Guselkumab (Tremfya®)	Place of Service **Self-Administration** *May be covered under the pharmacy benefit* **HCPCS**: **J1628** per 1 mg

Condition listed in policy (*see criteria for details*)

- Plaque psoriasis
- Psoriatic arthritis

AHFS therapeutic class: Antipsoriatic agent, systemic

Mechanism of action: anti-IL 23 monoclonal antibody

(1) Special Instructions and pertinent Information

Tremfya® is managed under the Outpatient Pharmacy Benefit. If the patient has a prescription drug benefit, please contact Blue Shield Pharmacy Services to obtain a prior authorization.

To submit a request to the medical benefit, please submit clinical information for prior authorization review via fax, including medical rationale why the patient cannot self-administer Tremfya® in the home.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Tremfya® (guselkumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Plaque psoriasis

1. Disease is moderate to severe, **AND**
2. Age ≥ 18 years of age, **AND**
3. Prescribed or recommended or by a dermatologist or rheumatologist, **AND**
4. One of the following:
    a. Baseline PASI score is 10 or more prior to starting biological therapy, OR
    b. Baseline BSA (body surface area) affected is 3% or more prior to starting biological therapy, OR
    c. Sensitive area is involved (i.e., groin, face, etc.), OR
    d. Disease is otherwise debilitating

    AND
5. Inadequate response, intolerable side effect, or contraindication to one of the following:
    a. Methotrexate, cyclosporine (Neoral), acitretin (Soriatane), OR
    b. PUVA or UVB treatment

    AND
6. Not used with Otezla or another targeted biologic

Covered Dose

Up to 100 mg SC at week 0, 4, then every 8 weeks thereafter

Coverage Period

Initial: 24 weeks

Reauthorization: Yearly if meets the following:

1. Not being used in combination with other targeted biologics, AND

2. One of the following:
    a. Improvement in PASI score from baseline, OR
    b. Improvement in BSA from baseline, OR
    c. Decrease in sensitive area disease severity, OR
    d. Decrease in debilitating disease severity

ICD-10:
L40.0-L40.9

Psoriatic arthritis

1. Diagnosed by a rheumatologist, **AND**
2. Inadequate response, intolerance, or contraindication to one or more disease modifying anti-rheumatic drugs (DMARDs) or has a medical reason why methotrexate, sulfasalazine, and leflunomide cannot be used, **AND**
3. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors, Otezla)

Covered Dose
Up to 100 mg SC at week 0, 4, then every 8 weeks thereafter

Coverage Period
Cover yearly, based upon continued response.

ICD-10:
L40.50-L40.59

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Tremfya® (guselkumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Rheumatoid arthritis

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How supplied:

- 100 mg/mL (single dose prefilled syringe or single dose One-Press patient-controlled injector)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

- Johnson & Johnson [Press Release]. Janssen Announces U.S. FDA Approval of Novel TREMFYA® (guselkumab) One-Press Patient-controlled Injector for Adults with Moderate-to-Severe Plaque Psoriasis. Updated February 27, 2019. Available at: https://www.jnj.com/janssen-announces-u-s-fda-approval-of-novel-tremfya-guselkumab-one-press-patient-controlled-injector-for-adults-with-moderate-to-severe-plaque-psoriasis. Accessed March 20, 2019.
- 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;80:1029-72.
- Tremfya® (guselkumab) [Prescribing information.] Horsham, PA. Janssen Biotech, Inc.; 7/2020.

(7) Policy Update

Date of last review: 4Q2022
Date of next review: 4Q2023
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee