UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

| | |
|---|---|
| Program Number | 2025 P 1425-3 |
| Program | Prior Authorization/Notification |
| Medication | * Omvoh™ (mirikizumab-mrkz)<br>*This program applies to the subcutaneous formulation of Omvoh. |
| P&T Approval Date | 1/2024, 1/2025, 3/2025 |
| Effective Date | 5/1/2025 |

**1. Background:**

Omvoh (mirikizumab-mrkz) is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults and moderately to severely active Crohn's disease in adults.

**2. Coverage Criteria[a]:**

**A. Ulcerative Colitis (UC)**

1. **Initial Authorization for Maintenance Dosing**

   a. **Omvoh** will be approved based on **both** of the following criteria:

      (1) Diagnosis of moderately to severely active ulcerative colitis

      **-AND-**

      (2) Patient is not receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Zeposia (ozanimod)]

   **Authorization will be issued for 12 months.**

2. **Reauthorization**

   a. **Omvoh** will be approved based on **both** of the following criteria:

      (1) Documentation of positive clinical response to Omvoh therapy

      **-AND-**

      (2) Patient is not receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Zeposia (ozanimod)]

**Authorization will be issued for 12 months.**

**B. Crohn's Disease (CD)**

1. **Initial Authorization for Maintenance Dosing**

   a. **Omvoh** will be approved based on **both** of the following criteria:

      (1) Diagnosis of moderately to severely active Crohn's disease

      **-AND-**

      (2) Patient is not receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab-rzaa), ustekinumab, Xeljanz (tofacitinib)]

   **Authorization will be issued for 12 months.**

2. **Reauthorization**

   a. **Omvoh** will be approved based on **both** of the following criteria:

      (1) Documentation of positive clinical response to Omvoh therapy

      **-AND-**

      (2) Patient is not receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab-rzaa), ustekinumab, Xeljanz (tofacitinib)]

   **Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- The intravenous infusion is typically covered under the medical benefit. Please refer to the UnitedHealthcare Drug Policy for Omvoh.

**4. Reference:**

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

| Program | Prior Authorization/Notification - Omvoh (mirikizumab-mrkz) |
|---|---|
| **Change Control** | |
| 1/2024 | New program |
| 1/2025 | Annual review with no change to clinical criteria. Updated examples with no change to clinical intent. Updated reference. |
| 3/2025 | Added coverage criteria for Crohn's disease. Updated background and reference. |