

Tremfya® Intravenous (guselkumab)

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

FDA-Approved indication

Induction treatment of ulcerative colitis

Coverage Guidelines

Ulcerative Colitis

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

- 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 (a biologic, azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus, corticosteroid); OR
Note: A trial of a mesalamine product or a biosimilar of the requested biologic do not count as a systemic therapy for ulcerative colitis.
 - 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 Recommendations

Administer 200 mg intravenously at Weeks 0, 4, and 8.

References

1. Tremfya® intravenous infusion, subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech/Johnson & Johnson; September 2024.
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 Apr158(5):1450-1461.