Original Effective Date: 01/31/2024
Current Effective Date: 01/31/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 10/2024
Policy Number: C27293-A

Omvoh (mirikizumab-mrkz)

PRODUCTS AFFECTED

Omvoh (mirikizumab-mrkz)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderately to severely active ulcerative colitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ULCERATIVE COLITIS:
1. Documentation of ulcerative colitis diagnosis with evidence of moderate to severe disease activity
   AND

2. (a) Documentation of treatment failure, serious side effects or clinical contraindication to a 2-month trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone) for ulcerative colitis or will continue to take concurrently.
   NOTE: A previous trial of a biologic (e.g., an adalimumab product [e.g., Humira], Simponi SC [golimumab SC injection], or Entyvio [vedolizumab IV infusion]) also counts as a trial of one systemic agent for UC
   OR
   b) The Member has pouchitis AND has tried therapy with an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema [for example, Cortenema® (hydrocortisone enema, generics)], or topical mesalamine
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
4. FOR INITIAL SC THERAPY: The member has received three induction doses with Omvoh IV within 4 weeks of initiating Omvoh SC
   AND
5. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
   AND
6. Member is not on concurrent treatment or will not be used in combination with TNF-inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
   AND
7. Prescriber attests member does not have an active infection, including clinically important localized infections
   AND
8. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. ULCERATIVE COLITIS:
   1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
      AND
   2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
      AND

3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
   AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
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   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified gastroenterologist or colorectal surgeon [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
Induction dosing: 300 mg by intravenous infusion over at least 30 minutes at Week 0, Week 4, and Week 8
Maintenance dosing: 200 mg by subcutaneous injection (given as two consecutive injections of 100 mg each) at Week 12 and every 4 weeks thereafter

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous (induction dosing), Subcutaneous (maintenance dosing)

DRUG CLASS:
Interleukin Antagonists

FDA-APPROVED USES:
Treatment of moderately to severely active ulcerative colitis in adults

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information

Texas Marketplace

Texas (Source: Texas Statutes, Insurance Code)

"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.

(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.

(b) This section does not apply to:

(1) opioids, benzodiazepines, barbiturates, or carisoprodol;

(2) prescription drugs that have a typical treatment period of less than 12 months;

(3) drugs that:

(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and

(B) must have specific provider assessment; or

(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Ulcerative colitis (UC) is a chronic inflammatory bowel disease (IBD) characterized by a relapsing and remitting course, typically emerging in early adulthood. Predominantly affecting the rectum, UC inflammation may extend to other parts of the colon, manifesting symptoms such as diarrhea, rectal bleeding, abdominal pain, fatigue, and weight loss during active disease. While the majority of UC cases exhibit a mild to moderate course, approximately 15% may experience an aggressive form, with 20% of those requiring hospitalization for severe disease. The primary treatment objective is to induce and sustain remission, aiming to prevent long-term disease progression.

Treatment decisions hinge on various factors, including disease extent and severity, presence of extraintestinal manifestations, age, comorbidities, and patient preferences (e.g., route and frequency of administration). Initial therapy for mild to moderate UC involves oral and/or topical 5-aminosalicylic acid therapies (5-ASAs). Moderate to severe UC management offers a range of options, encompassing conventional therapies (thiopurines and corticosteroids) and advanced therapies (e.g., tumor necrosis factor [TNF] antagonists, interleukin antagonist, anti-integrin, Janus kinase [JAK] inhibitors, sphingosine-1-phosphate [S1P] modulators).

The current treatment guidelines include the 2020 AGA and 2019 ACG. The 2020 AGA guidelines recommend prescribing outpatient adults with moderate to severe UC with infliximab, adalimumab, golimumab, vedolizumab, tofacitinib, or ustekinumab over no treatment for the induction and maintenance of remission.

The 2019 ACG guidelines recommend patients with moderately active UC, non-systemic corticosteroids such as budesonide MMX before the use of systemic therapy. Patients with severely active UC should consider systemic corticosteroids rather than topical corticosteroids.

Omvoh (mirikizumab-mrkz) secured FDA approval on October 26, 2023, as the first UC treatment selectively targeting the p19 subunit of IL-23, implicated in UC-related inflammation. Distinguishing itself from Stelara (ustekinumab) as Omvoh exclusively targets IL-23, not IL-12. The approval followed a

complete response letter (CRL) issued by the FDA in April 2023, solely related to Omvoh's proposed manufacturing, without concerns regarding clinical data, safety, or proposed labeling.

Omvoh's safety and efficacy were assessed in two randomized, double-blind, placebo-controlled clinical studies: LUCENT-1, an induction study, and LUCENT-2, a maintenance study. These trials included adult patients with moderately to severely active UC who had an inadequate response, loss of response, or intolerance to corticosteroids, 6-mercaptopurine, azathioprine, biologic therapy (TNF blocker, vedolizumab), or tofacitinib.

The evaluation of bowel urgency in both LUCENT-1 and LUCENT-2 utilized the Urgency Numeric Rating Scale (NRS), a patient-reported scale ranging from 0 to 10. This 11-point scale measures bowel urgency over the past 24 hours, with 0 indicating no urgency and 10 representing the worst possible urgency. Clinical Meaningful Improvement (CMI) in bowel urgency is defined as a ≥3-point improvement in Urgency NRS for patients with a baseline Urgency NRS ≥3. Bowel urgency remission is achieved when the Urgency NRS score is 0 or 1 (no or minimal urgency) in patients with a baseline Urgency NRS ≥3. At Week 40, a higher percentage of patients with a baseline Urgency NRS weekly average score ≥3, treated with Omvoh compared to placebo, reported a weekly average score of 0 or 1 (39% vs. 23%). Additionally, a greater proportion of patients treated with Omvoh, compared to placebo, exhibited Urgency NRS weekly average scores of 0 to 1 at Week 12.

In LUCENT-1, adverse drug reactions (ADRs) reported in at least 2% of patients and at a higher frequency than placebo included upper respiratory tract infections and arthralgia. In LUCENT-2, ADRs reported in at least 2% of patients and at a higher frequency than placebo included upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection. Patients receiving Omvoh experienced more frequent elevations in liver enzymes compared to those receiving placebo. Monitoring liver enzymes and bilirubin levels at baseline and for at least 24 weeks of treatment is recommended.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Omvoh (mirikizumab-mrkz) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Omvoh (mirikizumab-mrkz) include: history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients, active TB infections, avoid use of live vaccines.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J3590	Unclassified biologics (Omvoh)

AVAILABLE DOSAGE FORMS:
Omvoh SOLN 300MG/15ML single-dose vial
Omvoh SOAJ 100MG/ML single-dose prefilled pen

REFERENCES

1. Omvoh (mirikizumab-mrkz) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; October 2023.
2. Feuerstein, J., Isaacs, K., Schneider, Y., Siddique, S., Falck-Ytter, Y., & Singh, S. et al. (2020). AGAClinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology, 158(5), 1450-1461. Doi: 10.1053/j.gastro.2020.01.006
3. Rubin, David T. MD, FACG1; Ananthakrishnan, Ashwin N. MD, MPH2; Siegel, Corey A. MD, MS3; Sauer, Bryan G. MD, MSc (Clin Res), FACG (GRADE Methodologist)4; Long, Millie D. MD, MPH, FACG5. ACG Clinical Guideline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology 114(3):p 384-413, March 2019. | DOI: 10.14309/ajg.0000000000000152
4. An Induction Study of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT 1). https://clinicaltrials.gov/study/NCT03518086
5. A Maintenance Study of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT 2). https://clinicaltrials.gov/study/NCT03524092
6. A Study to Evaluate the Long-Term Efficacy and Safety of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT 3). https://clinicaltrials.gov/study/NCT03519945
7. D'Haens, Geert R, et al. "Mirikizumab as Induction and Maintenance Therapy for Ulcerative Colitis." NEJM, vol. 388, no. 26, 29 June 2023, pp. 2444–2455, https://doi.org/10.1056/nejmoa2207940.
8. Dubinsky, Marla C, et al. "Clinical Effect of Mirikizumab Treatment on Bowel Urgency in Patients with Moderately to Severely Active Ulcerative Colitis and the Clinical Relevance of Bowel Urgency Improvement for Disease Remission." Crohn's & Colitis 360, vol. 5, no. 1, 13 Dec. 2022, academic.oup.com/crohnscolitis360/article/5/1/otac044/6890447, https://doi.org/10.1093/crocol/otac044.
9. Feuerstein, Joseph D., et al. "AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis." Gastroenterology, vol. 158, no. 5, Jan. 2020, https://doi.org/10.1053/j.gastro.2020.01.006.
10. Magro, Fernando, et al. "Resolving Histological Inflammation in Ulcerative Colitis with Mirikizumab in the LUCENT Induction and Maintenance Trial Programmes." Journal of Crohn's and Colitis, 14 Apr. 2023, https://doi.org/10.1093/ecco-jcc/jjad050.

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA DEVELOPMENT	Q1 2024