mirikizumab-mrkz (Omvoh IV)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: GASTROINTESTINAL AGENTS
Mechanism of Action: Interleukin-23 antagonist
HCPCS:
J2267:Injection, mirikizumab-mrkz, 1 mg
How Supplied:

300 mg/15 mL (20 mg/mL) solution in a single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Crohn's Disease, moderate to severe
- Ulcerative Colitis, moderate to severe

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Omvoh given by intravenous (IV) injection is managed under the Medical Benefit. Omvoh given by subcutaneous (SC) injection can be obtained through the patient's pharmacy benefit. Please refer to the "Self-Administered Drugs" medical benefit drug policy for more information.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Crohn's Disease, moderate to severe

Meets medical necessity if all the following are met:

1. Age is consistent with the FDA approved indication (18 years and older)
2. ***Effective 2/1/2026 and after***: Prescribed by or in consultation with a gastroenterologist

3. Inadequate response, intolerable side effect or contraindication with two preferred products [i.e., infliximab (Avsola, Inflectra), Skyrizi, Yesintek SC, adalimumab-aacf, Tremfya, Rinvoq]
4. Not being used in combination with other targeted immunomodulators

Covered Doses:
Induction: 900 mg given intravenously at Week 0, Week 4, and Week 8.
This is followed by maintenance given subcutaneously. Subcutaneous Omvoh can be requested from your pharmacy benefit.

Coverage Period:
Induction: 2 months

ICD-10:
K50.00-K50.119, K50.80-K50.919

Ulcerative Colitis, moderate to severe
Meets medical necessity if all the following are met:
1. Age is consistent with the FDA approved indication (18 years and older)
2. ***Effective 2/1/2026 and after***: Prescribed by or in consultation with a gastroenterologist
3. Inadequate response or intolerable side effect with two preferred agents [e.g., adalimumab-aacf, infliximab (Avsola or Inflectra), Rinvoq, Skyrizi SC, Yesintek SC, Tremfya SC, and Xeljanz], or contraindication to all preferred agents
4. Not being used in combination with other targeted immunotherapies

Covered Doses:
Induction: 300 mg given intravenously at Week 0, Week 4, and Week 8.
This is followed by maintenance given subcutaneously. Subcutaneous Omvoh can be requested from your pharmacy benefit.

Coverage Period:
Induction: 2 months

ICD-10:
K51.0-K51.319, K51.5-K51.519, K51.80-K51.919

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Omvoh (mirikizumab-mrkz) Prescribing Information. Eli Lilly and Company, Indianapolis, IN: 10/2025.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:
- Crohn's disease and Ulcerative colitis:
  - ***Effective 2/1/2026 and after***, will require specialist requirement (Rationale: Ensure appropriate use)
  - Clarified preferred drugs

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee