

## PRIOR AUTHORIZATION POLICY

**POLICY:** Inflammatory Conditions – Omvoh Intravenous Prior Authorization Policy

- Omvoh<sup>®</sup> (mirikizumab-mrkz intravenous infusion – Eli Lilly)

**REVIEW DATE:** 12/04/2024

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### OVERVIEW

Omvoh intravenous, a monoclonal antibody against the p19 subunit of the interleukin (IL)-23 cytokine, is indicated for **induction treatment of ulcerative colitis (UC)**, in adults with moderate to severe active disease.<sup>1</sup>

In UC, a three-dose induction regimen (300 mg at Weeks 0, 4, and 8) is administered by intravenous (IV) infusion.<sup>1</sup> Following induction therapy with the IV product, the recommended maintenance dose is Omvoh 200 mg administered as a subcutaneous injection administered at Week 12 (4 weeks following the last induction dose), then once every 4 weeks thereafter.

### Guidelines

Current guidelines do not address the use of Omvoh for UC. The American Gastroenterological Association (2020) and the American College of Gastroenterology (2019) have clinical practice guidelines on the management of moderate to severe UC and make recommendations for the use of biologics for induction and maintenance of remission in adults.<sup>2,3</sup> Generally TNF inhibitors, Entyvio<sup>®</sup> (vedolizumab IV infusion/subcutaneous injection), Stelara<sup>®</sup> (ustekinumab IV infusion/subcutaneous injection), or Xeljanz<sup>®</sup>/Xeljanz<sup>®</sup> XR (tofacitinib tablets, tofacitinib extended-release tablets) are recommended for induction treatment of moderate to severe disease (strong recommendations, moderate quality of evidence). The guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Omvoh IV. Because of the specialized skills required for evaluation and diagnosis of patients treated with Omvoh IV as well as the monitoring required for adverse events and long-term efficacy, approval requires Omvoh IV to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for three months, which is an adequate duration for the patient to receive three doses.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Omvoh intravenous is recommended in those who meet the following criteria:

### FDA-Approved Indication

1. **Ulcerative Colitis.** Approve three doses for induction if the patient meets ALL of the following (A, B, C, and D):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) The medication will be used as induction therapy; AND
  - C) Patient meets ONE of the following (i or ii):
    - i. Patient has tried one systemic therapy; OR  
Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for ulcerative colitis.
    - ii. Patient meets BOTH of the following (a and b):
      - a) Patient has pouchitis; AND
      - b) Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND  
Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.
  - D) The medication is prescribed by or in consultation with a gastroenterologist.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Omvoh intravenous is not recommended in the following situations:

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.  
Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Omvoh® intravenous infusion, subcutaneous 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.

**APPENDIX**

**APPENDIX (CONTINUED)**

\* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.