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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	July 28, 2017
Subject:	Tremfya	**Page:**	1 of 9

Last Review Date: December 13, 2024

Tremfya

Description

Tremfya (guselkumab)

Background
Tremfya (guselkumab) is a subcutaneous injectable treatment or intravenous infusion that helps regulate inflammation in plaque psoriasis, psoriatic arthritis, and ulcerative colitis. 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 adult patients with: (1)

1. Moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy
2. Active psoriatic arthritis (PsA)
3. Moderately to severely active ulcerative colitis (UC)

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 18 years of age 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

Age 18 years of age or older

Diagnoses

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

1. Moderate to severe Plaque psoriasis (PsO)
    a. 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
    b. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 8 weeks

c. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Active psoriatic arthritis (PsA)
    a. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)
    b. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 8 weeks
    c. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Moderately to severely active ulcerative colitis (UC)
    a. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
    b. Prescriber will not exceed the FDA labeled maintenance dose of 200 mg every 4 weeks
    c. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicating through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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

Age 18 years of age or older

Diagnoses

Patient must have **ONE** the following:

1. Plaque psoriasis (PsO)
    a. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 8 weeks
    b. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Psoriatic arthritis (PsA)
    a. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 8 weeks
    b. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Ulcerative colitis (UC)
    a. Prescriber will not exceed the FDA labeled maintenance dose of 200 mg every 4 weeks
    b. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicating through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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	Strength	Quantity
Plaque Psoriasis	100 mg/mL	8 syringes or auto-injectors
Psoriatic Arthritis	100 mg/mL	8 syringes or auto-injectors
Ulcerative Colitis	200 mg/20 mL vial for IV infusion	3 vials **AND**
	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	Strength	Quantity
Plaque Psoriasis	100 mg/mL	1 syringe or auto-injector per 56 days
Psoriatic Arthritis	100 mg/mL	1 syringe or auto-injector per 56 days
Ulcerative Colitis	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, and ulcerative colitis. 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 have not been evaluated in pediatric patients (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 2024.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.

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
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
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 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