UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2195-10
Program	Prior Authorization/Medical Necessity
Medication	Cimzia® (certolizumab)
P&T Approval Date	5/2020, 5/2021, 6/2021, 12/2021, 5/2022, 5/2023, 7/2023, 10/2024, 11/2024, 11/2025
Effective Date	2/15/2026

1. 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 the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.

2. Coverage Criteria[a]:

A. Crohn's Disease (CD)

1. **Initial Authorization**

a. **Cimzia** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active Crohn's disease

-AND-

(2) **One** of the following:

(a) 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):

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

-OR-

(b) 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), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab].

-OR-

(c) **Both** of the following:

i. Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. 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, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

* 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.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cimzia** will be approved based on **all** of the following 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.

Authorization will be issued for 12 months.

B. Rheumatoid Arthritis (RA)

1. **Initial Authorization**

a. **Cimzia** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

(2) **One** of the following:

(a) 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)[b]

-OR-

(b) 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, Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

-OR-

(c) **Both** of the following:

i. Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. 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), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

-AND-

(4) Prescribed by or in consultation with a rheumatologist

* 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.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cimzia** will be approved based on **all** of the following 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), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

Authorization will be issued for 12 months.

C. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

a. **Cimzia** will be approved based on **all** of the following criteria:

(1) Diagnosis of active psoriatic arthritis

-AND-

(2) **One** of the following:

(a) 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)[b]

-OR-

(b) 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]

-OR-

(c) **Both** of the following:

i. Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. 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, 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-

(4) Prescribed by or in consultation with **one** of the following:

(a) Rheumatologist
(b) Dermatologist

* 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.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cimzia** will be approved based on **all** of the following 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.

Authorization will be issued for 12 months.

D. Ankylosing Spondylitis (AS) and non-radiographic Axial Spondyloarthritis (nr-axSpA)

1. **Initial Authorization**

a. **Cimzia** will be approved based on **all** of the following criteria:

(1) Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis

-AND-

(2) **One** of the following:

(a) 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-

(b) 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), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)]

-OR-

(c) **Both** of the following:

i. Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. 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, Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication.

-AND-

(4) Prescribed by or in consultation with a rheumatologist

***** 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.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cimzia** will be approved based on **all** of the following 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), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication.

Authorization will be issued for 12 months.

E. Plaque Psoriasis (PS)

1. **Initial Authorization**

a. **Cimzia** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe plaque psoriasis

-AND-

(2) **One** of the following:

(a) **All** of the following:

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

-AND-

ii. 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):

a. Corticosteroids (e.g., betamethasone, clobetasol, desonide)
b. Vitamin D analogs (e.g., calcitriol, calcipotriene)
c. Tazarotene
d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
e. Anthralin
f. Coal tar

-AND-

iii. 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)[b]

-OR-

(b) 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]

-OR-

(c) **Both** of the following:

i. Patient is currently on Cimzia therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. 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, 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-

(4) Prescribed by or in consultation with a dermatologist

***** 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.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cimzia** will be approved based on **all** of the following 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.

Authorization will be issued for 12 months.

F. Polyarticular Juvenile Idiopathic Arthritis (pJIA)

1. **Initial Authorization**

a. **Cimzia** will be approved based on **all** of the following criteria:

(1) Diagnosis of active polyarticular juvenile idiopathic arthritis

-AND-

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

-AND-

(3) Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cimzia** will be approved based on **both** of the following 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), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

Authorization will be issued for 12 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.
[b] For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.

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. Cimzia [package insert]. Smyrna, GA: UCB, Inc; September 2025.
2. 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.
3. Yu, DT, van Tubergen A. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. Sieper, J (Ed). UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on October 10, 2019.)
4. 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. 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.
6. 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.
7. 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.
8. 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.

Program	Prior Authorization/Medical Necessity - Cimzia (certolizumab)
Change Control	
5/2020	New Program
5/2021	Annual review. Removed preceding month requirement from failure criteria. Removed prescriber requirement from reauthorization criteria. Removed drug documentation where only one drug is required. Reference updated.
6/2021	Added coverage criteria for patients previously treated with a biologic DMARD. Added clarification that submission of medical records is required documenting previous or current therapy with a biologic DMARD in order to bypass step through non-biologic therapies if claim history not available.
12/2021	Updated conventional DMARD bypass language for rheumatoid arthritis, psoriatic arthritis and psoriasis with no change to clinical intent. Updated CT/KY footnote.
5/2022	Added targeted synthetic DMARD to bypass criteria for AS. Added Rinvoq and Xeljanz as a JAK inhibitor example where applicable. Added Mississippi to state mandate.
5/2023	Annual review. Updated drug examples to mirror other pharmacy programs. Updated reference.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
10/2024	Annual review. Updated state mandate footnote and reference.
11/2024	Added coverage criteria for pJIA. Updated background and reference.
11/2025	Annual review. Updated examples with no change to clinical intent. Updated references.