Mass General Brigham
Health Plan

Tremfya (guselkumab)
Effective 09/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	Tremfya prefilled syringe and autoinjector are only available through the pharmacy benefit Tremfya vial for intravenous injection is only available through the medical benefit		

Overview

Tremfya (guselkumab) is an interleukin-23 (IL-23) antagonist indicated for the treatment of adults with:

- Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Active psoriatic arthritis
- Moderately to severely active ulcerative colitis
- Moderately to severity active Crohn's disease

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance program

OR

Authorization may be granted if the member meets all the following diagnosis-specific criteria:

Moderate to severe plaque psoriasis

1. Diagnosis of moderate to severe plaque psoriasis
2. At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
3. Member meets ONE of the following:
    a. Minimum duration of 4-week trial and failure, intolerance, or contraindication to ONE of the following topical therapies
        i. Corticosteroids (e.g., betamethasone, clobetasol)
        ii. Vitamin D analogs (e.g., calcitriol, calcipotriene)
        iii. Tazarotene
        iv. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
        v. Anthralin

vi. Coal tar

b. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Active psoriatic arthritis (PsA)

1. Diagnosis of active psoriatic arthritis (PsA)
2. ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

Moderately to severely active ulcerative colitis (UC)

1. Diagnosis of moderately to severely active ulcerative colitis
2. ONE of the following:
    a. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
        i. 6-mercaptopurine
        ii. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
        iii. Azathioprine
        iv. Corticosteroids (e.g., prednisone)
    b. Disease severity warrants systemic biologic as first-line therapy

Moderately to severely active Crohn's disease

1. Diagnosis of moderately to severely active Crohn's disease
2. ONE of the following:
    a. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
        i. 6-mercaptopurine
        ii. Azathioprine
        iii. Corticosteroids (e.g., prednisone)
        iv. Methotrexate
    b. Disease severity warrants systemic biologic as first-line therapy

<u>Continuation of Therapy</u>

Requests for reauthorization for all diagnoses will be approved when the following criteria are met:

1. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial and reauthorization requests for Tremfya autoinjector and prefilled syringe will be approved for 24 months.
2. Approval of Tremfya IV will be limited to the treatment of ulcerative colitis and Crohn's disease. Approvals will be limited to three infusions over 12 weeks.
3. Loading doses for Crohn's disease can be accomplished via either IV or SC administrations. Members will only be approved for one route of administration for loading doses of Crohn's disease.
4. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limitations
Crohn's Disease and Ulcerative Colitis Loading Dose, IV: Tremfya IV 10 mg/mL	200 mg at weeks 0, 4, and 8
Crohn's Disease induction pack, SC: Tremfya 200 mg/2 mL	400 mg (4 mL) at weeks 0, 4, and 8
Tremfya 100mg/mL prefilled syringe, autoinjector	100 mg (1 mL) every 8 weeks
Tremfya 200 mg/2 mL prefilled syringe, autoinjector	200 mg (2 mL) every 4 weeks

References

1. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol.* 2009; 61:451-485.
3. Reich K, Armstrong, AW, Foley P, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: Results from the phase III, double-blind, placebo- and active comparator–controlled VOYAGE 2 trial. *Am J Clin Dermatol*. 2017;76(3):418-431.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. Tremfya (guselkumab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; March 2025.

Review History

02/26/18 – Reviewed
06/01/18 – Implemented
02/20/19 – Updated
11/20/19 – Added Skyrizi as a preferred trial for PS
07/19/2021- Reviewed at July P&T; started and stabilized statement updated to include "new to AllWays Health Partners"; Added criteria for PsA indication; overview updated; references updated; loading dose added to limitations. Effective 10/01/2021.
09/21/2022 – Reviewed and Updated for Sept P&T; added Skyrizi as a preferred agent for diagnosis of psoriatic arthritis. Effective 11/1/22.
11/15/2023 – Reviewed and Updated for Nov P&T; For Plaque Psoriasis: updated BSA requirement to > 3% BSA or crucial body area. Removed TB requirement. Updated requirement of topical therapies. For psoriatic arthritis: updated approval criteria; Updated continuation of therapy criteria to include examples of improvement in symptoms. Effective 1/1/24
10/9/2024- Reviewed and updated for October P&T. Added criteria for ulcerative colitis to the policy. Updated Limitations section to specify that Tremfya IV will only be approved for the treatment of ulcerative colitis. Added quantity limits for Tremfya IV and Tremfya 200 mg/2mL prefilled syringe/autoinjector. For plaque psoriasis removed age requirement and removed requirement for documentation for 4-week trial with a conventional therapy. Updated continuation of therapy criteria to require documentation supporting improvement in the member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition. Effective 1/1/2025.

05/14/2025 – Reviewed and updated for May P&T. Updated criteria for ulcerative colitis to remove disease characteristic requirement and allow for approval if disease severity warrants systemic biologic as first-line therapy. Added criteria for Crohn's disease. Updated listed quantity limitations. Effective 07/01/2025.
07/09/2025 – Reviewed and updated for July P&T. Updated approval length for Tremfya IV to 12 weeks. Effective 09/01/2025.