

Omvo[™] (mirikizumab-mrkz) Intravenous

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

Omvo is indicated for the treatment of moderately to severely active ulcerative colitis 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:
 - o Has tried one systemic agent for ulcerative colitis (e.g., adalimumab, infliximab, golimumab, ustekinumab, 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid); OR
Note: a trial of a mesalamine product or a biosimilar of the requested biologic do not count as systemic therapy.
 - o 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.

Approval duration: 3 months

Dosing Recommendation

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

References

1. Omvo injection [prescribing information]. Indianapolis, IN: Eli Lilly; April 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 Apr;158(5):1450-1461.
4. D'Haens G, et al LUCENT Study Group. Mirikizumab as Induction and Maintenance Therapy for Ulcerative Colitis. *N Engl J Med*. 2023 Jun 29;388(26):2444-2455. doi: 10.1056/NEJMoa2207940.