blue california
Promise Health Plan

guselkumab (Tremfya IV)

Medical Benefit Drug Policy

Place of Service
Home Infusion
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: Interleukin-23 antagonist
HCPCS:
J1628:Injection, guselkumab, 1 mg
How Supplied:
200 mg/20 mL (10 mg/mL) solution in a single-dose vial

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

- Crohn's Disease, moderate to severe
- Ulcerative Colitis, moderate to severe

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Crohn's Disease, moderate to severe
Meets medical necessity if all the following are met:
1. Age is consistent with the FDA-approved indication
2. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a gastroenterologist
3. Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, integrin receptor antagonists, JAK inhibitors)

Covered Doses:
Induction: Up to 200 mg given intravenously at Week 0, Week 4, and Week 8

Maintenance with the subcutaneous formulation can be requested from your pharmacy benefit

Coverage Period:
Induction: 3 months
Maintenance with the subcutaneous formulation can be requested from your pharmacy benefit.

ICD-10:
K50.00-K50.119, K50.80-K50.919

Ulcerative Colitis, moderate to severe
Meets medical necessity if all the following are met:
1. Age is consistent with the FDA-approved indication
2. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a gastroenterologist
3. Not used in combination with a targeted immunomodulator (e.g., anti-TNFs, interleukin inhibitors, integrin receptor antagonists, JAK inhibitors, S1P modulators)

Covered Doses:
Induction: 200 mg given intravenously at Week 0, Week 4, and Week 8
Maintenance with the subcutaneous formulation can be requested from your pharmacy benefit.

Coverage Period:
Induction: 3 months
Maintenance with the subcutaneous formulation can be requested from your pharmacy benefit.

ICD-10:
K51.0-K51.319, K51.5-K51.519, K51.80-K51.919

References

1. Tremfya (guselkumab) Prescribing Information. Janssen Biotech, Inc., Horsham, PA. September 2025.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:
- Crohn's disease and ulcerative colitis: Added specialist requirement (Rationale: Ensure appropriate use)

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee