

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Voyxact (sibeprenlimab-szsl) is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression. This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Voyxact slows kidney function decline over the long-term in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Voyxact [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; November 2025.
2. Kidney Disease: Improving Global Outcomes (KDIGO) IgAN and IgAV Work Group. (2025). KDIGO 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Kidney International, 108(Suppl 4), S1–S71.

5 . Revision History

Date	Notes
1/18/2026	New program.

Vtama

Prior Authorization Guideline

Guideline ID	GL-552225
Guideline Name	Vtama
Formulary	• UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	9/21/2022
P&T Revision Date:	12/14/2022 ; 11/17/2023 ; 12/18/2024 ; 01/15/2025 ; 05/16/2025 ; 3/18/2026

1 . Indications

Drug Name: Vtama (tapinarof)
Plaque Psoriasis Indicated for topical treatment of plaque psoriasis in adults. **Atopic Dermatitis** Indicated for the topical treatment of atopic dermatitis in adults and pediatric patients 2 years of age and older.

2 . Criteria

Product Name:Vtama [a]	
Diagnosis	Plaque Psoriasis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to TWO of the following topical therapies:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Coal tar

AND

3 - Patient is NOT receiving Vtama in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vtama [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving Vtama in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vtama [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of atopic dermatitis

AND

2 - History of failure, contraindication, or intolerance to BOTH of the following therapeutic classes of topical therapies (document drug, date of trial, and/ or contraindication to medication):

- Medium, high, or very-high potency topical corticosteroids [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]

• Topical calcineurin inhibitor [e.g., tacrolimus (generic Protopic)] **AND** **3** - Patient is NOT receiving Vtama in combination with a systemic targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vtama [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is NOT receiving Vtama in combination with a targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Vtama cream is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults and the topical treatment of atopic dermatitis in adults and pediatric patients 2 years of age and older. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Vtama [package insert]. Long Beach, CA: Dermavant Sciences Inc.; May 2025.
2. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

5 . Revision History

Date	Notes
3/17/2026	Updated plaque psoriasis and atopic dermatitis sections to require st ep through 2 topical therapies. Updated combination examples and l anguage.

Vyndaqel, Vyndamax

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-500246
Guideline Name	Vyndaqel, Vyndamax
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 02/18/2022 ; 06/21/2023 ; 08/18/2023 ; 09/18/2024 ; 01/15/2025 ; 1/21/2026

1 . Indications

Drug Name: Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)
Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) Indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. [1]

2 . Criteria

Product Name:Vyndaqel, Vyndamax [a]

Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)

AND

2 - ONE of the following:

2.1 Documentation that the patient has a pathogenic TTR mutation (e.g., V30M)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits

OR

2.3 ALL of the following:

2.3.1 Echocardiagram or cardiac magnetic resonance imaging suggestive of amyloidosis

AND

2.3.2 Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake*

AND

2.3.3 Absence of light chain amyloidosis

AND

3 - Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

4 - Physician attests that the patient has an N-terminal pro-B-type natriuretic peptide (NT-proBNP) level that, when combined with signs and symptoms, is considered definitive for a diagnosis of ATTR-CM

AND

5 - ONE of the following:

- History of heart failure, with at least one prior hospitalization for heart failure
- Presence of clinical signs and symptoms of heart failure (e.g., dyspnea, edema)

AND

6 - Prescribed by or in consultation with a cardiologist

AND

7 - Patient is not receiving Vyndaqel/Vyndamax in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Attruby (acoramadis), Onpattro (patisiran), Tegsedi (inotersen), or Wainua (eplontersen)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *May require prior authorization and notification.

Product Name:Vyndaqel, Vyndamax [a]	
Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation that the patient has experienced a positive clinical response to Vyndaqel/Vyndamax (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

AND

2 - Documentation that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

3 - Prescribed by or in consultation with a cardiologist

AND

4 - Patient is not receiving Vyndaqel/Vyndamax in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Attruby (acoramadis), Onpattro (patisiran), Tegsedi (inotersen), or Wainua (eplontersen)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background:

Vyndaqel® (tafamidis meglumine) and Vyndamax™ (tafamidis) are transthyretin stabilizers indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.[1]

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Vyndaqel and Vyndamax [package insert]. Pfizer, Inc: New York, NY; October 2023.
2. Mauer MS, Schwartz JH, Gundapeneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018; 379:1007-16.
3. Gillmore JD, Maurer MS, Falk RH, et al. Nonbiopsy diagnosis of cardiac transthyretin amyloidosis. Circulation. 2016; 133:2404-12.
4. Mckenna WJ. Treatment of amyloid cardiomyopathy. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on November 24, 2025).
5. Mckenna WJ. Clinical manifestations and diagnosis of amyloid cardiomyopathy. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on November 24, 2025.)
6. Kittleson MM, Ruberg FL, et al.. 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2023 Mar 21;81(11):1076-1126.

5 . Revision History

Date	Notes
1/21/2026	Annual review with no changes to coverage criteria. Updated references.

Vyvgart Hytrulo

Prior Authorization Guideline

Guideline ID	GL-400188
Guideline Name	Vyvgart Hytrulo
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	9/25/2025
P&T Revision Date:	

1 . Indications

Drug Name: Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
Generalized Myasthenia Gravis (gMG) Indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive and chronic inflammatory demyelinating polyneuropathy (CIDP).

2 . Criteria

Product Name:Vyvgart Hytrulo [a]	
Diagnosis	Generalized Myasthenia Gravis
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of generalized Myasthenia Gravis (gMG)

AND

2 - Positive serologic test for anti-AChR antibodies

AND

3 - Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy

AND

4 - Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy

AND

5 - ONE of the following:

5.1 History of failure of a minimum of two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.)

OR

5.2 BOTH of the following:

- History of failure of at least one immunosuppressive therapy

- Patient has required four or more courses of plasmapheresis/plasma exchanges and/or immune globulin over the course of at least 12 months without symptom control

AND

6 - Patient is NOT receiving Vyvgart Hytrulo in combination with ANY of the following for treatment of the same indication:

- A complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]
- Another FcRn blocker [e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab)]
- Immune globulin (e.g., Gammagard, Privigen, Hizentra)

AND

7 - Prescribed by or in consultation with a neurologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vyvgart Hytrulo [a]	
Diagnosis	Generalized Myasthenia Gravis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory tests) demonstrating ALL of the following:

- Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline
- Reduction in signs and symptoms of myasthenia gravis
- Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart Hytrulo. Note: Add on, dose escalation of IST, or

additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Vyvgart Hytrulo therapy will be considered as treatment failure

AND

2 - Patient is NOT receiving Vyvgart Hytrulo in combination with ANY of the following for treatment of the same indication:

- A complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]
- Another FcRn blocker [e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab)]
- Immune globulin (e.g., Gammagard, Privigen, Hizentra)

AND

3 - Prescribed by or in consultation with a neurologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vyvgart Hytrulo [a]	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP)

AND

2 - ALL of the following:

2.1 Progressive symptoms present for at least 2 months

AND

2.2 Symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor or sensory impairment of more than one limb

AND

2.3 Electrodiagnostic findings (consistent with EFNS/PNS guidelines for definite CIDP) indicating the presence of at least ONE of the following:

- Motor distal latency prolongation in 2 nerves
- Reduction of motor conduction velocity in 2 nerves
- Prolongation of F-wave latency in 2 nerves
- Absence of F-waves in at least 1 nerve
- Partial motor conduction block of at least 1 motor nerve
- Abnormal temporal dispersion in at least 2 nerves
- Distal CMAP duration increase in at least 1 nerve

AND

3 - Trial and failure (after a trial of at least two months b), contraindication, or intolerance to a corticosteroid (e.g., prednisone, methylprednisolone)

AND

4 - ONE of the following:

4.1 Trial and failure (after a trial of at least three months b) to an immune globulin (e.g., Gammagard, Privigen, Hizentra) with the maximally allowable and/or tolerated dose

OR

4.2 BOTH of the following:

- Intolerance to ALL immune globulins (e.g., Gammagard, Privigen, Hizentra)
- Dose has been adjusted or escalated to the maximally allowable and/or tolerated dose

OR

4.3 Contraindication to ALL immune globulins (e.g., Gammagard, Privigen, Hizentra)

AND

5 - Patient is not receiving Vyvgart Hytrulo in combination with an immune globulin (e.g., Gammagard, Privigen, Hizentra) for treatment of the same indication

AND

6 - Prescribed by or in consultation with a neurologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Vyvgart Hytrulo [a]	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of a positive clinical response to Vyvgart Hytrulo as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]

AND

2 - Patient is not receiving Vyvgart Hytrulo in combination with an immune globulin (e.g., Gammagard, Privigen, Hizentra) used for treatment of the same indication

AND **3** - Prescribed by or in consultation with a neurologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Vyvgart Hytrulo is a combination of efgartigimod alfa, a neonatal Fc receptor (FcRn) blocker, and hyaluronidase, an endoglycosidase, indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive and chronic inflammatory demyelinating polyneuropathy (CIDP). **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place

4 . References

1. Vyvgart Hytrulo® [prescribing information]. Boston, MA: Argenx US, Inc.; April 2025
2. Howard JF, Jr., Bril V, Vu T, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalized myasthenia gravis (ADAPT): a multicenter, randomized, placebo-controlled, phase 3 trial. The Lancet Neurology. 2021;20(7):526-536.
3. Bird S. Overview of the treatment of myasthenia gravis. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA.

4. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. Neurology. 2021;96(3):114-122.
5. Muppidi S, Silvestri NJ, Tan R, Riggs K, Leighton T, Phillips GA. Utilization of MG-ADL in myasthenia gravis clinical research and care. Muscle Nerve. 2022;65(6):630-639. doi:10.1002/mus.27476.
6. Van den Bergh PYK, van Doorn PA, Hadden RDM, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint Task Force-Second revision [published correction appears in J Peripher Nerv Syst. 2022 Mar;27(1):94. doi: 10.1111/jns.12479.] [published correction appears in Eur J Neurol. 2022 Apr;29(4):1288. doi: 10.1111/ene.15225.]. J Peripher Nerv Syst. 2021;26(3):242-268. doi:10.1111/jns.12455

5 . Revision History

Date	Notes
9/15/2025	New program.

Wainua

Prior Authorization Guideline

Guideline ID	GL-165048
Guideline Name	Wainua
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2025
P&T Approval Date:	2/16/2024
P&T Revision Date:	2/20/2025

1 . Indications

Drug Name: Wainua (eplontersen)
Polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults.

2 . Criteria

Product Name:Wainua [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - BOTH of the following:

- Diagnosis of hATTR amyloidosis with polyneuropathy
- Documentation that the patient has a pathogenic TTR mutation (e.g., V30M)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

- Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb
- Patient has a baseline FAP Stage 1 or 2
- Patient has a baseline neuropathy impairment (NIS) score ≥ 10 and ≤ 130

AND

4 - Patient has not had a liver transplant

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

AND

6 - Patient is not receiving Wainua in combination with EITHER of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran), Tegsedi (inotersen)]

• Transthyretin stabilizer [e.g., Vyndaqel/Vyndamax (tafamadis), Attruby (acoramidis)]	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Wainua [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation that the patient has experienced a positive clinical response to Wainua therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)

AND

2 - Patient is not receiving Wainua in combination with EITHER of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran), Tegsedi (inotersen)]
- Transthyretin stabilizer [e.g., Vyndaqel/Vyndamax (tafamadis), Attruby (acoramidis)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Wainua (eplontersen) is a transthyretin-directed antisense oligonucleotide indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4 . References

1. Wainua [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.

5 . Revision History

Date	Notes
2/12/2025	Added Attruby to Vyndaqel/Vyndamax and relabeled as transthyretin stabilizer agents not to be used in combination. Updated reference.

Wakix

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399266
Guideline Name	Wakix
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	2/17/2023
P&T Revision Date:	10/18/2023 ; 09/18/2024 ; 9/25/2025

1 . Indications

Drug Name: Wakix (pitolisant)
Narcolepsy Indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adults with narcolepsy and EDS in pediatric patients 6 years of age and older with narcolepsy

2 . Criteria

Product Name:Wakix [a]	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of narcolepsy with cataplexy (i.e., Narcolepsy Type 1) with BOTH of the following:

- The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months
- A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to BOTH of the following:

- Patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness
- Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Pulmonologist
- Sleep Medicine Specialist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Wakix [a]	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation demonstrating a reduction in frequency of cataplexy attacks associated with therapy

OR

2 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Wakix [a]	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy without cataplexy (i.e., Narcolepsy Type 2) with BOTH of the following:

- The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months
- A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep

onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to the following:

- Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance of ALL of the following:

- an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant
- modafinil (generic Provigil) or armodafinil (generic Nuvigil)
- Sunosi

OR

3.2 History of or potential for a substance abuse disorder

AND

4 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Pulmonologist
- Sleep Medicine Specialist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Wakix [a]	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Wakix is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adults with narcolepsy and EDS in pediatric patients 6 years of age and older with narcolepsy. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Wakix [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; June 2025.
2. American Academy of Sleep Medicine. International Classification of Sleep Disorders: Diagnostic and Coding Manual. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
3. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: An American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine. 2021. Sept (17):1881-1893.

5 . Revision History

Date	Notes
9/19/2025	Annual review. Updated references. Added Sunosi step and exceptio n for substance abuse history or potential.

Wayrilz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523213
Guideline Name	Wayrilz
Formulary	• UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	2/20/2026
P&T Revision Date:	

1 . Indications

Drug Name: Wayrilz (rilzabrutinib)
Chronic immune thrombocytopenia (ITP) Inhibitor indicated for the treatment of adult patients with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

2 . Criteria

Product Name:Wayrilz [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic immune thrombocytopenia (ITP)

AND

2 - ONE of the following:

2.1 Patient has had a prior splenectomy

OR

2.2 History of failure/inadequate response, contraindication, or intolerance to ONE of the following (document drug, date, and duration of trial):

- Corticosteroids (e.g., prednisone, methylprednisolone)
- Immunoglobulins

AND

3 - History of failure/inadequate response, contraindication, or intolerance, to eltrombopag (e.g. Alvaiz, generic Promacta) (document date and duration of trial)

AND

4 - Platelet count remains less than 30,000/mcL despite previous treatment

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Wayrilz [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to to Wayrilz therapy (e.g. an increase in platelet count to a level sufficient to avoid clinically important bleeding)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Wayrilz (rilzabrutinib) is a kinase inhibitor indicated for the treatment of adult patients with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. **Additional Clinical Rules:** • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. • Supply limits may be in place.

4 . References

1. Wayrilz [Package Insert]. Cambridge, MA: Genzyme Corporation; August 2025.
2. Neunert C,et. al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv. 2019 Dec 10;3(23):3829-3866.

5 . Revision History

Date	Notes
2/17/2026	New program.

Wegovy

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523235
Guideline Name	Wegovy
Formulary	UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	3/19/2025
P&T Revision Date:	11/21/2025 ; 2/20/2026

1 . Indications

Drug Name: Wegovy injection (semaglutide)
Cardiovascular Risk Reduction Indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight. **Weight Loss** Indicated to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 12 years and older with obesity, and in adults with overweight in the presence of at least one weight-related comorbid condition. **Noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH)** Indicated for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults.
Drug Name: Wegovy tablets (semaglutide)

Cardiovascular Risk Reduction Indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.

Weight Loss Indicated to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 12 years and older with obesity, and in adults with overweight in the presence of at least one weight-related comorbid condition.

2 . Criteria

Product Name:Wegovy injection or tablet [a]	
Diagnosis	Cardiovascular Risk Reduction
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested to reduce the risk of major adverse cardiovascular events

AND

2 - Patient is 45 years of age or older

AND

3 - Submission of medical records documenting ALL the following:

3.1 BMI ≥ 27 kg/m2

AND

3.2 Established cardiovascular disease as evidenced by ONE of the following:

3.2.1 Prior myocardial infarction (MI)

OR

3.2.2 Prior ischemic or hemorrhagic stroke

OR

3.2.3 Symptomatic peripheral arterial disease (PAD) evidenced by ONE of the following:

Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest)

Peripheral arterial revascularization procedure

Amputation due to atherosclerotic disease

AND

4 - Used in combination with a reduced calorie diet and increased physical activity

AND

5 - ONE of the following:

5.1 For patients with history of MI, ONE of the following:

5.1.1 Patient is on therapy from each of the following classes (as confirmed by claims history or submission of medical records):

cholesterol lowering medication (e.g. statin, PCSK9i)

beta blocker (i.e., carvedilol, metoprolol, or bisoprolol)

angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

antiplatelet (e.g. aspirin, clopidogrel)

OR

5.1.2 Patient has a history of intolerance or contraindication to all of the following therapeutic classes (please specify intolerance or contraindication):

cholesterol lowering medication (e.g. statin, PCSK9i)

beta blocker (i.e., carvedilol, metoprolol, or bisoprolol)

angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

antiplatelet (e.g. aspirin, clopidogrel)

OR

5.2 For patients with history of ischemic or hemorrhagic stroke, ONE of the following:

5.2.1 Patient is on therapy from each of the following classes (as confirmed by claims history or submission of medical records):

cholesterol lowering medication (e.g. statin, PCSK9i)

angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

antiplatelet (e.g. aspirin, clopidogrel)

OR

5.2.2 Patient has a history of intolerance or contraindication to all of the following therapeutic classes (please specify intolerance or contraindication):

cholesterol lowering medication (e.g. statin, PCSK9i)

angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

antiplatelet (e.g. aspirin, clopidogrel)

OR

5.3 For patients with history of symptomatic PAD, ONE of the following:

5.3.1 Patient is on therapy from each of the following classes (as confirmed by claims history or submission of medical records):

cholesterol lowering medication (e.g. statin, PCSK9i)

angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

antiplatelet (e.g. aspirin, clopidogrel)

OR

5.3.2 Patient has a history of intolerance or contraindication to all of the following therapeutic classes (please specify intolerance or contraindication):

cholesterol lowering medication (e.g. statin, PCSK9i)

angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

antiplatelet (e.g. aspirin, clopidogrel)

AND

6 - Patient does NOT have either of the following:

Diagnosis of diabetes or HgA1c > 6.5%

New York Heart Association class IV heart failure

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Note: Wegovy when used solely for the treatment of weight loss is excluded and is to be denied as a benefit exclusion.

Product Name:Wegovy injection or tablet [a]	
Diagnosis	Cardiovascular Risk Reduction
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used in combination with a reduced calorie diet and increased physical activity

AND

2 - Patient does NOT have either of the following:

Diagnosis of diabetes or HgA1c > 6.5%

New York Heart Association class IV heart failure

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Note: Wegovy when used solely for the treatment of weight loss is excluded and is to be denied as a benefit exclusion.

Product Name:Wegovy injection [a]	
Diagnosis	MASH
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Wegovy injection is being requested for the treatment of metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as nonalcoholic steatohepatitis (NASH)]

AND

2 - Submission of medical records documenting that disease is fibrosis stage F2 or F3 as confirmed by ONE of the following:

Liver stiffness measurement (LSM) by vibration-controlled transient elastography (VCTE) (e.g., FibroScan)

LSM by magnetic resonance elastography (MRE)

Liver biopsy within the past 12 months

AND

3 - Used in combination with a reduced calorie diet and increased physical activity

AND

4 - Provider attests Wegovy injection will not be initiated at the same time as Rezdiffra (resmetirom) for treatment of the same indication

AND

5 - Prescribed by or in consultation with ONE of the following:

Gastroenterologist

Hepatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Note: Wegovy when used solely for the treatment of weight loss is excluded and is to be denied as a benefit exclusion.

Product Name:Wegovy injection [a]

Diagnosis	MASH
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Wegovy injection (e.g., improvement in or stabilization of fibrosis)

AND

2 - Patient has not progressed to cirrhosis

AND

3 - Used in combination with a reduced calorie diet and increased physical activity

AND

4 - Prescribed by or in consultation with one of the following:

Gastroenterologist

Hepatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Note: Wegovy when used solely for the treatment of weight loss is excluded and is to be denied as a benefit exclusion.

3 . Background

Benefit/Coverage/Program Information

Background

Wegovy is a glucagon-like peptide-1 (GLP-1) receptor agonist. Wegovy injection and tablets are indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.

Wegovy injection and tablets are also indicated to reduce excess body weight and maintain weight reduction long term in adults with obesity, and in adults with overweight in the presence of at least one weight-related comorbid condition. Wegovy injection only is also approved to reduce excess body weight and maintain weight reduction long term in pediatric patients aged 12 years and older, and for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults.

Medications for the purpose of weight loss are typically a benefit exclusion. The program allows for coverage of Wegovy injection or tablet for the cardiovascular risk reduction indication and Wegovy injection for MASH.

Additional Clinical Rules

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
Supply limits may be in place.

4 . References

Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk; December 2025.

Smith SC Jr, Benjamin EJ, Bonow RO, Braun LT, Creager MA, Franklin BA, Gibbons RJ, Grundy SM, Hiratzka LF, Jones DW, Lloyd-Jones DM, Minissian M, Mosca L, Peterson ED, Sacco RL, Spertus J, Stein JH, Taubert KA. AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular

disease: 2011 update: a guideline from the American Heart Association and American College of Cardiology Foundation. Circulation. 2011;124:2458–2473.

American Heart Association/American Stroke Association Practice Guidelines. Secondary Prevention of Ischemic Stroke: Updated Guidelines from AHA/ASA. 2022. American Family Physicians. 2022; 105(1).

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Pablo Alonso-Coello , MD , PhD ; Sergi Bellmunt , MD ; Catherine McGorrian , MBBCh , BAO ; Sonia S. Anand , MD , PhD ; Randolph Guzman , MD, RVT ; Michael H. Criqui , MD , MPH ; Elie A. Akl , MD , MPH , PhD ; Per Olav Vandvik , MD , PhD ; Maarten G. Lansberg , MD , PhD ; Gordon H. Guyatt , MD, FCCP ; and Frederick A. Spencer, MD. Antithrombotic therapy in peripheral artery disease: antithrombic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2012;141(2 Suppl):e669S.

Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology. 2023;77(5):1797-1835. doi:10.1097/HEP.0000000000000323

5 . Revision History

Date	Notes
2/17/2026	Removed BMI requirement in CVD reauthorization criteria. Updated t o include tablets and differentiate approved indications by formulatio n. Updated footnote to clarify weight loss indication as benefit exclusi on.

Winrevair

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148719
Guideline Name	Winrevair
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2024
P&T Approval Date:	6/17/2024
P&T Revision Date:	

1 . Indications

Drug Name: Winrevair (sotatercept-csrk)
Pulmonary arterial hypertension Indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.

2 . Criteria

Product Name:Winrevair [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

Diagnosis of pulmonary arterial hypertension

PAH has been confirmed by right heart catheterization

Prescriber attestation that other types of pulmonary hypertension (PH) are excluded as a diagnosis

Pulmonary arterial hypertension is symptomatic

OR

1.2 BOTH of the following:

Diagnosis of pulmonary arterial hypertension

Patient is currently on Winrevair therapy as documented by claims history or submission of medical records (document date and duration of therapy)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient has a cardiopulmonary comorbidity (e.g., obesity, hypertension, diabetes mellitus, coronary heart disease)

AND

2.1.2 Patient is currently taking at least ONE of the following oral therapies:

Endothelin receptor antagonist (ERA) [e.g., ambrisentan, bosentan, Opsumit (macitentan)]

Phosphodiesterase-5 inhibitor (PDE5i) (e.g., sildenafil, tadalafil)

OR

2.2 BOTH of the following:

2.2.1 Patient does not have a cardiopulmonary comorbidity (e.g., obesity, hypertension, diabetes mellitus, coronary heart disease)

AND

2.2.2 Patient is currently taking oral combination therapy with BOTH of the following:

2.2.2.1 Endothelin receptor antagonist (ERA) [e.g., ambrisentan, bosentan, Opsumit (macitentan)]

AND

2.2.2.2 ONE of the following:

Phosphodiesterase-5 inhibitor (PDE5i) (e.g., sildenafil, tadalafil)

Soluble guanylate cyclase stimulator (sGC) [e.g., Adempas (riociguat)]

AND

3 - Prescribed by, or in consultation with, a cardiologist, pulmonologist, or rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Winrevair [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of a positive clinical response to Winrevair therapy [e.g., improvement in symptoms of right heart failure, exercise tolerance, six-minute walk distance (6MWD), resting and ambulatory oximetry] **AND** **2** - Prescribed by, or in consultation with, a cardiologist, pulmonologist, or rheumatologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Winrevair (sotatercept-csrk) is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events. [1] **Additional Clinical Rules:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limits may be in place.

4 . References

Winrevair [package insert]. Rahway, NJ: Merck & Co., Inc; March 2024.

Humbert M, Kovacs G, Hoeper MM, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. Eur Heart J 2022; 43:3618.

5 . Revision History

Date	Notes
6/20/2024	New program

Xdemvy

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-447196
Guideline Name	Xdemvy
Formulary	UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	11/17/2023
P&T Revision Date:	11/21/2025

1 . Indications

Drug Name: Xdemvy (lotilaner)
Demodex blepharitis Indicated for the treatment of Demodex blepharitis.

2 . Criteria

Product Name:Xdemvy [a]	
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of DEMODEX blepharitis

AND

2 - Patient demonstrates ONE of the following signs of DEMODEX infestation:

Cylindrical cuff at the root of the eyelashes

Lid margin erythema

Eyelash anomalies (eyelash misdirection)

AND

3 - Patient demonstrates TWO of the following symptoms of DEMODEX infestation

Itching/Burning

Foreign body sensation

Crusting/matter lashes

Blurry vision

Discomfort/irritation

AND

4 - Patient is practicing good eye-lid hygiene (e.g., non-prescription tree-tea oil)

AND

5 - Prescribed by, or in consultation with, ONE of the following:

Ophthalmologist Optometrist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Xdemvy (lotilaner) ophthalmic solution 0.25% is indicated for the treatment of Demodex blepharitis. **Additional Clinical Rules:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limits may be in place**.**

4 . References

Xdemvy [package insert]. Irvine, CA: Tarsus Pharmaceuticals, Inc. July 2023.

M.T Yen. Demodex Infestation. American Academy of Ophthalmology. EyeWiki. April 2025.

5 . Revision History

Date	Notes
11/10/2025	Annual review. Updated references.

Xeljanz, Xeljanz XR

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-461309
Guideline Name	Xeljanz, Xeljanz XR
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	01/21/2021 ; 05/21/2021 ; 06/16/2021 ; 09/15/2021 ; 02/18/2022 ; 05/20/2022 ; 06/15/2022 ; 09/21/2022 ; 02/17/2023 ; 05/25/2023 ; 09/20/2023 ; 10/16/2024 ; 01/15/2025 ; 10/15/2025 ; 12/17/2025

1 . Indications

Drug Name: Xeljanz /Xeljanz XR (tofacitinib)
Rheumatoid Arthritis Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs). **Psoriatic Arthritis** Indicated for the treatment of adult patients with active psoriatic arthritis who have an inadequate response or intolerance to one or more TNF blockers. **Ulcerative Colitis** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis, who have an inadequate response or intolerance to one or more TNF blockers.

Ankylosing Spondylitis Indicated for the treatment of active ankylosing spondylitis in patients who have an inadequate response or intolerance to one or more TNF blockers.
Drug Name: Xeljanz / Xeljanz Solution (tofacitinib)
Polyarticular Course Juvenile Idiopathic Arthritis Indicated for the treatment of active polyarticular course juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers. **Psoriatic arthritis** Indicated for the treatment of active psoriatic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.

2 . Criteria

Product Name:Xeljanz or Xeljanz XR [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

OR

2.1.1.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab)]

AND

2.1.2 ONE of the following:

History of failure, contraindication, or intolerance to at least ONE TNF inhibitor^

Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria [5])

OR

2.2 BOTH of the following:

2.2.1 Patient is currently on Xeljanz or Xeljanz XR therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy)

AND

2.2.2 Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer sponsored XELSOURCE program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Xeljanz or Xeljanz XR*

AND

3 - Patient is not receiving Xeljanz or Xeljanz XR in combination with EITHER of the following:

Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab)] for treatment of the same indication.

Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer sponsored XELSOURCE program shall be required to meet initial authorization criteria as if patient were new to therapy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. ^Tried/Failed alternatives(s) are supported by FDA labeling.

Product Name:Xeljanz or Xeljanz XR [a]	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xeljanz or Xeljanz XR therapy

AND

2 - Patient is not receiving Xeljanz or Xeljanz XR in combination with EITHER of the following:

Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab)] for treatment of the same indication Potent immunosuppressant (e.g., azathioprine or cyclosporine)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xeljanz, Xeljanz XR, Xeljanz Oral Solution [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

OR

2.1.1.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or

submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab]

AND

2.1.2 ONE of the following:

2.1.2.1 History of failure, contraindication, or intolerance to at least one TNF inhibitor^

OR

2.1.2.2 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria [5])

OR

2.2 BOTH of the following:

2.2.1 Patient is currently on Xeljanz, Xeljanz XR, Xeljanz Oral Solution therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy)

AND

2.2.2 Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer sponsored XELSOURCE program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Xeljanz, Xeljanz XR, Xeljanz Oral Solution*

AND

3 - Patient is not receiving Xeljanz, Xeljanz XR, Xeljanz Oral Solution in combination with EITHER of the following:

Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

4 - Prescribed by or in consultation with ONE of the following:

Rheumatologist

Dermatologist

Notes	*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer sponsored XELSOURCE program shall be required to meet initial authorization criteria as if patient were new to therapy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. ^Tried/Failed alternatives(s) are supported by FDA labeling.

Product Name:Xeljanz, Xeljanz XR, Xeljanz Oral Solution [a]	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xeljanz, Xeljanz XR therapy, Xeljanz Oral Solution

AND

2 - Patient is not receiving Xeljanz, Xeljanz XR, Xeljanz Oral Solution in combination with EITHER of the following:

Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xeljanz, Xeljanz XR [a]	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active UC

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

OR

2.1.1.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab, Zeposia (ozanimod)]

AND

2.1.2 ONE of the following:

2.1.2.1 History of failure, contraindication, or intolerance to at least ONE TNF inhibitor^

OR

2.1.2.2 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria [5])

OR

2.2 BOTH of the following:

2.2.1 Patient is currently on Xeljanz, Xeljanz XR, Xeljanz Oral Solution therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy)

AND

2.2.2 Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer sponsored XELSOURCE program (e.g. sample card which can be redeemed at a pharmacy for a free supply of

medication) as a means to establish as a current user of Xeljanz, Xeljanz XR, Xeljanz Oral Solution*

AND

3 - Patient is not receiving Xeljanz or Xeljanz XR in combination with EITHER of the following:

Systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication.

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer sponsored XELSOURCE program shall be required to meet initial authorization criteria as if patient were new to therapy. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. ^Tried/Failed alternatives(s) are supported by FDA labeling.

Product Name:Xeljanz, Xeljanz XR [a]	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xeljanz or Xeljanz XR

AND

2 - Patient is not receiving Xeljanz or Xeljanz XR in combination with EITHER of the following:

Systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication.

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xeljanz or Xeljanz XR [a]	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 History of failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

OR

2.1.1.2 Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab)]

AND

2.1.2 ONE of the following:

2.1.2.1 History of failure, contraindication, or intolerance to at least ONE TNF inhibitor^

OR

2.1.2.2 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria [5])

OR

2.2 BOTH of the following:

Patient is currently on Xeljanz or Xeljanz XR therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy)

Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer sponsored XELSOURCE program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Xeljanz or Xeljanz XR*

AND

3 - Patient is not receiving Xeljanz or Xeljanz XR in combination with EITHER of the following:

Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab)] for treatment of the same indication.

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer sponsored XELSOURCE program shall be required to meet initial authorization criteria as if patient were new to therapy. ^Tried/Failed alternatives(s) are supported by FDA labeling.

Product Name:Xeljanz or Xeljanz XR [a]	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xeljanz or Xeljanz XR therapy

AND

2 - Patient is not receiving Xeljanz or Xeljanz XR in combination with EITHER of the following:

Systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant

(baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab)] for treatment of the same indication. Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xeljanz or Xeljanz Oral Solution [a]	
Diagnosis	Polyarticular Course Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular course juvenile idiopathic arthritis

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to one of the preferred adalimumab products [b] (document date and duration of trial)

OR

2.2 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria 5)

OR

2.3 BOTH of the following:

Patient is currently on Xeljanz or Xeljanz Oral Solution therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy)

Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer sponsored XELSOURCE program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Xeljanz or Xeljanz Oral Solution*

AND

3 - Patient is not receiving Xeljanz or Xeljanz Oral Solution in combination with EITHER of the following:

Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab)] for treatment of the same indication.

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer sponsored XELSOURCE program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Xeljanz or Xeljanz Oral Solution [a]	
Diagnosis	Polyarticular Course Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Xeljanz or Xeljanz Oral Solution therapy **AND** **2** - Patient is not receiving Xeljanz or Xeljanz Oral Solution in combination with EITHER of the following: Systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab)] for treatment of the same indication. Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Xeljanz/Xeljanz XR (tofacitinib) is an inhibitor of Janus Kinases (JAKs) indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs). [1] Examples of non-biologic DMARDs commonly used in the treatment of rheumatoid arthritis include methotrexate, leflunomide, and sulfasalazine. [2,3] Xeljanz/Xeljanz XR is also indicated for the treatment of adult patients with active psoriatic arthritis, active ankylosing spondylitis, and moderately to severely active ulcerative colitis, who have an inadequate response or intolerance to one or more TNF blockers. Xeljanz/Xeljanz Solution is indicated for the treatment of active

polyarticular juvenile idiopathic arthritis and active psoriatic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers

Limitations of Use:

The use of Xeljanz/Xeljanz XR/Xeljanz Solution in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limits may be in place.

4 . References

Xeljanz/Xeljanz XR/Xeljanz Solution [package insert]. New York, NY: Pfizer Labs; October 2025.

Pavy S. Constantin A, Pham T, et al. Methotrexate therapy for rheumatoid arthritis: clinical practice guidelines based on published evidence and expert opinions. Joint Bone Spine 2006;73(4):388-95.

Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2016;68(1):1-26.

Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. Arthritis Rheumatol. 2016 May;68(5):1060-71.

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Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.

Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.

Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.

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Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.

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Gossec L, et al; European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update, Ann Rheum Dis 2016;75:499-510.

Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158(5):1450-61.

Ward MM, Deodhar, A, Gensler, LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis & Rheumatology. 2019; 71(10): 1599-1613.

Yu, DT, van Tubergen A. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. In: Post TW, ed. UpToDate. UpToDate; 2021. Accessed on December 17th, 2021.

5 . Revision History

Date	Notes
12/4/2025	Updated PsA criteria to include Xeljanz Oral Solution for new indicati on for 2 years of age and older. Updated background and reference.

Xenazine

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412215
Guideline Name	Xenazine
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 10/20/2021 ; 02/18/2022 ; 02/17/2023 ; 08/18/2023 ; 09/18/2024 ; 10/15/2025

1 . Indications

Drug Name: Xenazine (tetrabenazine)
Chorea associated with Huntington's disease Indicated for the treatment of chorea associated with Huntington's disease. **Off Label Uses:** **Tardive dyskinesia** Recommended by the American Psychiatric Association for consideration in the management of patients with tardive dyskinesia.

2 . Criteria

Product Name:Brand Xenazine, generic tetrabenazine [a]

Diagnosis	Chorea associated with Huntington's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea associated with Huntington's disease

AND

2 - Prescribed by or in consultation with ONE of the following:

Neurologist

Psychiatrist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Xenazine, generic tetrabenazine [a]	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia

AND

2 - ONE of the following:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with ONE of the following:

Neurologist

Psychiatrist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Brand Xenazine, generic tetrabenazine [a]	
Diagnosis	Chorea associated with Huntington’s disease, Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Xenazine (tetrabenazine) is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of chorea associated with Huntington's disease. [1] Xenazine is also recommended by the American Psychiatric Association for consideration in the management of patients with tardive dyskinesia. [2] **Additional Clinical Rules:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class Supply limits may be in place

4 . References

Xenazine [package insert]. Deerfield, IL: Lundbeck; November 2019.

Keepers GA, Fochtmann LJ, Anzia JM, et al. The American Psychiatric Association Practice Guideline for the Treatment of Patients With Schizophrenia. Focus (Am Psychiatr Publ). 2020;18(4):493-497. doi:10.1176/appi.focus.18402

5 . Revision History

Date	Notes
10/6/2025	Annual review. Updated references and background.

Xermelo

Prior Authorization Guideline

Guideline ID	GL-148652
Guideline Name	Xermelo
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2024
P&T Approval Date:	9/15/2021
P&T Revision Date:	06/15/2022 ; 06/21/2023 ; 6/17/2024

1 . Indications

Drug Name: Xermelo
Carcinoid syndrome diarrhea Indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.

2 . Criteria

Product Name:Xermelo [a]	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of carcinoid syndrome diarrhea

AND

2 - Diarrhea is inadequately controlled with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot, Lanreotide)

AND

3 - Used in combination with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot, Lanreotide)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xermelo [a]	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xermelo

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Xermelo (telotristat ethyl) is a tryptophan hydroxylase inhibitor indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy. [1] **Additional Clinical Rules:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limits may be in place.

4 . References

Xermelo [package insert]. Deerfield, IL: TerSera Therapeutics LLC; September 2022.

5 . Revision History

Date	Notes
6/19/2024	Annual review. Updated initial authorization duration to 12 months.

Xifaxan

Prior Authorization Guideline

Guideline ID	GL-328227
Guideline Name	Xifaxan
Formulary	UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	9/1/2025
P&T Approval Date:	9/15/2021
P&T Revision Date:	07/19/2023 ; 04/17/2024 ; 07/17/2024 ; 7/16/2025

1 . Indications

Drug Name: Xifaxan (rifaximin)
Travelers' diarrhea Indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adult and pediatric patients 12 years of age and older. **Hepatic Encephalopathy** Indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults. **Irritable bowel syndrome with diarrhea** Indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

2 . Criteria

Product Name:Xifaxan [a]	
Diagnosis	Travelers' Diarrhea
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of travelers' diarrhea

AND

2 - History of failure, contraindication, or intolerance to ONE of the following:

Azithromycin (generic Zithromax)

Ciprofloxacin (generic Cipro)

Levofloxacin (generic Levaquin)

Ofloxacin (generic Floxin)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xifaxan [a]	
Diagnosis	Hepatic Encephalopathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for prophylaxis of hepatic encephalopathy (HE) recurrence

AND

2 - ONE of the following:

2.1 BOTH of the following:

Used as add-on therapy to lactulose

Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

2.2 History of contraindication or intolerance to lactulose

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xifaxan [a]	
Diagnosis	Hepatic Encephalopathy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xifaxan therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xifaxan [a]	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)

Approval Length	14 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of IBS-D

AND

2 - History of failure, contraindication, or intolerance to a tricyclic antidepressant (e.g. amitriptyline)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xifaxan [a]	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	14 Day(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xifaxan will be approved based on ALL of the following criteria:

Patient has experienced a recurrence of IBS-D after a prior 14 day course of therapy with Xifaxan

Patient has had a treatment-free period between courses of therapy

Patient has not already received 3 treatment courses of Xifaxan for IBS-D in the previous 6 months

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Xifaxan is an antibacterial agent indicated for the treatment of travelers' diarrhea caused by noninvasive strains of Escherichia coli in patients 12 years of age and older, for the risk reduction of overt hepatic encephalopathy recurrence in adults and for the treatment of irritable bowel syndrome with diarrhea (IBS-D). **Additional Clinical Rules:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limits may be in place.

4 . References

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AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Diarrhea. Gastroenterology. 2022.

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ACG Clinical Guideline: Small Intestinal Bacterial Overgrowth. Am J Gastroenterol. 2020; 115:165-78.

5 . Revision History

Date	Notes
7/15/2025	Annual review. Removed inflammatory bowel disease due to limited data available. Updated references.

Xolair

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-259207
Guideline Name	Xolair
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/14/2025
P&T Approval Date:	7/21/2021
P&T Revision Date:	11/19/2021 ; 12/15/2021 ; 02/18/2022 ; 09/21/2022 ; 07/19/2023 ; 08/18/2023 ; 10/18/2023 ; 04/17/2024 ; 05/17/2024 ; 06/17/2024 ; 04/16/2025

Note:

This program applies to the prefilled syringe and prefilled autoinjector for self-administered subcutaneous use

1 . Indications

Drug Name: Xolair (omalizumab) prefilled syringe and prefilled autoinjector
Asthma Indicated for moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids **Nasal Polyps** Indicated for chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment

Chronic Idiopathic Urticaria (CIU) Indicated for chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment

IgE-Mediated Food Allergy Indicated for IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance.

2 . Criteria

Product Name:Xolair prefilled syringe and prefilled autoinjector [a]	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xolair for self-administration will be approved based on ONE of the following:

1.1 ALL of the following:

1.1.1 Patient has been established on therapy with Xolair for moderate to severe persistent asthma under an active UnitedHealthcare medical benefit prior authorization

AND

1.1.2 Documentation of positive clinical response to Xolair therapy as demonstrated by at least ONE of the following:

Reduction in the frequency of exacerbations

Decreased utilization of rescue medications

Increase in percent predicted FEV1 from pretreatment baseline

Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

AND

1.1.3 Xolair is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

1.1.4 Patient is not receiving Xolair in combination with ANY of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

OR

1.2 ALL of the following:

1.2.1 Diagnosis of moderate or severe asthma

AND

1.2.2 Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:

Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)

Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])

Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

1.2.3 Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting a baseline (pre-omalizumab treatment) serum total IgE (immunoglobulin E) level greater than or equal to 30 IU/mL (international units/milliliter) and less than or equal to 1300 IU/mL

AND

1.2.4 Positive skin test or in vitro reactivity to a perennial aeroallergen

AND

1.2.5 Used in combination with ONE of the following:

1.2.5.1 One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2-agonist (LABA) product [e.g., fluticasone propionate/salmeterol (AirDuo/Advair), budesonide/formoterol (Symbicort)]

OR

1.2.5.2 Combination therapy including BOTH of the following:

One maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist - montelukast (Singulair); theophylline]

AND

1.2.6 Patient is not receiving Xolair in combination with ANY of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

1.2.7 Prescribed by ONE of the following:

Allergist

Immunologist

Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xolair prefilled syringe and prefilled autoinjector [a]	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response as demonstrated by at least ONE of the following:

Reduction in frequency of exacerbations

Decreased utilization of rescue medications

Increase in percent predicted FEV1 from pretreatment baseline

Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

AND

2 - Used in combination with an ICS-containing controllermaintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

3 - Patient is not receiving Xolair in combination with ANY of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xolair prefilled syringe and prefilled autoinjector [a]	
Diagnosis	Chronic Urticaria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xolair for self-administration will be approved based on ONE of the following:

1.1 ALL of the following:

1.1.1 Patient has been established on therapy with Xolair for chronic urticaria under an active UnitedHealthcare medical benefit prior authorization

AND

1.1.2 Documentation of positive clinical response to Xolair therapy (e.g., reduction in exacerbations, itch severity, hives)

AND

1.1.3 Patient is not receiving Xolair in combination with ANY of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

OR

1.2 ALL of the following:

1.2.1 Diagnosis of chronic urticaria

AND

1.2.2 ONE of the following:

1.2.2.1 Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, TWO H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]*^

OR

1.2.2.2 Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to BOTH of the following taken in combination:^

1.2.2.2.1 Second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

AND

1.2.2.2.2 ONE of the following:

Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]*

H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]

Leukotriene modifier [e.g., Singulair (montelukast)]

AND

1.2.3 Patient is not receiving Xolair in combination with ANY of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

1.2.4 Prescribed by ONE of the following:

Allergist

Dermatologist

Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may ap

	ply. *Patients 65 years of age and older in whom first generation H1-antihi stamines are considered high risk medications to be avoided (e.g., Be ers criteria, HEDIS) should be directed to try alternatives that are not c onsidered high risk. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Xolair prefilled syringe and prefilled autoinjector [a]	
Diagnosis	Chronic Urticaria
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., reduction in exacerbations, itch severity, hives)

AND

2 - Patient is not receiving Xolair in combination with ANY of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply. *Patients 65 years of age and older in whom first generation H1-antihi stamines are considered high risk medications to be avoided (e.g., Be ers criteria, HEDIS) should be directed to try alternatives that are not c onsidered high risk.

Product Name:Xolair prefilled syringe and prefilled autoinjector [a]

Diagnosis	Nasal Polyps
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xolair for self-administration will be approved based on ONE of the following:

1.1 ALL of the following:

1.1.1 Patient has been established on therapy with Xolair for nasal polyps under an active UnitedHealthcare medical benefit prior authorization

AND

1.1.2 Documentation of positive clinical response to Xolair therapy

AND

1.1.3 Patient will continue to receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

1.1.4 Patient is not receiving Xolair in combination with ANY of the following:

Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

OR

1.2 ALL of the following:

1.2.1 Diagnosis of nasal polyps

AND

1.2.2 TWO OR MORE of the following symptoms for longer than 12 weeks duration:

Nasal mucopurulent discharge

Nasal obstruction, blockage, or congestion

Facial pain, pressure, and/or fullness

Reduction or loss of sense of smell

AND

1.2.3 ONE of the following findings using nasal endoscopy and/or sinus computed tomography (CT):

Purulent mucus or edema in the middle meatus or ethmoid regions

Polyps in the nasal cavity or the middle meatus

Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

AND

1.2.4 ONE of the following:

1.2.4.1 Patient has required prior sinus surgery

OR

1.2.4.2 Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for nasal polyps in the previous 2 years

OR

1.2.4.3 Patient has been unable to obtain symptom relief after trial of BOTH of the following:

Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)^

ONE other therapy used in the management of nasal polyps [i.e., nasal saline irrigations. antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)]

AND

1.2.5 Patient will receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

1.2.6 Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

1.2.7 Prescribed by ONE of the following:

Allergist

Immunologist

Otolaryngologist

Pulmonologist

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply. ^Tried/failed alternative(s) are supported by FDA labeling.

Product Name:Xolair prefilled syringe and prefilled autoinjector [a]	
Diagnosis	Nasal Polyps
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response

AND

2 - Patient will continue to receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

3 - Patient is not receiving Xolair in combination with ANY of the following:

Anti-intrleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Notes	[a] State mandates may apply. Any federal regulatory requirements an d the member specific benefit plan coverage may also impact coverag e criteria. Other policies and utilization management programs may ap ply.

Product Name:Xolair prefilled syringe and prefilled autoinjector [a]

Diagnosis	IgE-Mediated Food Allergy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Patient has been established on therapy with Xolair for IgE-mediated food allergy under an active UnitedHealthcare medical benefit prior authorization

AND

1.2 Documentation of positive clinical response to Xolair therapy (e.g., reduction in type I allergic reactions)

AND

1.3 Xolair will be used in conjunction with food allergen avoidance

AND

1.4 Patient has access to epinephrine

AND

1.5 Patient is not receiving Xolair in combination with ANY of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

1.6 Prescribed by an allergist or immunologist

OR

2 - ALL of the following:

2.1 Diagnosis of IgE-mediated food allergy to one or more foods

AND

2.2 Patient is aged greater than or equal to 1 year

AND

2.3 IgE-mediated food allergy to specific food(s) has been confirmed by BOTH of the following:

2.3.1 History of type I allergic reactions (e.g., nausea, vomiting, cramping, diarrhea, flushing, pruritus, urticaria, swelling of the lips, face or throat, wheezing, lightheadedness, syncope)

AND

2.3.2 ONE of the following:

Skin prick testing (SPT)

IgE antibody in vitro testing

Oral food challenge (OFC)

AND

2.4 Xolair will be used in conjunction with food allergen avoidance

AND

2.5 Patient has access to epinephrine

AND

2.6 Patient is not receiving Xolair in combination with ANY of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

2.7 Prescribed by an allergist or immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xolair prefilled syringe and prefilled autoinjector [a]	
Diagnosis	IgE-Mediated Food Allergy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xolair therapy (e.g., reduction in type I allergic reactions)

AND **2** - Xolair will be used in conjunction with food allergen avoidance **AND** **3** - Patient has access to epinephrine **AND** **4** - Patient is not receiving Xolair in combination with ANY of the following: Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)] Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] **AND** **5** - Prescribed by an allergist or immunologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background Xolair (omalizumab) is an anti-IgE antibody indicated for:

Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance.
Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment

This policy refers to Xolair (omalizumab) subcutaneous injection for self-administered subcutaneous injection. Xolair (omalizumab) for administration by a healthcare professional is obtained under the medical benefit.

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limits may be in place.

4 . References

Xolair [package insert]. South San Francisco, CA: Genentech USA, Inc. February 2024.

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5 . Revision History

Date	Notes
5/13/2025	Annual review. No changes to coverage criteria.

Xolremdi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-355238
Guideline Name	Xolremdi
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	10/1/2025
P&T Approval Date:	8/16/2024
P&T Revision Date:	8/22/2025

1 . Indications

Drug Name: Xolremdi (mavorixafor)
WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) Indicated in patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.

2 . Criteria

Product Name:Xolremdi [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome

AND

2 - Patient has a genotype-confirmed mutation of chemokine (C-X-C motif) receptor 4 (CXCR4) consistent with WHIM phenotype

AND

3 - Patient has an absolute neutrophil count (ANC) less than or equal to 500 cells /µL

AND

4 - Prescribed by or in consultation with one of the following:

Allergist

Geneticist

Hematologist

Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xolremdi [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response [e.g., improvement in absolute neutrophil counts (ANC), improvement in absolute lymphocyte counts (ALC), reduction in infections] to Xolremdi therapy

AND

2 - Prescribed by or in consultation with one of the following:

Allergist

Geneticist

Hematologist

Immunologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Xolremdi™ (mavorixafor) is a CXC chemokine receptor 4 antagonist indicated in patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes. **Additional Clinical Rules:**

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limit may be in place.

4 . References

Xolremdi [package insert]. Boston, MA: X4 Pharmaceuticals, Inc.; September 2024.

5 . Revision History

Date	Notes
8/6/2025	Annual review. Updated reference.

Xospata

Prior Authorization Guideline

Guideline ID	GL-527215
Guideline Name	Xospata
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 09/15/2021 ; 02/18/2022 ; 02/17/2023 ; 02/16/2024 ; 02/20/2025 ; 2/20/2026

1 . Indications

Drug Name: Xospata (gilteritinib)
Acute myeloid leukemia Indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with an FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

2 . Criteria

Product Name:Xospata [a]	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive

AND

3 - ONE of the following:

Used as low-intensity treatment induction when not a candidate for intensive induction therapy

Follow-up after induction therapy with response to previous lower intensity therapy with the same regimen

Post-allogeneic hematopoietic cell transplantation and in remission

Disease is relapsed or refractory

Consolidation therapy as continuation of low-intensity regimen used for induction in patients with poor-risk AML

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xospata [a]	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xospata therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xospata [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - ONE of the following:

Patient has an FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic phase

Patient has an FMS-like tyrosine kinase 3 (FLT3) rearrangement in blast phase

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xospata [a]	
Diagnosis	Myeloid/Lymphoid Neoplasms

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Xospata therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xospata [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Xospata will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xospata [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Xospata therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background

Xospata (gilteritinib) is a kinase inhibitor indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with an FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

The National Cancer Comprehensive Network (NCCN) recommends the use of Xospata for the treatment of myeloid/lymphoid neoplasms with eosinophilia and FMS-like tyrosine kinase 3 (FLT3) rearrangement. NCCN also recommends Xospata for treatment of AML for relapsed/refractory disease as targeted therapy in patients with FLT3 mutation (ITD or TKD), in patients with FLT3 ITD or TKD AML without IDH1 mutation for low-intensity treatment induction when not a candidate for intensive induction therapy, follow-up treatment after induction therapy following response to previous lower intensity therapy with the same regimen, consolidation therapy as continuation therapy as continuation of low-intensity regimen used for induction in patients with poor-risk AML, or for maintenance therapy as a single agent in patients who are post-allogeneic hematopoietic cell transplantation, in remission, and have a history of FLT3 mutation.

Additional Clinical Rules

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
Supply limits may be in place.

4 . References

Xospata [package insert]. Northbrook, IL: Astellas Pharma US; January 2022.

The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed December 16, 2025.

5 . Revision History

Date	Notes
2/25/2026	Annual review. Updated background.

Xphozah

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-500232
Guideline Name	Xphozah
Formulary	UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	3/1/2026
P&T Approval Date:	3/20/2024
P&T Revision Date:	1/21/2026

1 . Indications

Drug Name: Xphozah (tenapanor)
Chronic Kidney Disease (CKD) Indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy

2 . Criteria

Product Name:Xphozah [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Patient is receiving dialysis

AND

3 - Serum phosphorus is ≥ 5.5 mg/dL

AND

4 - Patient has had an inadequate response to at least a 4-week maximally tolerated dose of BOTH of the following phosphate binders:

Calcium acetate (generic PhosLo)

Sevelamer carbonate (generic Renvela)

AND

5 - Xphozah will be used as add-on therapy

AND

6 - Prescribed by or in consultation with a nephrologist.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xphozah [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to Xphozah therapy [e.g., reduction of serum phosphorus towards the normal range (3.5 to 5.5 mg/dL)]

AND

2 - Prescribed by or in consultation with a nephrologist.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Xphozah (tenapanor) is a sodium hydrogen exchanger 3 (NHE3) inhibitor indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
Supply limits may be in place.

4 . References

Xphozah® [package insert]. Waltham, MA: Ardelyx, Inc.; June 2025

National Kidney Foundation. K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. Am J Kidney Dis. 2003;42(4 Suppl 3):S1-S201.

Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney Int Suppl. 2009;(113):S1-S130.

Ketteler M, Block GA, Evenepoel P, et al. Executive summary of the 2017 KDIGO Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) Guideline Update: what's changed and why it matters [published correction appears in Kidney Int. 2017 Dec;92(6):1558]. Kidney Int. 2017;92(1):26-36.

5 . Revision History

Date	Notes
1/18/2026	Annual review. Updated serum phosphorus requirement. Updated ref erences.

Xtandi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-291203
Guideline Name	Xtandi
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	8/1/2025
P&T Approval Date:	5/16/2025
P&T Revision Date:	6/18/2025

1 . Indications

Drug Name: Xtandi (enzalutamide)
Prostate Cancer Indicated for the treatment of patients with castration-resistant prostate cancer (CRPC), metastatic castration-sensitive prostate cancer (mCSPC), and non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR).

2 . Criteria

Product Name:Xtandi [a]	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Disease is castration-resistant

AND

2.1.2 ONE of the following:

Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

Patient has had bilateral orchiectomy

OR

2.2 BOTH of the following:

2.2.1 Disease is metastatic castration-sensitive

AND

2.2.2 ONE of the following:

Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

Patient has had bilateral orchiectomy

OR

2.3 Disease is non-metastatic castration-sensitive with biochemical recurrence at high risk for metastasis

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xtandi [a]	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xtandi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xtandi [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Xtandi will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xtandi [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Xtandi therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Xtandi® (enzalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with castration-resistant prostate cancer (CRPC), metastatic castration-sensitive prostate cancer (mCSPC), and non-metastatic castration-sensitive prostate

cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR).

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limits may be in place.

4 . References

Xtandi [package insert]. Northbrook, IL: Astellas Pharma US, Inc. March 2025.

The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed April 28, 2025.

5 . Revision History

Date	Notes
6/9/2025	Annual review, updated references.

Xyrem, Xywav, Lumryz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399267
Guideline Name	Xyrem, Xywav, Lumryz
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 05/20/2022 ; 11/18/2022 ; 02/17/2023 ; 12/13/2023 ; 09/18/2024 ; 10/01/2024 ; 9/25/2025

1 . Indications

Drug Name: Xyrem, Lumryz (sodium oxybate)
Narcolepsy Indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in patients with narcolepsy.
Drug Name: Xywav (calcium, magnesium, potassium, and sodium oxybates)
Narcolepsy Indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in patients with narcolepsy. **Idiopathic hypersomnia (IH)** Indicated for idiopathic hypersomnia (IH) in adults.

2 . Criteria

Product Name:Lumryz, sodium oxybate (Xyrem AG), Xyrem or Xywav [a]	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of narcolepsy with cataplexy (i.e., Narcolepsy Type 1) with BOTH of the following:

The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset REM periods (SOREMPs) on an MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to BOTH of the following:

Patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness

Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

AND

3 - If the request is for Lumryz, Xyrem or Xywav, the patient has a history of failure, contraindication, or intolerance to sodium oxybate (Xyrem authorized generic)*

AND

4 - Prescribed by ONE of the following:

Neurologist

Psychiatrist

Pulmonologist

Sleep Medicine Specialist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *sodium oxybate (Xyrem authorized generic) may require prior authorization

Product Name:Lumryz, sodium oxybate (Xyrem AG), Xyrem or Xywav [a]	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation demonstrating a reduction in frequency of cataplexy attacks associated with therapy

OR

2 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverag

	e criteria. Other policies and utilization management programs may ap ply.

Product Name:Lumryz, sodium oxybate (Xyrem AG), Xyrem or Xywav [a]	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy without cataplexy (i.e., Narcolepsy Type 2) with BOTH of the following:

The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to the following:

Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - History of failure, contraindication, or intolerance of ALL of the following:

3.1 ONE of the following:

Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)

Methylphenidate based stimulant

AND

3.2 ONE of the following:

modafinil (generic Provigil)

armodafinil (generic Nuvigil)

AND

3.3 Sunosi (solriamfetol)

AND

4 - If the request is for Lumryz, Xyrem or Xywav, the patient has a history of failure, contraindication, or intolerance to sodium oxybate (Xyrem authorized generic)*

AND

5 - Prescribed by ONE of the following:

Neurologist

Psychiatrist

Pulmonologist

Sleep Medicine Specialist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *sodium oxybate (Xyrem authorized generic) may require prior authorization

Product Name:Lumryz, sodium oxybate (Xyrem AG), Xyrem or Xywav [a]	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xywav [a]	
Diagnosis	Idiopathic Hypersomnia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of idiopathic hypersomnia with BOTH of the following:

The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

A mean sleep latency of less than 8 minutes and fewer than two REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram, or no SOREMPs if the REM sleep latency on the preceding polysomnogram was less than 15 minutes

AND

2 - Physician attestation to the following:

Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - History of failure, contraindication, or intolerance of BOTH of the following:

3.1 ONE of the following:

Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)

Methylphenidate based stimulant

AND

3.2 ONE of the following:

modafinil (generic Provigil)

armodafinil (generic Nuvigil)

AND

4 - Prescribed by ONE of the following:

Neurologist

Psychiatrist

Pulmonologist

Sleep Medicine Specialist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Xywav [a]	
Diagnosis	Idiopathic Hypersomnia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Additional Clinical Rules

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limits may be in place.

Background

Lumryz, Xyrem (sodium oxybate) and Xywav are central nervous system depressants indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in patients with narcolepsy. Xywav is also indicated for idiopathic hypersomnia (IH) in adults.

Lumryz, Xyrem and Xywav are classified as a Schedule III controlled substance by Federal law. The active ingredient, sodium oxybate or gamma-hydroxybutyrate (GHB), is listed in the most restrictive schedule of the Controlled Substances Act (Schedule I). Thus, non-medical uses are classified under Schedule I.

Lumryz, Xyrem and Xywav are available only through a REMS program with restricted distribution. The REMS Program provides educational materials to the prescriber and the patient explaining the risks and proper use of Lumryz, Xyrem and Xywav, and the required prescription form. Once it is documented that the patient has read and/or understood the materials, the drug will be shipped to the patient. The REMS Program also recommends patient follow-up every 3 months. Physicians are expected to report all serious adverse events to the manufacturer.

4 . References

Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; July 2025.

Maski, K., Trotti, L. M., Kotagal, S., Auger, R. R., Rowley, J. A., Hashmi, S. D., & Watson, N. F. (2021). Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine, 17(9), 1881–1893.

American Academy of Sleep Medicine. International Classification of Sleep Disorders: Diagnostic and Coding Manual [online]. 3rd ed. Westchester, IL: American Academy of Sleep Medicine; 2014.

Morgenthaler TI1, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007 Dec;30(12):1705-11.

Xywav [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; April 2023.

Sodium Oxybate [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals NY LLC; April 2023.

Sodium Oxybate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; April 2023.

Lumryz [package insert]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; October 2024.

5 . Revision History

Date	Notes
9/19/2025	Annual review. Updated references.

Yonsa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-400189
Guideline Name	Yonsa
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	5/16/2025
P&T Revision Date:	9/25/2025

1 . Indications

Drug Name: Yonsa (abiraterone acetate)
Prostate Cancer Indicated for use in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer.

2 . Criteria

Product Name:Yonsa [a]	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Disease is metastatic

AND

2.1.2 ONE of the following:

History of failure, contraindication or intolerance to Xtandi (enzalutamide)

Provider attests that the patient is not an appropriate candidate for Xtandi (enzalutamide)

OR

2.2 BOTH of the following:

2.2.1 ONE of the following:

Disease is regional node positive (Any T, N1, M0)

Patient is in a very-high-risk group receiving radiation therapy

AND

2.2.2 ONE of the following:

Life expectancy > 5 years

Patient has symptomatic disease

OR

2.3 ALL of the following:

2.3.1 Disease is non-metastatic

AND

2.3.2 Life expectancy > 5 years

AND

2.3.3 ONE of the following:

Positive pelvic persistence/recurrence after radical prostatectomy (RP)

Lymph node metastases after RP

Studies positive for regional lymph nodes after radiation therapy

AND

3 - Used in combination with methylprednisolone

AND

4 - ONE of the following:

Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Firmagon (degarelix)]

Patient has had bilateral orchiectomy

AND

5 - ONE of the following:

Prescriber provides a reason or special circumstance the patient cannot take abiraterone (generic Zytiga)

Patient is currently on Yonsa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Yonsa [a]	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Yonsa therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Yonsa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Yonsa will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Yonsa [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria **1** - Documentation of positive clinical response to Yonsa therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Yonsa (abiraterone acetate) is a CYP 17 inhibitor indicated for use in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently while taking Yonsa or should have had bilateral orchiectomy. The National Comprehensive Cancer Network (NCCN) recommends the use of Yonsa in combination with methylprednisolone and androgen deprivation therapy (ADT) as initial therapy for patients with metastatic or regional node positive

prostate cancer if life expectancy is greater than 5 years or symptomatic. Yonsa is recommended in combination with ADT and radiation therapy as initial therapy in patients with very-high-risk group if life expectancy is greater than 5 years or symptomatic. Yonsa is also recommended in combination with methylprednisolone and ADT for M0 if life expectancy > 5 years for: prostate-specific antigen (PSA) persistence/recurrence after radical prostatectomy in combination with external beam radiation therapy (EBRT) if studies are positive for pelvic recurrence, undetectable PSA after RP as a treatment consideration if lymph node metastases, PSA recurrence or positive DRE after radiation therapy (RT) if studies positive for regional lymph nodes. Yonsa is recommended for treatment of castration-resistant distant metastatic (M1) disease as secondary hormone therapy or in certain circumstances in combination with methylprednisolone, ADT, and either niraparib or olaparib.

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limits may be in place.

4 . References

Yonsa [package insert]. Cranbury, NJ: Sun Pharma Global FZE; July 2022.

The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/. Accessed August 7, 2025

5 . Revision History

Date	Notes
9/15/2025	Updated step therapy for metastatic prostate cancer to step through only Xtandi. Updated prostate cancer section per NCCN recommend ations. Updated references.

Yorvipath

Prior Authorization Guideline

Guideline ID	GL-161960
Guideline Name	Yorvipath
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	2/1/2025
P&T Approval Date:	12/18/2024
P&T Revision Date:	

1 . Indications

Drug Name: Yorvipath (palopegteriparatide)
Hypoparathyroidism Indicated for the treatment of hypoparathyroidism in adults.

2 . Criteria

Product Name:Yorvipath [a]	
Diagnosis	Hypoparathyroidism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hypoparathyroidism

AND

2 - Confirmation of initial diagnosis by BOTH of the following:

Pretreatment low albumin-corrected serum calcium (i.e., less than or equal to 8.5 mg/dL) confirmed on at least two occasions separated by at least 2 weeks

Pretreatment undetectable or inappropriately low intact PTH concentration (i.e., less than 20 pg/mL), by second- or third-generation immunoassay, on at least two occasions

AND

3 - Yorvipath is not being used to treat acute post-surgical hypoparathyroidism

AND

4 - Patient is currently on adequate supplemental calcium and active vitamin D (e.g., calcitriol) therapy as evidenced by BOTH of the following:

Albumin-corrected serum calcium 7.8–10.6 mg/dL

Serum 25(OH) vitamin D 20–80 ng/mL

AND

5 - Prescribed by ONE of the following:

Endocrinologist

Nephrologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Yorvipath [a]	
Diagnosis	Hypoparathyroidism
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response [e.g., albumin-corrected serum calcium level in normal range (approximately 8.3-10.6 mg/dL), independence from conventional therapy (e.g., requiring no active vitamin D, less than or equal to 600 mg/day of calcium)]

AND

2 - Prescribed by ONE of the following:

Endocrinologist

Nephrologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background:

Yorvipath is a parathyroid hormone analog (PTH(1-34)) indicated for the treatment of hypoparathyroidism in adults.

Additional Clinical Rules:

Supply limits may be in place.
Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References

Yorvipath® [package insert]. Princeton, NJ: Ascendis Pharma, Inc.; August 2024.

Khan AA, Rejnmark L, Rubin M, et al. PaTH Forward: A Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial of TransCon PTH in Adult Hypoparathyroidism. J Clin Endocrinol Metab. 2022;107(1):e372-e385.

Khan AA, Rubin MR, Schwarz P, et al. Efficacy and Safety of Parathyroid Hormone Replacement With TransCon PTH in Hypoparathyroidism: 26-Week Results From the Phase 3 PaTHway Trial. J Bone Miner Res. 2023;38(1):14-25.

Brandi ML, Bilezikian JP, Shoback D, et al. Management of Hypoparathyroidism: Summary Statement and Guidelines. J Clin Endocrinol Metab. 2016;101(6):2273-2283.

Clarke BL. Hypoparathyroidism: update of guidelines from the 2022 International Task Force. Arch Endocrinol Metab. 2022;66(5):604-610.

5 . Revision History

Date	Notes
12/12/2024	New program.

Zelboraf

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-224199
Guideline Name	Zelboraf
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	5/1/2025
P&T Approval Date:	8/14/2020
P&T Revision Date:	03/17/2021 ; 09/15/2021 ; 11/18/2022 ; 03/15/2023 ; 03/20/2024 ; 3/19/2025

1 . Indications

Drug Name: Zelboraf (vemurafenib)
Melanoma Indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. [1] **Erdheim-Chester Disease** Indicated for the treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation. **Off Label Uses: Other Uses:** The National Cancer Comprehensive Network (NCCN) guideline recommends use of Zelboraf in combination with Cotellic (cobimetinib) for treatment of central nervous system (CNS) cancer and metastatic or unresectable melanoma with a BRAF V600 mutation (or as a single agent if BRAF/MEK inhibitor combination therapy is contraindicated). Zelboraf is also recommended for the treatment of hairy cell leukemia, non-small cell lung cancer (NSCLC), Langerhans cell histiocytosis (LCH), and follicular, oncocytic, and papillary thyroid carcinomas with a BRAF mutation. [2]

2 . Criteria

Product Name:Zelboraf [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following diagnoses: Unresectable melanoma Metastatic melanoma **AND** **2** - Patient is positive for BRAF V600 mutation	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient has metastatic brain lesions

AND

1.1.2 Zelboraf is active against primary tumor (melanoma)

OR

1.2 Both of the following:

1.2.1 Diagnosis of Glioma

AND

1.2.2 One of the following:

Incomplete resection, biopsy, or surgically inaccessible location

Disease is recurrent for progressive

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - Used in combination with Cotellic (cobimetinib)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hairy cell leukemia	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Zelboraf therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Disease is one of the following:

Metastatic

Advanced

Recurrent

AND

3 - Cancer is positive for BRAF V600E mutation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	Histiocytic Neoplasms

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

Erdheim-Chester Disease

Langerhans Cell Histiocytosis

AND

2 - Cancer is positive for BRAF V600 mutation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

Follicular carcinoma

Oncocytic carcinoma

Papillary carcinoma

AND

2 - One of the following

Unresectable locoregional recurrent disease

Metastatic disease

Persistent disease

AND

3 - One of the following

Patient has symptomatic disease

Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine

AND **5** - Cancer is positive for BRAF V600 mutation

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Zelboraf will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zelboraf [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Zelboraf therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Clinical Practice Guidelines
The National Cancer Comprehensive Network (NCCN): Zelboraf™ (vemurafenib) is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. It is also indicated for the treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation. Zelboraf is not recommended for use in patients with wild-type BRAF melanoma.[1] The National Cancer Comprehensive Network (NCCN) guideline recommends use of Zelboraf in combination with Cotellic (cobimetinib) for treatment of central nervous system (CNS) cancer and metastatic or unresectable melanoma with a BRAF V600 mutation (or as a single agent if BRAF/MEK inhibitor combination therapy is contraindicated). Zelboraf is also recommended for the treatment of hairy cell leukemia, non-small cell lung cancer

(NSCLC), Langerhans cell histiocytosis (LCH), and follicular, oncocytic, and papillary thyroid carcinomas with a BRAF mutation. [2]
Benefit/Coverage/Program Information
Background: Information on FDA-approved tests for the detection of BRAF V600 mutations in melanoma may be found at: http://www.fda.gov/CompanionDiagnostics. [1] **Additional Clinical Rules:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limits may be in place.

4 . References

Zelboraf [package insert]. South San Francisco, CA: Genentech, Inc.; May 2020.

The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed February 10, 2025.

5 . Revision History

Date	Notes
3/21/2025	Annual review with no change to coverage criteria. Updated references

Zepbound

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-527218
Guideline Name	Zepbound
Formulary	UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	3/19/2025
P&T Revision Date:	12/17/2025 ; 2/20/2026

1 . Indications

Drug Name: Zepbound (tirzepatide)
Obstructive sleep apnea Indicated to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

2 . Criteria

Product Name:Zepbound [a]	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested for obstructive sleep apnea (OSA)

AND

2 - Patient is 18 years of age or older

AND

3 - Submission of medical records confirming ALL of the following:

3.1 Moderate-to-severe obstructive sleep apnea evidenced by BOTH of the following:

3.1.1 Sleep study

AND

3.1.2 ONE of the following:

Apnea Hypopnea Index (AHI) ≥ 15

Respiratory Disturbance Index (RDI) ≥ 15

Respiratory Event Index (REI) ≥ 15

AND

3.2 BMI ≥ 30 kg/m2 in the past 6 months

AND

3.3 At least one previous unsuccessful dietary effort to lose weight

AND

3.4 ONE of the following:

3.4.1 BOTH of the following:

Patient is currently on positive airway pressure (PAP) therapy for at least 3 consecutive months

Patient is adherent to PAP therapy, defined as ≥ 4 hours of use per night for ≥ 70 percent of nights

OR

3.4.2 Patient is not a candidate for, or is intolerant to, PAP therapy (e.g., upper airway anatomic abnormalities, etc.)

AND

4 - Used in combination with a reduced calorie diet and increased physical activity

AND

5 - Provider attests to BOTH of the following:

Patient counseled on appropriate positional therapy

Patient counseled on avoidance of alcohol and/or sedatives before bedtime

AND

6 - Patient does not have a diagnosis of diabetes or HgA1c > 6.5%

AND

7 - Prescriber attests the patient does not have EITHER of the following:

Planned surgery for sleep apnea or obesity

A diagnosis of predominant central or mixed sleep apnea (i.e. percentage of mixed or central apneas/hypopneas > 50% of all respiratory events)

AND

8 - Prescribed by, or in consultation with, a sleep specialist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. Note: Zepbound when used solely for the treatment of weight loss is excluded and is to be denied as a benefit exclusion.

Product Name:Zepbound [a]	
Approval Length	Patients who have been on Zepbound therapy for fewer than 52 weeks of consecutive therapy: Authorization of 6 months; Patients who have been on Zepbound therapy for greater than or equal to 52 weeks of consecutive therapy: Authorization of 12 months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Patient has been on Zepbound for less than 52 weeks of consecutive therapy

AND

1.1.2 Submission of medical records confirming a decrease from baseline after initiation of Zepbound in one of the following:

Apnea Hypopnea Index (AHI)

Respiratory Disturbance Index (RDI)

Respiratory Event Index (REI)

OR

1.2 BOTH of the following:

1.2.1 Patient has been on Zepbound for greater than or equal to 52 weeks of consecutive therapy

AND

1.2.2 Submission of medical records confirming a 50% decrease from baseline after initiation of Zepbound in one of the following:

Apnea Hypopnea Index (AHI)

Respiratory Disturbance Index (RDI)

Respiratory Event Index (REI)

AND

2 - Patient has had a weight loss of greater than or equal to 10% of baseline body weight

AND

3 - Used in combination with a reduced calorie diet and increased physical activity

AND

4 - Patient does not have a diagnosis of diabetes or HgA1c > 6.5%

AND **5** - Patient continues to require treatment for obstructive sleep apnea	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. Note: Zepbound when used solely for the treatment of weight loss is excluded and is to be denied as a benefit exclusion.

3 . Background

Benefit/Coverage/Program Information

Background:

Zepbound is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

Zepbound is also indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.

Medications for the purpose of weight loss are typically a benefit exclusion. The program allows for coverage of Zepbound for obesity with obstructive sleep apnea.

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limits may be in place.

4 . References

Zepbound [package insert]. Indianapolis, IN: Eli Lilly and Company; April 2025.

Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of adult obstructive sleep apnea with positive airway pressure: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2019;15(2):335–343.

Practice Guidlines : Obstructive Sleep Apnea and Chronic Insomnia Disorder : Updated Guidelines from the VA/DoD. Ann Intern Med. March 3, 2020; 172(5):325-336.

Task Force Members Guidelines Committee Members on behalf of the Governing Council of the World Sleep Society, Endorsement of: “clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American academy of sleep medicine clinical practice guideline” by the World Sleep Society, Sleep Medicine, https://doi.org/10.1016/j.sleep.2020.12.044.

Nancy Collop. Home sleep apnea testing for obstructive sleep apnea in adults. UpToDate, Collop N, Finlay G, UpToDate, Waltham, MA, December 2024.

Malhorta A, Kundel V, et al. Obstructive sleep apnea: Overview of management in adults. In: UpToDate, Coop N, Finlay G, UpToDate, Waltham, MA, 2024.

Schulman, D. (2024, April 26). Polysomnography in the evaluation of sleep-disordered breathing in adults. In S. M. Harding & A. F. Eichler (Eds.), UpToDate. Wolters Kluwer. Retrieved November 4, 2025.

5 . Revision History

Date	Notes
2/25/2026	Updated footnote to clarify weight loss indication as benefit exclusion .

Zeposia

Prior Authorization Guideline

Guideline ID	GL-399200
Guideline Name	Zeposia
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	5/20/2022
P&T Revision Date:	08/19/2022 ; 09/21/2022 ; 01/18/2023 ; 05/25/2023 ; 08/18/2023 ; 04/17/2024 ; 01/15/2025 ; 9/25/2025

1 . Indications

Drug Name: Zeposia (ozanimod)
Multiple Sclerosis (MS) Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. **Ulcerative Colitis (UC)** Indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

2 . Criteria

Product Name:Zeposia [a]

Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - History of failure, contraindication, or intolerance to TWO of the following preferred products or classes (document drug, date, and duration of trial):

dimethyl fumarate (generic Tecfidera)

fingolimod (generic Gilenya)

glatiramer acetate

interferon beta-1a or beta-1b (e.g., Betaseron, Avonex)

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zeposia [a]	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active UC

AND

2 - ONE of the following:

2.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

OR

2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Simponi (golimumab), ustekinumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance to TWO of the following preferred products (document drug, date, and duration of trial):

One of the preferred adalimumab products [b]

Rinvoq (upadacitinib)

Simponi (golimumab)

Skyrizi (risankizumab-rzaa)

One of the preferred ustekinumab products [c]

Xeljanz/Xeljanz XR (tofacitinib)

OR

3.2 BOTH of the following:

3.2.1 Patient is currently on Zeposia therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy)

AND

3.2.2 Patient has NOT received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Bristol Myers Squibb sponsored Zeposia 360 Support Program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Zeposia*

AND

4 - Patient is not receiving Zeposia in combination with a targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]

AND

5 - Prescribed by or in consultation with a gastroenterologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For a list of preferred adalimumab products please reference drug coverage tools. [c] For a list of preferred ustekinumab products please reference drug coverage tools. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Bristol Myers Squibb sponsored Zeposia 360 Support Program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name:Zeposia [a]	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria **1** - Documentation of positive clinical response to Zeposia therapy **AND** **2** - Patient is not receiving Zeposia in combination with a targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Zeposia (ozanimod) is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults and moderately to severely active ulcerative colitis (UC) in adults. **Additional Clinical Rules:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class Supply limits may be in place.

4 . References

Zeposia [package insert]. Summit, NJ: Celegene Corporation; August 2023.

Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158(5):1450-61.

5 . Revision History

Date	Notes
9/16/2025	Added Skyrizi as a step through option in the Ulcerative Colitis sectio n.

Zero Dollar Contraceptives Cost Share

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-429194
Guideline Name	Zero Dollar Contraceptives Cost Share
Formulary	UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	1/20/2021
P&T Revision Date:	

Note:

This policy applies to formulary drugs that process at a non-$0 cost share or are non-formulary.

1 . Criteria

Product Name:OTC and Prescription Non-Formulary and Formulary Contraceptives	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - Requests to waive cost-sharing for a medication not included on a zero-cost-sharing coverage list must meet ALL of the following:

1.1 Patient is using the prescribed drug for contraception

AND

1.2 If the request is for a prescription product that is non-formulary, one of the following:

1.2.1 There must be an appropriate clinical reason why the patient cannot take TWO (2) products that are covered at the $0 preventative medications cost share+ (i.e., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)

OR

1.2.2 Provider attests the non-formulary contraceptive drug is the preferred product for this patient (e.g., provider attestation that the non-formulary contraceptive is medically necessary, patient is stable on the requested non-formulary contraceptive, patient requires continuation of therapy to complete the course of treatment, transition to another agent could result in destabilization)

Notes	If approved, authorizations should have overrides to allow for $0 cost share for non-formulary or formulary drugs. +Products covered at the $0 preventative medications cost share can be identified under the Status column of the Formulary Lookup Tool a s having a status of “Zero Cost Share Preventative Drug”.

2 . Background

Benefit/Coverage/Program Information
Technician Note: Non-Formulary Alternatives Table link: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x01200027C80175A8369D44AC45A99A99328B80&View=%7B4B6D25AD%2D6A95%2D496D%2D9937%2D65CECD43AFE7%7D&viewid=c2ad0afa%2D814c%2D499e

%2Dbf25%2D3411fac9171f&id=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FUHCGP%20Exchange%2FNF%20Alt%20Tables

Background:

The Patient Protection and Affordable Care Act (PPACA) provides for $0 cost share conditional coverage for contraceptives when used for contraception. Examples of covered products include: OTC contraceptive products (with prescription) including male and female condoms, spermicides, or sponges; OTC emergency contraceptive (with prescription) or prescription emergency contraceptive drug; Contraceptive patch; Contraceptive ring; Injectable contraceptives; Diaphragm or cervical caps; Contraceptive implant; Non-emergency oral contraceptives.

This policy applies to formulary drugs that process at a non-$0 cost share or are non-formulary.

Formulary: 2026 UnitedHealthcare Government Programs Exchange Formulary

3 . References

U.S. Preventive Services Task Force http://www.uspreventiveservicestaskforce.org/ Accessed July 29, 2025

4 . Revision History

Date	Notes
10/23/2025	Annual review. Updated references.

Zero Dollar Preventative Medications Cost Share

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-429195
Guideline Name	Zero Dollar Preventative Medications Cost Share
Formulary	UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	1/1/2026
P&T Approval Date:	1/20/2021
P&T Revision Date:	12/15/2021 ; 08/18/2023

Note:

This policy applies to formulary drugs that process at a non-$0 cost share or are non-formulary.

1 . Criteria

Product Name:Formulary HIV Pre-Exposure Prophylaxis Medications: Generic emtricitabine/tenofovir 200-300 mg (generic Truvada), tenofovir 300 mg (generic Viread), Descovy; Applies to Florida only: Brand Viread, Brand Truvada 200/300 mg	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria **1** - Preventive care coverage for pre-exposure prophylaxis (PrEP) is being requested	
Notes	This program is designed to meet Patient Protection and Affordable C are Act (PPACA) requirements which require coverage of effective HI V PrEP regimens at zero-dollar cost share if being used for preexposu re prophylaxis (PrEP) and criteria are met. If approved, authorizations should have overrides to allow for $0 cost share for formulary drugs.

Product Name:Brand Truvada 200/300 mg	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria **1** - Preventive care coverage for pre-exposure prophylaxis (PrEP) is being requested **AND** **2** - Provider attests use of generic Truvada (emtricitabine/tenofovir disoproxil fumarate) is medically inappropriate	
Notes	This program is designed to meet Patient Protection and Affordable C are Act (PPACA)requirements which require coverage of effective HIV PrEP regimens at zero-dollar cost share if being used for preexposur e prophylaxis (PrEP) and criteria are met. If approved, authorizations should have overrides to allow for $0 cost share for formulary drugs.

Product Name:Brand Viread 300 mg	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria **1** - Preventive care coverage for pre-exposure prophylaxis (PrEP) is being requested	

AND **2** - Provider attests use of generic Viread (tenofovir disoproxil fumarate) is medically inappropriate

Notes	This program is designed to meet Patient Protection and Affordable Care Act (PPACA)requirements which require coverage of effective HIV PrEP regimens at zero-dollar cost share if being used for preexposure prophylaxis (PrEP) and criteria are met. If approved, authorizations should have overrides to allow for $0 cost share for formulary drugs.

Product Name:OTC Aspirin 81 mg	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Pregnancy at greater than 12 weeks with high risk of preeclampsia

Notes	If approved, authorizations should have overrides to allow for $0 cost share for non-formulary or formulary drugs.

Product Name:tamoxifen 20 mg, Soltamox, generic raloxifene, Brand Evista, generic anastrozole, Brand Arimidex, generic exemestane, Brand Aromasin, generic letrozole, Brand Femara	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Patient is greater than or equal to 35 years of age

AND

2 - Patient is at increased risk for breast cancer

AND

3 - Patient is at low risk for adverse medication effects

AND

4 - MEMBER does not have a prior diagnosis of ANY of the following:

breast cancer

ductal carcinoma in situ (DCIS)

AND

5 - One of the following:

5.1 Request is for a FORMULARY drug

OR

5.2 Both of the following:

5.2.1 Request is for a NON-FORMULARY drug

AND

5.2.2 The patient must try and fail, or have specific medical reason(s) why the number of alternatives specified by the Non-Formulary Alternatives Table is not appropriate (see technician note for NF Alts Table URL)

Notes	If approved, authorizations should have overrides to allow for $0 cost share for non-formulary or formulary drugs.

Product Name:Immunizations	
Approval Length	Authorization will be issued for one time
Guideline Type	Administrative

Approval Criteria

1 - Preventative immunizations as a single-entity or combination vaccination will be approved when used for an Advisory Committee on Immunization Practices (ACIP) recommended vaccine regimen*

Notes	*https://www.cdc.gov/acip-recs/hcp/vaccine-specific/ If approved, authorizations should have overrides to allow for $0 cost share for non-formulary or formulary drugs.

Product Name:Non-Formulary and Formulary HMG-CoA Reductase Inhibitors (statins)	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Patient is 40 to 75 years old

AND

2 - Patient has one or more cardiovascular disease (CVD) risk factors (e.g., dyslipidemia, diabetes, hypertension, smoking, etc.)

AND

3 - Patient has a calculated 10-year risk of a cardiovascular event of 10% or greater

AND

4 - Patient has no history of cardiovascular disease (i.e., symptomatic coronary artery disease or ischemic stroke)

AND

5 - ONE of the following:

5.1 The request is for a FORMULARY medication

OR

5.2 BOTH of the following:

5.2.1 The request is for a NON-FORMULARY medication

AND

5.2.2 The patient must try and fail, or have specific medical reason(s) why the number of alternatives specified by the Non-Formulary Alternatives Table is not appropriate (see technician note for NF Alts Table URL)

Notes	If approved, authorizations should have overrides to allow for $0 cost share for non-formulary or formulary drugs.

Product Name:Bowel preparation agents for colorectal cancer screening	
Approval Length	Authorization will be issued for one time
Guideline Type	Administrative

Approval Criteria

1 - OTC oral generic - bisacodyl EC 5 mg tablet, magnesium citrate solution, and polyethylene glycol 3350 powder will be approved if the requested product is being prescribed for bowel preparation prior to colon cancer screening

OR

2 - Formulary combination Prep Kits will be approved if both of the following are met:

2.1 Requested product is being prescribed for bowel preparation prior to colon cancer screening

AND

2.2 Appropriate clinical reason provided as to why the patient cannot use two individual generic products (such as separate bisacodyl tablets and polyethylene glycol 3350 powder taken together) that are covered at the $0 preventative medications cost share+ concurrently (i.e., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)

OR

3 - Non-formulary combination Prep Kits will be approved if all of the following are met:

3.1 Requested product is being prescribed for bowel preparation prior to colon cancer screening

AND

3.2 Appropriate clinical reason provided as to why the patient cannot use two individual generic products (such as separate bisacodyl tablets and polyethylene glycol 3350 powder taken together) that are covered at the $0 preventative medications cost share+ concurrently (i.e., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)

AND

3.3 Appropriate clinical reason provided as to why the patient cannot use two formulary combination bowel prep kits

Notes	If approved, authorizations should have overrides to allow for $0 cost share for non-formulary or formulary drugs. +Products covered at the $0 preventative medications cost share can be identified under the Status column of the Formulary Lookup Tool a s having a status of “Zero Cost Share Preventative Drug”.

Product Name:Fluoride supplementation products	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Patient is less than or equal to 16 years of age

AND

2 - The use is for prophylaxis of dental carries

AND

3 - Requested product is a prescription oral fluoride supplementation product (e.g., sodium fluoride tablets, chewable tablets, and drops)

Notes	If approved, authorizations should have overrides to allow for $0 cost share for non-formulary or formulary drugs.

Product Name:Folic acid supplementation products	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Patient is pregnant, planning pregnancy, or could become pregnant

AND

2 - Requested product is a prescription or OTC folic acid product (with prescription), including prenatal vitamins containing folic acid

AND

3 - Requested product contains between 0.4 mg to 0.8 mg of folic acid

Notes	If approved, authorizations should have overrides to allow for $0 cost share for non-formulary or formulary drugs.

Product Name:Erythromycin 0.5% ophthalmic ointment	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria **1** - Member or health care provider intends to administer medication to newborn for the prophylaxis of gonococcal ophthalmia neonatorum* **OR** **2** - Newborn is 0-1 month of age	
Notes	If approved, authorizations should have overrides to allow for $0 cost share for non-formulary or formulary drugs. This program is designed to meet Patient Protection and Affordable Care Act (PPACA) requirements which require coverage of erythromycin 0.5% ophthalmic ointment at zero dollar cost share if being used for primary prevention of gonococcal ophthalmia neonatorum (GON) and criteria are met. *Requests may be submitted before the infant's birth and could be requested under the mother's account.

2 . Background

Benefit/Coverage/Program Information
Technician Note: Non-Formulary Alternatives Table link: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x01200027C80175A8369D44AC45A99A99328B80&View=%7B4B6D25AD%2D6A95%2D496D%2D9937%2D65CECD43AFE7%7D&viewid=c2ad0afa%2D814c%2D499e

%2Dbf25%2D3411fac9171f&id=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FUHCGP%20Exchange%2FNF%20Alt%20Tables

Background:

The Patient Protection and Affordable Care Act (PPACA) provides for $0 cost share conditional coverage of preventative medications in the following drug categories:

Drug Category of Prevention*	Example Medications
HIV Pre-Exposure Prophylaxis	Truvada (emtricitabine-tenofovir disoproxil fumarate), emtricitabine-tenofovir disoproxil fumarate (generic Truvada), Viread (tenofovir disoproxil fumarate), tenofovir disoproxil fumarate 300mg (generic Viread), Descovy (emtricitabine-tenofovir alafenamide fumarate)
Aspirin Use to Prevent Preeclampsia and Related Morbidity and Mortality: Preventive Medication: pregnant persons at high risk for preeclampsia	OTC aspirin 81 mg
Breast Cancer: Medication Use to Reduce Risk: women at increased risk for breast cancer aged 35 years or older	tamoxifen citrate, tamoxifen citrate solution (generic Soltamox), raloxifene (generic Evista), Aromatase inhibitors [anastrozole (generic Arimidex), exemestane (generic Aromasin), letrozole (generic Femara)]
Immunizations	Diphtheria, tetanus, acellular pertussis (Daptacel, Infanrix, Adacel, Boostrix); Hepatitis B (Engerix-B, Recombivax HB); Human papillomavirus (Gardasil); Influenza (Fluzone, Fluad, FluMist Quadrivalent); Zoster (Zostavax, Shingrix)
Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication	atorvastatin 10 & 20 mg (generic Lipitor), lovastatin all strengths (generic Mevacor), and simvastatin 5, 10, 20, 40 mg (generic Zocor)
Bowel preparations for colonoscopy needed for preventive colon cancer screening	OTC oral generic - bisacodyl EC 5mg tablet (Dulcolax), magnesium citrate solution (Citroma), and polyethylene glycol 3350 powder (Miralax)

Fluoride Supplements to Prevent Dental Caries in Children younger than 5 years	oral sodium fluoride tablets, chewable tablets, solution, and drops (Ludent, Nafrinse, Floriva)
Folic Acid for the Prevention of Neural Tube Defects	folic acid 400 & 800 mcg, or Prenatal vitamins with 400 - 800 mcg folic acid
Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum	Erythromycin 0.5% ophthalmic ointment

* The Patient Protection and Affordable Care Act (PPACA) also provides for $0 cost share for smoking cessation and contraceptive products. Refer to the Tobacco Cessation Zero Dollar Cost Share Review guideline for reviews of smoking cessation related products. Refer to the Contraceptives Zero Dollar Cost Share Review guideline for reviews for contraceptive related products. PPACA also provides for $0 cost share for contraceptives. Refer to the Contraceptives Zero Dollar Cost Share guideline for reviews of contraceptive products.

This policy applies to formulary drugs that process at a non-$0 cost share or are non-formulary.

Formulary:

2026 UnitedHealthcare Government Programs Exchange Formulary

3 . References

U.S. Preventive Services Task Force http://www.uspreventiveservicestaskforce.org/ Accessed September 3, 2025.

4 . Revision History

Date	Notes
10/29/2025	Updated ACIP link for vaccinations, updated age requirements for fluoride supplements.Removed Yeztugo.

Zilbrysq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-399201
Guideline Name	Zilbrysq
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	11/1/2025
P&T Approval Date:	1/17/2024
P&T Revision Date:	01/15/2025 ; 9/25/2025

1 . Indications

Drug Name: Zilbrysq (zilucoplan)
Generalized myasthenia gravis (gMG) Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are antiacetylcholine receptor (AChR) antibody positive.

2 . Criteria

Product Name:Zilbrysq [a]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming ALL of the following:

Diagnosis of generalized myasthenia gravis (gMG)

Positive serologic test for anti-AChR antibodies

Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy

Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 6 at initiation of therapy

AND

2 - ONE of the following:

History of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.)

Patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/ plasma exchanges and/or intravenous immune globulin over the course of at least 12 months without symptom control

AND

3 - ONE of the following:

Patient has a history of failure to one FcRn blocker [e.g., Imaavy (nipocalimab), Vyvgart (efgartigimod alfa), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)]

Patient has an intolerance or contraindication to all FcRn blockers [i.e., Imaavy (nipocalimab), Rystiggo (rozanolixizumab), Vyvgart (efgartigimod alfa), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)]

AND

4 - Patient is not receiving Zilbrysq in combination with another complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab-cwvz)] or an FcRn blocker [e.g., Imaavy (nipocalimab), Vyvgart (efgartigimod alfa-fcab),Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]

AND

5 - Prescribed by, or in consultation with, a neurologist

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zilbrysq [a]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory tests) demonstrating ALL of the following:

Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline [4]

Reduction in signs and symptoms of myasthenia gravis

Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Zilbrysq Note: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Zilbrysq therapy will be considered as treatment failure

AND

2 - Patient is not receiving Zilbrysq in combination with another complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab-cwvz)] or an FcRn blocker [e.g., Imaavy (nipocalimab), Vyvgart (efgartigimod alfa-fcab),Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)] **AND** **3** - Prescribed by, or in consultation with, a neurologist	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Zilbrysq (zilucoplan) is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are antiacetylcholine receptor (AChR) antibody positive. [1] **Additional Clinical Rules:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limit may be in place**.**

4 . References

Zilbrysq [package insert], Smyrna, GA: UCB, Inc.; April 2024.

Howard JF Jr, Bresch S, Genge A, et al. Safety and efficacy of zilucoplan in patients with generalised myasthenia gravis (RAISE): a randomised, double-blind, placebo-controlled, phase 3 study. Lancet Neurol. 2023;22(5):395-406. doi:10.1016/S1474-4422(23)00080-7

Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. Neurology. 2021;96(3):114-122. doi:10.1212/WNL.0000000000011124

Barnett C, Herbelin L, Dimachkie MM, Barohn RJ. Measuring Clinical Treatment Response in Myasthenia Gravis. Neurol Clin. 2018;36(2):339-353. doi:10.1016/j.ncl.2018.01.006

5 . Revision History

Date	Notes
9/16/2025	Addition of criteria requiring a trial and failure, intolerance, or contrain dication to an FcRn blocker. Updated list of FcRn blocker examples.

Zoryve

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-552226
Guideline Name	Zoryve
Formulary	UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	5/1/2026
P&T Approval Date:	9/21/2022
P&T Revision Date:	02/17/2023 ; 11/17/2023 ; 02/16/2024 ; 12/18/2024 ; 01/15/2025 ; 07/16/2025 ; 11/21/2025 ; 3/18/2026

1 . Indications

Drug Name: Zoryve 0.3% cream (roflumilast)
Plaque Psoriasis Indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.
Drug Name: Zoryve 0.15% cream (roflumilast)
Atopic Dermatitis Indicated for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.
Drug Name: Zoryve foam (roflumilast)
Seborrheic Dermatitis Indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

Plaque Psoriasis Indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.
Drug Name: Zoryve 0.05% cream (roflumilast)
Atopic Dermatitis Indicated for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.

2 . Criteria

Product Name:Zoryve 0.3% cream, Zoryve foam [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to TWO of the following topical therapies:

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Coal tar

AND

3 - Patient is not receiving the requested product in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zoryve 0.3% cream, Zoryve foam [a]	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving the requested product in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zoryve foam [a]	
Diagnosis	Seborrheic Dermatitis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of seborrheic dermatitis

AND

2 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to at least TWO of the following therapies:

Topical corticosteroids (e.g., betamethasone, hydrocortisone)

Topical, shampoo, or systemic antifungals (e.g., ketoconazole, ciclopirox, itraconazole)

Topical calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

3 - Patient is not receiving Zoryve foam in combination with EITHER of the following for treatment of the same indication:

Biologic immunomodulator [e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm)]

Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zoryve foam [a]	
Diagnosis	Seborrheic Dermatitis
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving Zoryve foam in combination with EITHER of the following for treatment of the same indication:

Biologic immunomodulator [e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm)]

Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zoryve 0.15% cream, Zoryve 0.05% cream [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of mild to moderate atopic dermatitis

AND

2 - History of failure, contraindication, or intolerance to BOTH of the following therapeutic classes of topical therapies:

2.1 ONE of the following:

For mild atopic dermatitis: a topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)

For moderate atopic dermatitis: a topical corticosteroid of at least a medium- to high-potency (e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]

AND

2.2 One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

AND

3 - Patient is NOT receiving Zoryve 0.15% cream or Zoryve 0.05% cream in combination with a systemic targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)] for treatment of the same indication.

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zoryve 0.15% cream, Zoryve 0.05% cream [a]	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND **2** - Patient is NOT receiving Zoryve 0.15% cream or Zoryve 0.05% cream in combination with a systemic targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)] for treatment of the same indication.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Zoryve (roflumilast) 0.3% cream is a phosphodiesterase 4 inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.[1] Zoryve (roflumilast) foam is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older and plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older. Zoryve (roflumilast) 0.15% cream is indicated for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older. Zoryve (roflumilast) 0.05% cream is indicated for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.

Additional Clinical Rules

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limits may be in place.

4 . References

Zoryve cream [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; October 2025.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Zoryve foam [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; May 2025.

5 . Revision History

Date	Notes
3/17/2026	Updated plaque psoriasis and seborrheic dermatitis sections to require step through 2 topical therapies. Updated combination examples and language.

Zurzuvae

Prior Authorization Guideline

Guideline ID	GL-162222
Guideline Name	Zurzuvae
Formulary	UnitedHealthcare Government Programs Exchange Formulary

Guideline Note:

Effective Date:	2/1/2025
P&T Approval Date:	1/17/2024
P&T Revision Date:	12/18/2024

1 . Indications

Drug Name: Zurzuvae
Postpartum depression Indicated for the treatment of postpartum depression (PPD) in adults.

2 . Criteria

Product Name:Zurzuvae [a]	
Approval Length	1 month(s)
Guideline Type	Non Formulary

Approval Criteria **1** - Diagnosis of postpartum depression (PPD) **AND** **2** - Onset of current depressive episode was during the third trimester or within 4 weeks postpartum	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background: Zurzuvae™ is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression (PPD) in adults. **Additional Clinical Programs:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limits may be in place.

4 . References

Zurzuvae [package insert]. Cambridge, MA; Biogen Inc.; July 2024.

5 . Revision History

Date	Notes
12/18/2024	Annual review without changes to clinical criteria. Updated reference.

Zydelig

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-272214
Guideline Name	Zydelig
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	7/1/2025
P&T Approval Date:	10/20/2021
P&T Revision Date:	05/20/2022 ; 09/21/2022 ; 05/25/2023 ; 05/17/2024 ; 5/16/2025

1 . Indications

Drug Name: Zydelig (idelalisib)
Chronic lymphocytic leukemia Indicated for relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.

2 . Criteria

Product Name:Zydelig [a]	
Diagnosis	Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL)

AND

2 - ONE of the following:

Disease has relapsed

Disease is refractory

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zydelig [a]	
Diagnosis	Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zydelig therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zydelig [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Zydelig will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zydelig [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Zydelig therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information

Background:

Zydelig (idelalisib) is a kinase inhibitor indicated for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. [1,2] The National Cancer Comprehensive Network (NCCN) also recommends the use of Zydelig as second-line and subsequent therapy as a single agent or in combination with rituximab for CLL/SLL with del(17p)/TP53 mutation in patients who have indications for treatment.[2]

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limits may be in place.

4 . References

Zydelig [package insert]. Foster City, CA: Gilead Science, Inc.; February 2022.

The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 27, 2025.

5 . Revision History

Date	Notes
5/20/2025	Annual review. No changes to clinical criteria. Updated references.

Zykadia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-523237
Guideline Name	Zykadia
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	4/1/2026
P&T Approval Date:	8/14/2020
P&T Revision Date:	02/19/2021 ; 06/16/2021 ; 02/18/2022 ; 09/21/2022 ; 02/17/2023 ; 02/16/2024 ; 02/20/2025 ; 2/20/2026

1 . Indications

Drug Name: Zykadia (ceritinib)
Anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

2 . Criteria

Product Name:Zykadia [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

Disease is metastatic

Disease is recurrent

Disease is advanced

AND

3 - Tumor is ALK-positive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zykadia therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of inflammatory myofibroblastic tumor (IMT) with ALK translocation	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Zykadia therapy	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]

Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from NSCLC

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zykadia therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	Histiocytic Neoplasms

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Erdheim-Chester Disease

AND

2 - Disease is positive for ALK rearrangement

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zykadia therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

AND

3 - Disease is relapsed or refractory

AND

4 - Used as palliative intent therapy or second-line and subsequent therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zykadia therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT) with ALK translocation

AND

2 - ONE of the following:

Disease is metastatic

Disease is recurrent

Disease is advanced

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zykadia therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Zykadia will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zykadia [a]	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zykadia Therapy

Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background Zykadia® (ceritinib) is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. The National Cancer Comprehensive Network (NCCN) also recommends Zykadia as first-line therapy for ALK-positive advanced or metastatic NSCLC, for the treatment of inflammatory myofibroblastic tumor (IMT) with ALK translocation in soft tissue sarcoma, in treatment of ALK-positive brain metastases from NSCLC, in the treatment of ALK-positive Erdheim-Chester Disease, advanced, recurrent, metastatic, or inoperable inflammatory myofibroblastic tumor (IMT) with positive ALK translocation in uterine neoplasms, and ALK-positive relapsed or refractory anaplastic large cell lymphoma as palliative intent therapy or second-line and subsequent therapy. **Additional Clinical Rules:** Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limits may be in place.

4 . References

Zykadia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2021.

The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed January 9, 2026.

5 . Revision History

Date	Notes
2/17/2026	Annual review. Updated background and coverage criteria for uterine neoplasms per NCCN. Updated references.

Zymfentra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-412216
Guideline Name	Zymfentra
Formulary	UnitedHealthcare Government Programs Exchange Formulary SP

Guideline Note:

Effective Date:	12/1/2025
P&T Approval Date:	10/15/2025
P&T Revision Date:	

1 . Indications

Drug Name: Zymfentra (infliximab-dyyb)
Ulcerative Colitis Indicated in adults for maintenance treatment of moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously **Crohn's Disease** Indicated in adults for maintenance treatment of moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously

2 . Criteria

Product Name:Zymfentra [a]

Diagnosis	Ulcerative Colitis
Approval Length	All requests for authorization will be denied.
Guideline Type	Non Formulary
Approval Criteria **1** - Zymfentra provides similar efficacy as intravenous administration of infliximab products; therefore, Zymfentra is not medically necessary for treatment of ulcerative colitis since its use is mainly for convenience as compared to intravenous administration of infliximab.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name:Zymfentra [a]	
Diagnosis	Crohn’s Disease
Approval Length	All requests for authorization will be denied.
Guideline Type	Non Formulary
Approval Criteria **1** - Zymfentra provides similar efficacy as intravenous administration of infliximab products; therefore, Zymfentra is not medically necessary for treatment of Crohn’s disease since its use is mainly for convenience as compared to intravenous administration of infliximab.	
Notes	[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3 . Background

Benefit/Coverage/Program Information
Background:

Zymfentra (infliximab-dyyb) is a tumor necrosis factor (TNF) blocker indicated in adults for maintenance treatment of moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously and moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously.

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limits may be in place.

4 . References

Zymfentra [package insert]. Jersey City, NJ: Celltrion USA, Inc.; February 2024.

5 . Revision History

Date	Notes
10/6/2025	Policy reviewed and approved for application to UnitedHealthcare Val ue & Balance Exchange for 12/2025 implementation.