

PHARMACY POLICY STATEMENT

Marketplace

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 must have a trial and failure of **TWO** preferred biologic DMARD therapies (see appendix); 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.
03/12/2024	Replaced TNfi trial with trial of two preferred biologics and added appendix.

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: 03/12/2024

Appendix: Preferred Biologic Products	
Approved for Rheumatoid Arthritis	<ul style="list-style-type: none"> • Actemra (<i>requires step through adalimumab</i>) • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Juvenile Idiopathic Arthritis	<ul style="list-style-type: none"> • Actemra (<i>requires step through Humira</i>) • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Ankylosing Spondylitis	<ul style="list-style-type: none"> • Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Rinvoq
Approved for Non-radiographic Axial	<ul style="list-style-type: none"> • Cimzia • Cosentyx
Approved for Atopic Dermatitis	<ul style="list-style-type: none"> • Rinvoq
Approved for Psoriatic Arthritis	<ul style="list-style-type: none"> • Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Otezla • Skyrizi • Stelara • Tremfya

<p>Approved for Psoriasis</p>	<ul style="list-style-type: none"> • Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Otezla • Skyrizi • Stelara • Tremfya
<p>Approved for Crohn's Disease</p>	<ul style="list-style-type: none"> • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Stelara
<p>Approved for Ulcerative Colitis</p>	<ul style="list-style-type: none"> • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Stelara • Rinvoq