

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;
- Meets one of the following:
 - o Has tried one other systemic agent for Crohn's disease (e.g., adalimumab, certolizumab pegol, infliximab, ustekinumab, risankizumab, 6-mercaptopurine, azathioprine, methotrexate); OR
Note: Mesalamine products do not count as systemic therapy.
 - o Has tried or is currently taking a systemic corticosteroid; OR
 - o Has a contraindication to a systemic corticosteroids; OR
 - o Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
 - o Had ileocolonic resection
- 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;
- Meets one of the following:
 - o Has tried one systemic therapy for ulcerative colitis (adalimumab, infliximab, golimumab, ustekinumab, risankizumab, azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus, corticosteroid); OR
Note: Mesalamine products do not count as a systemic therapy.

- o Has pouchitis and has tried an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema (e.g., hydrocortisone enema), or mesalamine enema;
- 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 Week 0, Week 4, and Week 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*. 2019;114(3):384-413.
3. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology*. 2020 Apr;158(5):1450-1461.
4. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2018;113(4):481-517.
5. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology*. 2021;160(7):2496-2508.