UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1230-11
Program	Prior Authorization/Notification
Medication	*Tremfya® (guselkumab) *This program applies to the subcutaneous formulations of Tremfya
P&T Approval Date	9/2017, 9/2018, 9/2019, 9/2020, 9/2021, 9/2022, 7/2023, 10/2024, 11/2024, 3/2025, 10/2025
Effective Date	12/1/2025

1. Background:

Tremfya (guselkumab) is an interleukin-23 blocker indicated for the treatment of patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy, active psoriatic arthritis, moderately to severely active ulcerative colitis, and moderately to severely active Crohn's disease.

2. Coverage Criteria[a]:

A. Plaque Psoriasis

1. **Initial Authorization**

a. Tremfya will be approved based on **both** of the following criteria:

(1) Diagnosis of moderate to severe plaque psoriasis

-AND-

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

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Tremfya will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Tremfya therapy

-AND-

(2) Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab,

Skyrizi (risankizumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

B. Psoriatic Arthritis

1. **Initial Authorization**

a. Tremfya will be approved based on **both** of the following criteria:

(1) Diagnosis of active psoriatic arthritis

-AND-

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

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Tremfya will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Tremfya therapy

-AND-

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

Authorization will be issued for 12 months.

C. Ulcerative Colitis (UC)

1. **Initial Authorization**

a. **Tremfya** will be approved based on **both** of the following criteria:

(1) Diagnosis of moderately to severely active ulcerative colitis

-AND-

(2) Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, adalimumab, Skyrizi (risankizumab)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tremfya** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Tremfya therapy

-AND-

(2) Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, adalimumab, Skyrizi (risankizumab)]

Authorization will be issued for 12 months.

D. Crohn's Disease (CD)

1. **Initial Authorization**

a. **Tremfya** will be approved based on **both** of the following criteria:

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

-AND-

(2) Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tremfya** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Tremfya therapy

-AND-

(2) Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab]

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.

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, Step Therapy, and/or Medical Necessity may be in place.

4. Reference:

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; September 2024.

Program	Prior Authorization/Notification - Tremfya (guselkumab)
Change Control	
9/2017	New program
9/2018	Annual review. No changes.
9/2019	Annual review. No changes.
9/2020	Annual review. Changed psoriasis reauthorization duration to 12 months. Added review criteria for psoriatic arthritis. Updated background and reference.
9/2021	Annual review with no change to coverage criteria.
9/2022	Annual review with no change to coverage criteria. Added Rinvoq to examples of JAK inhibitors. Added state mandate footnote.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
10/2024	Annual review with no changes to coverage criteria. Updated reference.
11/2024	Added coverage criteria for ulcerative colitis. Updated background and reference.
3/2025	Added coverage criteria for ulcerative colitis. Updated background.
10/2025	Updated background only.