

Tremfya® Intravenous (guselkumab)

When requesting Tremfya® Intravenous (guselkumab), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Tremfya Intravenous is indicated for the treatment of adult patients with:

- moderately to severely active Crohn's disease
- moderately to severely active ulcerative colitis

Coverage Guidelines

Crohn's Disease

The individual must meet **all** of the following criteria for approval:

- Is 18 years of age or older;
- Tremfya intravenous will be used as induction therapy;
- Tremfya Intravenous is prescribed by or in consultation with a gastroenterologist.

Ulcerative Colitis

The individual must meet **all** of the following criteria for approval:

- Is 18 years of age or older;
- Tremfya Intravenous will be used as induction therapy;
- Tremfya Intravenous is prescribed by or in consultation with a gastroenterologist.

Approval duration: 3 months

Dosing Recommendation

The recommended induction dosage of Tremfya is 200 mg administered by intravenous infusion over at least one hour at Weeks 0, 4, and 8.

References

1. Tremfya® intravenous infusion, subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech/Johnson & Johnson; March 2025.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2025 June;120(6):1187-1224.
3. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024 Dec;167(7):1307-1343.

4. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2025 June;120(6):1225-1264.
5. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease. *Gastroenterology*. 2025 Dec;169(7):1397-1448.