

Omvo[™] (mirikizumab-mrkz) Intravenous

When requesting Omvo[™] (mirikizumab-mrkz) intravenous, 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

Omvo is indicated for the treatment of:

- moderately to severely active ulcerative colitis in adults.
- moderately to severely active Crohn's disease in adults.

Coverage Guidelines

Ulcerative Colitis

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

- Is 18 years of age or older;
- Omvo intravenous is used as induction therapy;
- Meets one of the following:
 - Has tried one systemic agent for ulcerative colitis (e.g., adalimumab, infliximab, golimumab, ustekinumab, 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid); OR
 - Has pouchitis and tried one of the following: an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema (e.g., hydrocortisone enema), or mesalamine enema;
- Omvo is prescribed by or in consultation with a gastroenterologist.

Crohn's Disease

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

- Is 18 years of age or older;
- Omvo intravenous is used as induction therapy;
- Meets one of the following:
 - Has tried or is currently taking a systemic corticosteroid unless contraindicated; OR
 - Has tried one systemic therapy for Crohn's disease (e.g., adalimumab, certolizumab, infliximab, ustekinumab, azathioprine, 6-mercaptopurine, or methotrexate); OR
 - Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
 - Had ileocolonic resection;
- Omvo is prescribed by or in consultation with a gastroenterologist.

Approval duration: 3 months

Dosing Recommendations

Ulcerative Colitis

The recommended induction dosage is 300 mg administered by intravenous infusion over at least 30 minutes at Weeks 0, 4, and 8.

Crohn's Disease

The recommended induction dosage is 900 mg administered by intravenous infusion over at least 90 minutes at Weeks 0, 4, and 8.

References

1. Omvoh® intravenous infusion, subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; January 2025.
2. 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.
3. 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.
4. 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.
5. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.