AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Omvoh (mirikizumab-mrkz)	Page:	1 of 3
Effective Date:	1/30/2025	Last Review Date:	01/08/2024; 4/2024; 12/2024
Applies to:	☐Illinois ☒Maryland ☐Michigan	☐Florida ☒Florida Kids ☐Virginia	☒New Jersey ☒Pennsylvania Kids ☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Omvoh under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

Omvoh is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

All other indications are considered experimental/investigational and not medically

Applicable Drug List:

Non-preferred: Omvoh

Policy/Guideline:

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Documentation

The patient is unable to take a preferred adalimumab product and Rinvoq, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

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

- Chart notes or medical record documentation supporting positive clinical response to therapy or remission

Prescriber Specialties
This medication must be prescribed by or in consultation with a gastroenterologist

Criteria for Initial Approval:
Authorization may be granted for adult members for treatment of moderately to severely active ulcerative colitis

Criteria for Continuation of Therapy:
A. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

B. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain 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:
    1. Stool frequency
    2. Rectal bleeding
    3. Urgency of defecation
    4. C-reactive protein (CRP)
    5. Fecal calprotectin (FC)
    6. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
    7. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 Months

Quantity Level Limit:

Medication	Standard Limit	FDA-recommended dosing
Omvoh (mirikizumab-mrkz)	3 vials per 56 days	

Medication	Standard Limit	FDA-recommended dosing
300 mg/15 mL single-dose vial		Induction dose: 300 mg administered by intravenous infusion over at least 30 minutes at Weeks 0, 4, and 8. Maintenance dose: 200 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg each) at Week 12, and every 4 weeks thereafter.
Omvoh (mirikizumab-mrkz) subcutaneous injection 100 mg/mL single-dose prefilled pen/syringe	1 carton per 28 days	

References:

1. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company.; October 2023.
2. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 5, 2023 from: https://www.cdc.gov/tb/topic/basics/risk.htm.
3. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.
4. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114:384-413.
5. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology.* 2020; 158:1450.