

PHARMACY POLICY STATEMENT North Carolina Marketplace

DRUG NAME	Tremfya (guselkumab)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Tremfya (guselkumab) is an anti-psoriatic agent, interleukin-23 inhibitor, and monoclonal antibody initially approved by the FDA in 2017. It is currently FDA approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy and active psoriatic arthritis in adults. Plaque psoriasis is a skin disease that causes dry, raised, red patches covered with silvery scales on the skin, whereas psoriatic arthritis affects points where tendons and ligaments attach to bones- causing painful, sausage-like swelling of the fingers and toes.

Tremfya (guselkumab) will be considered for coverage when the following criteria are met:

PLAQUE PSORIASIS (PsO)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has tried and failed to respond to treatment with at least **one**
 6. **Member has tried and failed, or unable to tolerate a systemic biologic DMARD (i.e., cyclosporin, methotrexate, acitretin) for at least 12 weeks**
 7. **Dosage allowed/Quantity limit:** 100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter. Tremfya has a quantity limit of 1 syringe every 8 weeks after loading doses.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

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3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-1486.
4. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
5. Elmetts CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy [published correction appears in *J Am Acad Dermatol*. 2020 Mar;82(3):780]. *J Am Acad Dermatol*. 2019;81(3):775-804.
6. Menter A, Cordoro KM, Davis DM, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol* 2020;82:161-201
7. ClinicalTrials.gov. A Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants With Active Psoriatic Arthritis Including Those Previously Treated With Biologic Anti-Tumor Necrosis Factor (TNF) Alpha Agent(s) (Discover-1). Identifier: NCT03162796. Available at: <https://clinicaltrials.gov/ct2/show/NCT03162796>.
8. 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 Jan;71(1):5-32.
9. Gladman DD, Ritchlin C. Clinical manifestations and diagnosis of psoriatic arthritis. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed September 23, 2020.
10. Gladman DD, Ritchlin C. Treatment of psoriatic arthritis. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed September 23, 2020.
11. Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. *Arthritis Rheumatol*. 2016 May;68(5):1060-71.
12. Guselkumab: Drug information. In: Post TW, ed. UpToDate; 2022. Accessed February 22, 2022. https://www.uptodate.com/contents/guselkumab-drug-information?search=Tremfya&source=panel_search_result&selectedTitle=1~20&usage_type=panel&kp_tab=drug_general&display_rank=1#F50414379
13. Psoriatic arthritis. <https://www.mayoclinic.org/diseases-conditions/psoriatic->