CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Omvoh (mirikizumab-mrkz)
BENEFIT TYPE	Medical or Pharmacy
STATUS	Prior Authorization Required

Omvoh, initially approved by the FDA in 2023, is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults. IL-23 is involved in mucosal inflammation and affects the differentiation, expansion, and survival of T cell subsets, and innate immune cell subsets, which represent sources of pro-inflammatory cytokines Omvoh inhibits the release of pro-inflammatory cytokines and chemokines.
Ulcerative colitis is a type of inflammatory bowel disease (IBD) in which the colon becomes inflamed. Symptoms include abdominal pain, frequent bowel movements, and bloody or pus-filled diarrhea. The pattern of disease activity is characterized by periods of active inflammation alternating with periods of remission.

Omvoh (mirikizumab-mrkz) will be considered for coverage when the following criteria are met:

Ulcerative Colitis

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a diagnosis of moderately to severely active UC; AND
4. Member must have a documented trial and inadequate response with **ONE** of the following:
   a) 3 months of 6-mercaptopurine or azathioprine;
   b) 30 days of a corticosteroid (e.g., budesonide, prednisone, methylprednisolone);
   c) 3 months of 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.); AND
5. Member has had a trial of a tumor necrosis factor inhibitor (e.g., Remicade, Humira, Cimzia); AND
6. Member has baseline liver function tests completed or scheduled; AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:**
   a) Induction: 300 mg administered by intravenous infusion over at least 30 minutes at Week 0, Week 4, and Week 8.
   b) Maintenance: 200 mg administered by subcutaneous injection at Week 12, and then every 4 weeks. Quantity Limit: 2 mL per 28 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided showing an improvement in signs and symptoms of disease such as clinical remission, reduced rectal bleeding, decreased stool frequency, or endoscopic-histologic mucosal healing.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Omvoh (mirikizumab-mrkz) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/03/2023	New policy for Omvoh created.

References:

1. Omvoh [prescribing information]. Indianapolis, IN: Eli Lilly and Company; 2023.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. 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;158(5):1450-1461
4. Sands BE, Schreiber S, Blumenstein I, Chiorean MV, Ungaro RC, Rubin DT. Clinician's Guide to Using Ozanimod for the Treatment of Ulcerative Colitis [published online ahead of print, 2023 Jul 12]. *J Crohns Colitis.* 2023;jjad112. doi:10.1093/ecco-jcc/jjad112
5. Raine T, Bonovas S, Burisch J, et al. ECCO Guidelines on Therapeutics in Ulcerative Colitis: Medical Treatment. *J Crohns Colitis*. 2022;16(1):2-17. doi:10.1093/ecco-jcc/jjab178

Effective date: 04/01/2024
Revised date: 11/03/2023