AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Omvoh (mirikizumab-mrkz)	Page:	1 of 4
Effective Date:	5/1/2025	Last Review Date:	01/08/2024; 4/2024; 12/2024; 4/2025
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
- Treatment of moderately to severely active Crohn's disease in adults

All other indications are considered experimental/investigational and not medically

Applicable Drug List:

Non-preferred: Omvoh

Policy/Guideline:

Documentation
The patient is unable to take TWO preferred products (a preferred adalimumab product, a preferred ustekinumab product, 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:
Ulcerative colitis (UC) and Crohn's disease (CD):

- Continuation requests: 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:
Ulcerative colitis (UC)
Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

Crohn's disease (CD)
Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

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

Authorization of 12 months may be granted for all 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:

- Stool frequency
- Rectal bleeding
- Urgency of defecation
- C-reactive protein (CRP)
- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Crohn's disease (CD)
Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease 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:

- Abdominal pain or tenderness
- Diarrhea
- Body weight
- Abdominal mass
- Hematocrit
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 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.

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 Months

Quantity Level Limit:

Medication	Standard Limit
Omvoh (mirikizumab-mrkz) 300 mg/15 mL singledose vial	9 vials per 56 days
Omvoh (mirikizumab-mrkz) subcutaneous injection 100 mg/mL single-dose prefilled pen/syringe	1 carton (2 pens/syringes) per 28 days

Omvoh (mirikizumab-mrkz) subcutaneous injection 200 mg/2 mL single-dose prefilled pen/syringe and 100 mg/mL single-dose prefilled pen/syringe	1 carton (2 pens/syringes) per 28 days

FDA-Recommended Dosing:

Ulcerative colitis

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.

Crohn's disease

Induction dose

900 mg administered by intravenous infusion over at least 90 minutes at Weeks 0, 4, and 8.

Maintenance dose

300 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg and 200 mg) at Week 12, and every 4 weeks thereafter.

References:

1. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company; January 2025.
2. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on January 21, 2025 from: https://www.cdc.gov/tb/testing/index.html.
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, Siegel CA, 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.
6. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113:481-517.
7. 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;160:2496-2508.