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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Topical Products	**Original Policy Date:**	July 28, 2017
Subject:	Tremfya	**Page:**	1 of 10

Last Review Date: December 12, 2025

Tremfya

Description

Tremfya (guselkumab)

Background
Tremfya (guselkumab) is a subcutaneous injectable treatment or intravenous infusion that helps regulate inflammation in plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease. Tremfya is a monoclonal antibody that binds to interleukin 23 (IL-23), a protein involved in inflammation. Tremfya binds to IL-23 and prevents it from binding to its receptor, and it inhibits its ability to trigger an inflammatory response. Tremfya inhibits the release of proinflammatory cytokines and chemokines (1).

Regulatory Status
FDA-approved indications: Tremfya is an interleukin-23 blocker indicated for the treatment of: (1)

1. Adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.
2. Adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with active psoriatic arthritis (PsA).
3. Adults with moderately to severely active ulcerative colitis (UC).
4. Adults with moderately to severely active Crohn's disease (CD).

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Tremfya. Do not administer to patients with active TB infection. Initiate treatment for latent TB prior to administering Tremfya. Consider anti-TB therapy prior to initiation of Tremfya in patients with a

past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients receiving Tremfya for signs and symptoms of active TB during and after treatment (1).

Tremfya affects the immune system, thus patients may be at greater risk for infection. If a patient develops a serious infection or is not responding to standard therapy for the infection, monitor the patient closely and discontinue Tremfya therapy until the infection resolves. Avoid use of live vaccines in patients treated with Tremfya. There is no data available on the ability of live or inactive vaccines to elicit an immune response in patients being treated with Tremfya (1).

The safety and effectiveness of Tremfya in pediatric patients less than 6 years of age and weighing less than 40 kg with plaque psoriasis and psoriatic arthritis have not been established. The safety and effectiveness of Tremfya in pediatric patients less than 18 years of age with ulcerative colitis and Crohn's disease have not been established (1).

Related policies
Ilumya, Skyrizi, Stelara

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tremfya may be considered **medically necessary** if the conditions indicated below are met.

Tremfya may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severe plaque psoriasis (PsO)
    a. 6 years of age or older
    b. Patient weight ≥ 40 kg
    c. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy

i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option

d. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 8 weeks

2. Active psoriatic arthritis (PsA)
   a. 6 years of age or older
   b. Patient weight ≥ 40 kg
   c. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)
   d. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 8 weeks

3. Moderately to severely active ulcerative colitis (UC)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
   c. Prescriber will not exceed the FDA labeled maintenance dose of 200 mg every 4 weeks

4. Moderately to severely active Crohn's disease (CD)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
   c. Prescriber will not exceed the FDA labeled maintenance dose of 200 mg every 4 weeks

AND ALL of the following for **ALL** diagnoses:
   a. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
   b. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
   c. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
   d. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** the following:

1. Plaque psoriasis (PsO)
    a. 6 years of age or older
    b. Patient weight ≥ 40 kg
    c. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 8 weeks

2. Psoriatic arthritis (PsA)
    a. 6 years of age or older
    b. Patient weight ≥ 40 kg
    c. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 8 weeks

3. Ulcerative colitis (UC)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of 200 mg every 4 weeks

4. Crohn's disease (CD)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of 200 mg every 4 weeks

AND ALL of the following for **ALL** diagnoses:

a. Condition has shown improvement or stabilization
b. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
c. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
d. **NOT** given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Phase	Strength	Quantity
Plaque Psoriasis	Maintenance	100 mg/mL	8 syringes or auto-injectors
Psoriatic Arthritis	Maintenance	100 mg/mL	8 syringes or auto-injectors
Ulcerative Colitis	Induction	200 mg/20 mL vial for IV infusion	3 vials **OR**
		200 mg/2 mL	6 syringes or auto-injectors **AND**
	Maintenance	100 mg/mL	5 syringes or auto-injectors **OR**
		200 mg/2 mL	11 syringes or auto-injectors
Crohn's Disease	Induction	200 mg/20 mL vial for IV infusion	3 vials **OR**
		200 mg/2 mL	6 syringes or auto-injectors **AND**
	Maintenance	100 mg/mL	5 syringes or auto-injectors **OR**
		200 mg/2 mL	11 syringes or auto-injectors

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

Diagnosis	Phase	Strength	Quantity
Plaque Psoriasis	Maintenance	100 mg/mL	1 syringe or auto-injector per 56 days
Psoriatic Arthritis	Maintenance	100 mg/mL	1 syringe or auto-injector per 56 days
Ulcerative Colitis	Maintenance	100 mg/mL	1 syringe or auto-injector per 56 days **OR**

		200 mg/2 mL	2 syringes or auto-injectors per 56 days
Crohn's Disease	Maintenance	100 mg/mL	1 syringe or auto-injector per 56 days **OR**
		200 mg/2 mL	2 syringes or auto-injectors per 56 days

Duration 18 months

Rationale

Summary
Tremfya (guselkumab) is a subcutaneous injectable or intravenous infusion treatment that helps regulate inflammation in plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease. Tremfya is a monoclonal antibody that binds to interleukin 23 (IL-23) a protein involved in inflammation. Tremfya binds to IL-23 and prevents it from binding to its receptor, and it inhibits its ability to trigger an inflammatory response. Tremfya inhibits the release of proinflammatory cytokines and chemokines. The safety and effectiveness of Tremfya in pediatric patients less than 6 years of age and weighing less than 40 kg with plaque psoriasis and psoriatic arthritis have not been established. The safety and effectiveness of Tremfya in pediatric patients less than 18 years of age with ulcerative colitis and Crohn's disease have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tremfya while maintaining optimal therapeutic outcomes.

References
1. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2025.

Policy History

Date	Action
July 2017	Addition to PA
September 2017	Annual review
December 2017	Annual review

June 2018	Addition of additional requirements to initiation criteria - For diagnosis of PsO: if the patient is intolerant or contraindicated to either therapy then the other treatment option needs to be tried Addition of List of DMARDs Appendix Removal of requirements: documented baseline evaluation of the condition using one of the scoring tools and scoring tools in renewal
September 2018	Annual editorial review and reference update
September 2019	Annual review and reference update
December 2019	Annual review. Addition of requirement to trial preferred product
August 2020	Addition of indication: active psoriatic arthritis
September 2020	Annual review
December 2020	Annual editorial review. Revised requirements to t/f preferred products to apply to Blue Focus patients only. Changed initial approval duration to 12 months. Added requirements to dose within the FDA labeled maintenance dosing. Changed renewal quantity to 1 per 56 days
March 2021	Annual editorial review. Revised background and summary sections. Clarification added to the t/f, intolerance, C/I to preferred products requirement indicating that it only applies to claims adjudicated through the pharmacy benefit. Appendix 1 updated.
September 2022	Annual review
December 2022	Annual review
December 2023	Annual review
March 2024	Annual editorial review and reference update. Revised FDA dosing language
September 2024	Annual review
October 2024	Per PI update, added indication of UC
December 2024	Annual review
March 2025	Annual review
April 2025	Per PI update, added indication of CD
June 2025	Annual review
October 2025	Per PI update, added subcutaneous option for induction for UC, lowered age limit for plaque psoriasis and psoriatic arthritis to 6 years and older weighing at least 40 kg
December 2025	Annual review. Removed Blue Focus t/f requirements

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
infliximab-dyyb	Zymfentra
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla

baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 2 - List of Conventional Therapies

Conventional Therapy Options for CD
1. Mild to moderate disease – induction of remission: a. Oral budesonide, oral mesalamine b. Alternatives: metronidazole, ciprofloxacin
2. Mild to moderate disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission: a. Prednisone, methylprednisolone intravenously (IV) b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission c. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission d. Azathioprine, mercaptopurine e. Alternative: methotrexate IM

Conventional Therapy Options for UC
1. Mild to moderate disease – induction of remission: a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine b. Rectal mesalamine (e.g., Canasa, Rowasa) c. Rectal hydrocortisone (e.g., Colocort, Cortifoam) d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission: a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission: a. Prednisone, hydrocortisone IV, methylprednisolone IV b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: sulfasalazine
5. Pouchitis: a. Metronidazole, ciprofloxacin b. Alternative: rectal mesalamine