CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

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

Omvoh, approved by the FDA in 2023, is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD) 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.
CD and UC are inflammatory bowel diseases. CD can affect any part of the GI tract whereas UC only affects the large intestine (colon and rectum). CD can affect the entire thickness of the bowel wall whereas UC only affects the inner-most lining.

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.

Crohn's Disease (CD)

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 CD; AND
4. Member has had a documented trial and inadequate response, or intolerance to **ONE** of the following conventional therapies:
   a) Corticosteroid;
   b) 6-mercaptopurine, azathioprine, or methotrexate;
   c) Biologic with CD indication; 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: 900 mg administered by intravenous infusion at week 0, week 4 and week 8.
   b) Maintenance: 300 mg administered subcutaneously (given as two consecutive injections of 100 mg and 200 mg in any order) at week 12 and every 4 weeks thereafter. Quantity limit: 3 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 improved endoscopic response, fewer flare-ups of symptoms, improved quality of life, etc.

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.
02/14/2025	Updated references. New indication for CD added.

References:

1. Omvoh [prescribing information]. Indianapolis, IN: Eli Lilly and Company; 2025.
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. *J Crohns Colitis.* 2023;17(12):2012-2025. 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

6. Vasudevan A, Gibson PR, van Langenberg DR. Time to clinical response and remission for therapeutics in inflammatory bowel diseases: What should the clinician expect, what should patients be told? *World J Gastroenterol.* 2017;23(35):6385-6402. doi:10.3748/wjg.v23.i35.6385
7. Gordon H, Minozzi S, Kopylov U, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. *J Crohns Colitis.* 2024;18(10):1531-1555. doi:10.1093/ecco-jcc/jjae091
8. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology*. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022

Effective date: 07/01/2025
Revised date: 02/14/2024

Appendix: Preferred Biologic Products	
Approved for Rheumatoid Arthritis	• Actemra *(requires step through adalimumab)* • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Juvenile Idiopathic Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Ankylosing Spondylitis	• Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Rinvoq
Approved for Non-radiographic Axial	• Cimzia • Cosentyx
Approved for Atopic Dermatitis	• Rinvoq
Approved for Psoriatic Arthritis	• Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Psoriasis	• Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Crohn’s Disease	• Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Stelara
Approved for Ulcerative Colitis	• Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Stelara

	• Rinvoq