Mass General Brigham
Health Plan

Tremfya (guselkumab)
Effective 01/01/2024

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	N/A		

Overview
Tremfya is a monoclonal antibody against interleukin-23, FDA indicated for Plaque psoriasis and Psoriatic arthritis

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Moderate to severe plaque psoriasis
Authorization may be granted for members new to the plan who are currently receiving treatment with Tremfya, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when all the following criteria are met:

1. The patient is 18 years of age or older
2. The member has a diagnosis of moderate to severe plaque psoriasis
3. 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.
4. Member meets ONE of the following:
    a. Paid claims or physician documentation confirming 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)
Authorization may be granted for members new to the plan who are currently receiving treatment with Tremfya for treatment of PsA, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted the following criteria are met:

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

Continuation of Therapy
Reauthorization may be granted for all members who achieve or maintain positive clinical response by documentation of the following:

Moderate to severe plaque psoriasis

1. One of the following:
    a. Reduction of body surface area (BSA) involvement from baseline
    b. Improvement in symptoms (e.g., pruritis, inflammation) from baseline

Active psoriatic arthritis (PsA)

1. ONE of the following:
    a. Reduction in the total active (swollen and tender) joint count from baseline
    b. Improvement in symptoms (e.g., pain stiffness, pruritis, inflammation) from baseline
    c. Reduction in the body surface area (BSA) involvement from baseline

Limitations

1. Approvals will be granted for 24 months
2. The following quantity limits apply:

Tremfya 100mg/ml Loading Dose	100mg at week 0 and week 4
Tremfya 100mg/ml Maintenance Dose	100 mg (1 ml) every 8 weeks

References

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2020
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. 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.

5. 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.

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 tot 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