Omvoh® (mirikizumab-mrkz)
(Intravenous)

Effective Date: 05/01/2024
Review Date: 02/08/2024, 07/17/2024, 1/22/2025, 5/14/2025
Pharmacy Scope (subcutaneous formulation only): Medicaid
Medical Scope (intravenous formulation only): Medicaid, Commercial, Medicare

I. Length of Authorization

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

      ** For members that meet criteria, subcutaneous Omvoh 200 mg for ulcerative colitis or Omvoh 300 mg for Crohn's disease 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

- **Max Units (per dose and over time) [HCPS Unit]:**
    - Ulcerative Colitis:
        1. Induction Dose: 300 mg or 300 units at Weeks 0, 4, & 8
    - Crohn's Disease:
        1. Induction Dose: 900mg or 900 units at Weeks 0, 4, & 8

B. Pharmacy Scope: Subcutaneous

- **Quantity Limit (max daily dose) [NDC Unit]:**
    - Ulcerative Colitis:
        1. Omvoh 100 mg/mL pen injection: 2 pens per 28 days (daily dose of 0.072)
    - Crohn's Disease:
        1. Omvoh 300 mg/mL pen injection: 1 carton (containing one 200 mg/2 mL and one 100 mg/mL pen per carton) per 28 days (daily dose of 0.108)

III. Summary of Evidence

Omvoh (mirikizumab-mrkz) is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease in adults. The safety

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and efficacy of Omvoh in ulcerative colitis 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]). The safety and efficacy of Omvoh in Crohn's disease was evaluated in a randomized, double-blind, placebo-controlled study, CD-1 (n = 679), a 52-week study with primary endpoints of clinical remission. In CD-1, adult patients with moderately to severely active Crohn's disease who had an inadequate response, loss of response, or intolerance to corticosteroids, immunomodulators, and/or biologics were randomized 3:1 to receive Omvoh 900mg by IV infusion at Week 0, Week 4, and Week 8 followed by a dosage of 300mg by subcutaneous injection at Week 12 and then every 4 weeks for 40 weeks, or placebo. At Week 52, 53% of patients achieved clinical remission compared to 36% in the placebo group (treatment difference 17% [95% CI: 9, 25; P<0.001). In patients with ulcerative colitis, 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.In patients with Crohn's disease, the most common adverse reactions (≥5%) are upper respiratory tract infections, injection site reactions, headache, arthralgia, and elevated liver tests

IV. Initial Approval Criteria

Coverage of IV Omvoh is provided in the following conditions:

For all indications:

Medicare 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

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- 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), ustekinumab (e.g., Stelara, Wevlana, etc.) 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
- Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses; **AND**
- Member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab at maximum tolerated doses

B. Moderately to severely active Crohn's disease (CD)

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

- Prescribed by, or in consultation with, a specialist in gastroenterology
- Documented moderate to severe active disease
- Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses
- Member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses

V. Renewal Criteria

Ulcerative Colitis:

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

- 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 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:

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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)

Crohn's Disease:

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

- 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 is using the requested medication for moderate to severely active Crohn's disease 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. Abdominal pain or tenderness
    b. Diarrhea
    c. Body weight
    d. Abdominal mass
    e. Hematocrit
    f. Endoscopic appearance of the mucosa
    g. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

VI. 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.
Moderately to severely active Crohn's disease (CD)	• IV- Induction dosage is 900 mg administered by intravenous infusion over at least 90 minutes at Weeks 0, 4, and 8.

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	• SC- Maintenance dosage is 300 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg and 200 mg in any order) 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 100 mg/mL single-dose prefilled pen or prefilled syringe consists of a 1 mL glass syringe with a fixed 27-gauge ½ inch needle. - Each 200 mg/2 mL single-dose prefilled pen or 200 mg/2 mL (100 mg/mL) prefilled syringe consists of a 2 mL glass syringe with a fixed 27-gauge 8 mm needle.	

Per §§ 42 CFR 422.101, this clinical medical policy only applies to Medicare 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 Medicare 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.

VII. Billing Code/Availability Information

HCPCS:

- J2267 – 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
- For ulcerative colitis and Crohn's disease induction: 0002-7575-01
- For ulcerative colitis maintenance: 0002-8011- 27, 0002-8870- 27
- For Crohn's disease maintenance: 0002-7717- 11, 0002-7722- 11

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VIII. References

1. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company; January 2025.Accessed May 2025.

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