

**Tremfya® (guselkumab)
Effective 02/20/19**

| | | | |
|------------------------------|--|---------------------|---|
| Plan | <input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| Benefit | <input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> 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 an interleukin-23 blocker indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. (1)

Coverage Guidelines

Approval will be granted if the member meets the following criteria:

1. Member has a diagnosis of moderate-severe plaque psoriasis **AND**
2. Member is at least 18 years of age **AND**
3. Prescriber has provided documentation of ONE of the following:
 - a. Inadequate response, adverse reaction, or contraindication to at least TWO conventional therapies in any one of the following combinations (combinations DO NOT have to be used concurrently):
 - i. 1 topical agent + 1 systemic agent
 - ii. 1 topical agent + 1 phototherapy (required for diagnosis of guttate psoriasis)
 - iii. 1 systemic agent + 1 phototherapy
 - iv. 2 systemic agents
 - b. Contraindication to ALL conventional therapies
 - i. Topical agents
 - ii. Phototherapy
 - iii. Systemic agents
 - c. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for plaque psoriasis

AND

4. Dosing is appropriate (see appendix)



Continuation of Therapy

Reauthorization will be granted if documentation is submitted indicating a positive response to therapy

Limitations

1. Initial approvals will be granted for 3 months
2. Reauthorizations will be granted for up to 1 year

Appendix

| | |
|--------------------------|--|
| Tremfya® (guselkumab) | Plaque Psoriasis: SQ: 100 mg initially at week 0 and 4; followed by 100 mg every eight weeks |
|--------------------------|--|

References

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2017.
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

03/01/2018: Implemented

02/20/2019: Reviewed P&T Mtg

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.