Mass General Brigham
Health Plan

Tremfya (guselkumab)
Effective 11/01/2022

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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 for treatment of moderate to severe plaque psoriasis when all the following criteria are met:

1. Member has had a documented inadequate response or intolerable adverse event with ALL the preferred products (Cosentyx, Enbrel, Humira, Otezla, Skyrizi and Stelara) unless there is a documented clinical reason to avoid these products.
2. At least 5% 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 any of the following criteria:
   - Member has experienced an inadequate response or adverse reaction to TWO conventional therapies in any one of the following combinations:
     - 1 topical agent + 1 systemic agent (methotrexate, acitretin or cyclosporine)
     - 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)

- 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
- 2 systemic agents

- Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy and systemic agents). See Appendix.
- 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 for treatment of active PsA when ONE the following criteria are met:

1. The member has had a documented inadequate response or intolerable adverse event with ALL the preferred products indicated for PsA (Cosentyx, Enbrel, Humira, Otezla, Rinvoq, Skyrizi and Stelara).
2. The member has a contraindication to all the preferred agents and BOTH of the following criteria is met:
   - The member has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
   - The member has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

Continuation of Therapy

Reauthorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Tremfya as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Approvals will be granted for 24 months
2. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
   a. Note: Members who have received Tremfya or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.
3. 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

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Cannot be used due to risk of treatment-related toxicity
4. Drug interaction
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

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. Blauvelt A, Papp KA, Griffiths, CEM, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the continuous treatment of patients with moderate to severe psoriasis: Results from the phase III, double-blinded, placebo- and active comparator-controlled VOYAGE 1 trial. *Am J Clin Dermatol*. 2017;76(3):405-417.
5. Langley RG, Tsai TF, Flavin S, et al. Efficacy and safety of guselkumab in patients with psoriasis who have an inadequate response to ustekinumab: results of the randomized, double-blind, phase III NAVIGATE trial. Br J Dermatol 2018; 178:114.

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.