Louisiana Medicaid
Mirikizumab-mrkz (Omvoh™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for mirikizumab-mrkz (Omvoh™).

Additional Point-of-Sale edits may apply.

*This agent may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

When currently posted criteria are not met, a clinical reviewer will consider the most current FDA-approved prescribing information for the requested agent when evaluating the request.

General approval criteria (ALL criteria must be met):

- An appropriate diagnosis is required, and the agent must be prescribed according to U.S. Food and Drug Administration approved indications, dosing, safety and monitoring regulations; **AND**
- If the request is for a non-preferred agent, there is no preferred alternative that is:
    - The exact same chemical entity, formulation, strength, etc.; **OR**
    - An FDA-approved biosimilar to the requested medication that is indicated for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The recipient will not receive the requested medication in combination with any other cytokine or CAM antagonist; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling; **AND**
- If request is for a non-preferred agent - **ONE** of the following is required: (See Pain Management – Cytokine and CAM Antagonists on the PDL/NPDL for list of preferred agents)
    - The recipient had documented *intolerable side effects* or a documented *treatment failure* with an adequate trial (6-12 weeks) of **TWO** preferred agents, if the preferred agents are indicated for the specified diagnosis; **OR**
    - The recipient has a *contraindication* to the preferred agents indicated for the specified diagnosis.

Approval criteria for specific diagnoses:

Ulcerative Colitis

- The recipient is 18 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The disease is moderate to severe; **AND**
  - The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gastroenterologist.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria (general and drug/diagnosis specific); **AND**
- The prescriber **states on the request** that there is evidence of a positive response to treatment as indicated by improvement in signs and symptoms compared to baseline, or by halting of disease progression (no progression of disease signs and symptoms as compared to baseline).

Initial Approval: 6 months
Reauthorization Approval: 12 months

Reference

Omvoh (mirikizumab-mrkz) [package insert]. Indianapolis, IN: Eli Lilly and Company; October 2023. https://pi.lilly.com/us/omvoh-uspi.pdf

Revision / Date	Implementation Date
Policy Created / November 2023	April 2024