guselkumab (Tremfya IV)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Tremfya given as a subcutaneous injection: Refer to the "Self-Administered Drugs" Medical Benefit drug policy.

Tremfya given as an intravenous injection is managed under the Medical Benefit. Please submit clinical information for prior authorization review.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating therapy (allowed for the first 3 doses) with Tremfya or is being re-initiated on Tremfya after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Tremfya based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Tremfya based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

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