UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2206-11
Program	Prior Authorization/Medical Necessity
Medication	*Tremfya® (guselkumab) *This program applies to the subcutaneous formulations of Tremfya
P&T Approval Date	5/2020, 11/2020, 6/2021, 12/2021, 12/2022, 3/2023, 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 **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 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), adalimumab, Otezla (apremilast), Skyrizi (risankizumab), ustekinumab].

-OR-

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

i. Patient is currently on Tremfya 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 Janssen 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 Tremfya*

-AND-

(3) 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)]

-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 Janssen sponsored CarePath Savings 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. Tremfya will be approved based on **all** 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 (PsA)

1. **Initial Authorization**

a. **Tremfya** 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 the 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 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), adalimumab, Simponi (golimumab), ustekinumab, Xeljanz (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)].

-OR-

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

i. Patient is currently on Tremfya 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 Janssen 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 Tremfya*

-AND-

(3) 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)]

-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 Janssen sponsored CarePath Savings 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. **Tremfya** will be approved based on **all** 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 **all** of the following criteria:

(1) Diagnosis of moderately to severely active ulcerative colitis

-AND-

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

(a) Patient has been approved for loading dose of Tremfya under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis

-OR-

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

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

-OR-

ii. Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)]

-OR-

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

i. 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):

-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 Janssen 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 Tremfya*

-AND-

(3) 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)]

-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 Janssen sponsored CarePath Savings 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. **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 **all** of the following criteria:

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

-AND-

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

(a) Patient has been approved for loading dose of Tremfya under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active Crohn's disease

-OR-

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

i. 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-

ii. Patient has been previously treated with a 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]

-OR-

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

i. 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):

-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 Janssen 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 Tremfya*

-AND-

(3) 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]

-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 Janssen sponsored CarePath Savings 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. **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.
[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. Reference:

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; September 2025.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.

7. 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.
8. 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.
9. 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.

Program	Prior Authorization/Medical Necessity - Tremfya (guselkumab)
Change Control	
5/2020	New program
11/2020	Added review criteria for psoriatic arthritis due to new indication. Updated background and references.
6/2021	Removed preceding month requirement from failure criteria. Added coverage criteria for patients previously treated with a biologic DMARD. Removed prescriber requirement from reauthorization criteria. 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 psoriasis and psoriatic arthritis with no change to clinical intent. Updated CT/KY footnote.
12/2022	Annual review with no change to clinical criteria. Added Rinvoq as an example where appropriate.
3/2023	Updated state mandate footnote to include Mississippi. Updated examples to adalimumab.
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 state mandate footnote and 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	Update ulcerative colitis criteria to allow for newly approved subcutaneous induction dosing. Updated background and reference.