Omvoh (Mirikizumab-mrkz)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Omvoh drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Adalimumab-aacf, Enbrel, Entyvio, Cosentyx, Otezla, Rinvoq, Simponi, Skyrizi, Otulfi (Ustekinumab-aauz), Tremfya, Velsipity, and Xeljanz/Xeljanz XR are the preferred products and will apply to members requesting treatment for an indication that is FDA-approved for the preferred product. The criteria will require the use of two of the health plan's preferred products before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome, or there is only one preferred product for an indication.

FDA-Approved Indications

1. Treatment of moderately to severely active ulcerative colitis in adults
2. Treatment of moderately to severely active Crohn's disease in adults

POLICY

Documentation

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

A) **Ulcerative Colitis (UC)**

1. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

B) **Crohn's Disease (CD)**
   1. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

A) Ulcerative Colitis
   1. Criteria for initial approval for ulcerative colitis will only apply when at least ONE of the following criteria are met:
      i. Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Adalimumab-aacf, Entyvio, Rinvoq, Simponi, Skyrizi, Otulfi [Ustekinumab-aauz] , Velsipity, Tremfya, and Xeljanz/Xeljanz XR)
      ii. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

B) Crohn's Disease
   1. Criteria for initial approval for Crohn's disease will only apply when at least ONE of the following criteria are met:
      i. Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Adalimumab-aacf, Entyvio, Rinvoq, Simponi, Skyrizi, Tremfya, and Otulfi [Ustekinumab-aauz])
      ii. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

Prescriber Specialties (initial approvals only)

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

Criteria for Initial Approval

A) Ulcerative colitis (UC)
   1. Authorization of 12 months may be granted for the treatment of moderately to severely active ulcerative colitis.

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

Continuation of Therapy

A) Ulcerative colitis (UC)
   1. 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.
   2. 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:
      i. Stool frequency

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

B) Crohn's Disease (CD)

1. 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.
2. 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:
   i. Abdominal pain or tenderness
   ii. Diarrhea
   iii. Body weight
   iv. Abdominal mass
   v. Hematocrit
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Other

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* 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. 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.

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

Omvoh is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary

Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Trade Name	Generic Name	Quantity Limit
Omvoh™	Mirikizumab-mrkz	**Ulcerative Colitis** Induction: 300mg IV at weeks 0, 4 and 8. Maintenance: 200 mg (1 x 200 mg/ 2mL prefilled pen/syringe/autoinjector or 2 x 100mg prefilled pens/syringes) per 28 days **Crohn's Disease** Induction: 900mg IV at weeks 0, 4 and 8. Maintenance: 300 mg (1 carton containing 1 x 200 mg/2 mL prefilled pen/syringe/autoinjector and 1 x 100 mg/mL prefilled pen/syringe/autoinjector) per 28 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J2267 - Injection, mirikizumab-mrkz, 1 mg (effective 7/1/2024)
- C9168 - Injection, mirikizumab-mrkz, 1 mg (cancelled 7/1/2024)

REFERENCES

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

- Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114:384-413.
- 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.

POLICY HISTORY

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