UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2320-3
Program	Prior Authorization/Medical Necessity
Medication	* Omvoh™ (mirikizumab-mrkz) *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 **all** of the following criteria:

(1) Diagnosis of moderately to severely active ulcerative colitis

-AND-

(2) **One** of the following:

(a) Patient has been established on therapy with Omvoh under an active UnitedHealthcare medical benefit prior authorization for moderately to severely active ulcerative colitis

-OR-

(b) **Both** of the following:

i. Patient is currently on Omvoh therapy for moderately to severely active ulcerative colitis as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from an Eli Lilly sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Omvoh*

-AND-

(3) 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)]

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from an Eli Lilly sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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 **all** of the following criteria:

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

-AND-

(2) **One** of the following:

(a) Patient has been established on therapy with Omvoh under an active UnitedHealthcare medical benefit prior authorization for moderately to severely active Crohn's disease

-OR-

(b) **Both** of the following:

i. Patient is currently on Omvoh therapy for moderately to severely active Crohn's disease as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from an Eli Lilly sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Omvoh*

-AND-

(3) 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)]

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

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 of 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/Medical Necessity - Omvoh (mirikizumab-mrkz)
Change Control	
1/2024	New program
1/2025	Annual review. Reworded criteria for established therapy through a medical prior authorization for clarity and not to change clinical intent. Updated examples with no change to clinical intent. Updated reference.
3/2025	Added coverage criteria for Crohn's disease. Updated background and references.