

Promise Health Plan

mirikizumab-mrkz (Omvoh IV)

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

Coverage Criteria

Effective: 12/01/2025

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. Meets ONE of the following:
 - a. Patient has had an inadequate response, intolerable side effect with preferred infliximab (i.e., Avsola, Inflectra or Renflexis)

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- b. Patient has not been treated with infliximab and has a contraindication to all infliximab products (Avsola, Inflectra, and Renflexis)
- 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. Meets ONE of the following:
 - a. Patient has had an inadequate response or intolerable side effect with preferred infliximab (i.e., Avsola, Inflectra, or Renflexis)
 - b. Patient has not been treated with infliximab AND has a contraindication to all infliximab products (Avsola, Inflectra, and Renflexis)
- 4. Not being used in combination with other targeted immunotherapies

Covered Doses:

<u>Induction</u>: 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
- Omvoh (mirikizumab-mrkz) Prescribing Information. Eli Lilly and Company, Indianapolis, IN: 10/2025.

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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)

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

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