

PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Omvoh Subcutaneous Prior Authorization Policy

- Omvoh® (mirikizumab-mrkz subcutaneous injection – Eli Lilly)

REVIEW DATE: 11/08/2023

OVERVIEW

Omvoh subcutaneous injection, a monoclonal antibody against the p19 subunit of the interleukin (IL)-23 cytokine, is indicated for the **maintenance treatment of ulcerative colitis (UC)**, in adults with moderate to severe active disease.¹

In UC, a three-dose induction regimen (300 mg at Weeks 0, 4, and 8) is administered by IV infusion.¹ Following induction therapy with the IV product, the recommended maintenance is Omvoh subcutaneous injection, given as a 200 mg 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.^{2,3} Generally TNF inhibitors, Entyvio® (vedolizumab intravenous infusion/subcutaneous injection), Stelara® (ustekinumab intravenous infusion/subcutaneous injection), or Xeljanz®/Xeljanz® 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 subcutaneous. Because of the specialized skills required for evaluation and diagnosis of patients treated with Omvoh subcutaneous as well as the monitoring required for adverse events and long-term efficacy, approval requires Omvoh subcutaneous to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Omvoh subcutaneous is recommended in those who meet one of the following:

FDA-Approved Indication

1. **Ulcerative Colitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) **Initial Therapy.** Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
 - i. Patient is \geq 18 years of age; AND
 - ii. According to the prescriber, the patient will receive three induction doses with Omvoh intravenous within 3 months of initiating therapy with Omvoh subcutaneous; AND
 - iii. Patient meets ONE of the following (a or b):
 - a) Patient has had a trial of one systemic agent for ulcerative colitis; OR
Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, 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 drug 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.
 - b) Patient meets BOTH of the following [(1) and (2)]:
 - (1) Patient has pouchitis; AND
 - (2) 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.
 - iv. The medication is prescribed by or in consultation with a gastroenterologist; OR
 - B) **Patient is Currently Receiving Omvoh Subcutaneous.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
 - i. Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least one of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
 - b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Omvoh should not be administered in combination with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see [Appendix](#) for examples). Data are lacking evaluating concomitant use of Omvoh with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects and lack of controlled data supporting additive efficacy. Note: This does NOT exclude the use of conventional agents (e.g., methotrexate, 6-mercaptopurine, azathioprine, and sulfasalazine) in combination with Omvoh.

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 injection [prescribing information]. Indianapolis, IN: Eli Lilly; October 2023.
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

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). 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; TYK2 – Tyrosine kinase 2.