Omvoh® (mirikizumab-mrkz) (Intravenous and Subcutaneous)

Effective Date: 05/01/2024
Review Date: 02/08/2024
Pharmacy Scope (subcutaneous formulation only): Medicaid
Medical Scope (intravenous formulation only): Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

- **Medical Scope:**
  - Coverage for intravenous (IV) Omvoh will provided once for 12 weeks (for 3 IV doses) and may not be renewed.

    ** For members that meet criteria, Omvoh 200 mg (subcutaneous dose) will be approved for every 4 weeks thereafter for 4 months for Medicaid and Commercial ONLY**
- **Pharmacy Scope:**
  - Coverage for subcutaneous (SC) Omvoh will be provided for 6 months and may be renewed for 6 months.

II. Dosing Limits

A. Medical Scope: Intravenous

- **Quantity Limit (max daily dose) [NDC Unit]:**
  - Omvoh 300 mg/15 mL single-dose vial: 1 vial at Weeks 0, 4 & 8 (3 vials total)
- **Max Units (per dose and over time) [HCPS Unit]:**
  - 900 mg per 90 days

B. Pharmacy Scope: Subcutaneous

- **Quantity Limit (max daily dose) [NDC Unit]:**
  - Omvoh 100 mg/mL pen injection: 2 pens per 28 days (daily dose of 0.072)

III. Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
B. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

IV. Summary of Evidence

Omvoh (mirikizumab-mrkz) is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults. The safety and efficacy of Omvoh was evaluated in two randomized, double-blind, placebo-controlled, Phase 3 clinical trials consisting of a 12-week induction study, LUCENT-1 (n=1062), and a 40-week maintenance study, LUCENT-2 (n=506), with primary endpoints of clinical remission. In LUCENT-1, adults with moderately to severely active ulcerative colitis who had inadequate response, loss of response, or failed to tolerate conventional or biologic therapy were randomized 3:1 at Week 0 to receive 300 mg IV Omvoh or placebo at Week 0, Week 4, and Week 8. At Week 12, 24% of patients achieved clinical remission compared to 15% in the placebo group (treatment difference 10% [95% CI: 5,15; P <0.001]). Patients with clinical response to induction in LUCENT-1 progressed into LUCENT-2. In LUCENT-2, patients were randomized 2:1 to receive 200 mg SC Omvoh or placebo every 4 weeks for 40 weeks, for a total of 52 weeks of treatment. 51% of patients in the Omvoh group achieved clinical remission compared to 27% in the placebo group (treatment difference 22% [95% CI: 14,31; P <0.001]). The most common adverse reactions for both IV and SC formulations of Omvoh (≥ 2%) are upper respiratory tract infections, and arthralgia. In addition, common adverse reactions for Omvoh SC include injection site reactions, rash, headache, and herpes viral infection.

V. Initial Approval Criteria

Coverage is provided in the following conditions:

For all indications:

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; **AND**
- Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *[Note: Members who have received another biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.]*; **AND**
- Member is free of any clinically important active infection, including clinically important localized infections; **AND**
- Member will not receive live vaccines during therapy; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Baseline liver enzymes and bilirubin levels have been obtained prior to initiating therapy
- Omvoh will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), Simponi (golimumab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), Stelara (ustekinumab), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab)„ etc.) or other oral non-biologic agent (e.g., Otezla (apremilast),

Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Velsipity (etrasimod), etc.)

A. Moderately to severely active ulcerative colitis (UC)

Authorization may be granted for treatment of moderately to severely active UC when all of the following criteria are met:

- Member is 18 years of age or older; **AND**
- This medication must be prescribed by or in consultation with a gastroenterologist; **AND**
- Documented moderate to severe UC (e.g., Mayo Clinical Score 6-12, with Mayo Endoscopic Subscore 2 or 3); **AND**
- Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of one conventional therapy option (e.g., mesalamine, corticosteroids, 6-mercaptopurine, or azathioprine) at maximum tolerated doses; **AND**
- Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses; **AND**
- Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of Entyvio, except if the member has failed to respond to infliximab; **AND**
- Coverage will not be provided in the following circumstances:
  - Member has Crohn's disease or IBD-unclassified
  - Member has previous bowel resection or intestinal or intra-abdominal surgery
  - Member has current evidence of toxic megacolon, intra-abdominal abscess or stricture/stenosis

VI. Renewal Criteria

Authorization of 6 months may be granted for all members (including new members) when all of the following criteria are met:

- Member continues to meet all initial authorization criteria; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: anaphylaxis or other serious allergic reactions, severe infections, jaundice or other evidence of significant liver injury, etc.; AND
- Member has annual eye exams to monitor for macular edema; AND
- Member is using the requested medication for moderate to severe active ulcerative colitis and one of the following must apply:
  - Member has achieved or maintained remission; OR

- Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    a. Stool frequency
    b. Rectal bleeding
    c. Urgency of defecation
    d. C-reactive protein (CRP)
    e. Fecal calprotectin (FC)
    f. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
    g. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

VII. Dosage/Administration

Indication	Dose
Moderately to severely active ulcerative colitis (UC)	• IV- Induction dosage is 300 mg administered by intravenous infusion over at least 30 minutes at Weeks 0, 4, and 8. • SC- Maintenance dosage is 200 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg each) at Week 12, and every 4 weeks thereafter.
- The vial and prefilled pen are not made with dry natural rubber latex. - OMVOH (mirikizumab-mrkz) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow to slightly brown solution for intravenous infusion or subcutaneous injection. - Each single-dose prefilled pen consists of a 1 mL glass syringe with a fixed 27-gauge ½ inch needle.	

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD)

Policy Rationale:

Omvoh was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Omvoh according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are

using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

VIII. Billing Code/Availability Information

HCPCS:

- C9168 – Injection, mirikizumab-mrkz, 1 mg

NDC:

- OMVOH (mirikizumab-mrkz) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow to slightly brown solution for intravenous infusion or subcutaneous injection.: 0002-7575-01

IX. References

1. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company; October 2023.