

**OmvoH (mirikizumab-mrkz)**  
**Effective 12/01/2024**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Exceptions</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	OmvoH IV is available on Medical Benefit Only OmvoH SC is available on Pharmacy Benefit Only		

**Overview**

OmvoH (mirikizumab-mrkz) is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults.

**Coverage Guidelines**

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**

Authorization may be granted when the following diagnosis-specific criteria have been met:

**Ulcerative Colitis**

1. Diagnosis of moderately to severely active ulcerative colitis.
2. ONE of the following:
  - a. Greater than 6 stools per day
  - b. Frequent blood in stools
  - c. Frequent urgency
  - d. Presence of ulcers
  - e. Abnormal lab values (e.g., hemoglobin, ESR, CRP)
  - f. Dependent on, or refractory to, corticosteroids
3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
  - a. 6-mercaptopurine
  - b. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
  - c. Azathioprine
  - d. Corticosteroids (e.g., prednisone)
4. Trial and failure, intolerance, or contraindication to TWO of the following:
  - a. Humira, Hadlima, Adalimumab-adaz, Adalimumab-fkjp

- b. Simponi
- c. Skyrizi
- d. Stelara
- e. Rinvoq
- f. Xeljanz/XR

**Continuation of Therapy**

Authorization may be granted for continued treatment in members who demonstrate a positive clinical response when ONE the following criteria are met:

- 1. Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- 2. Reversal of high fecal output state

**Limitations**

- 1. Initial approvals will be granted for: 3 months
- 2. Reauthorizations will be granted for Omvoh SC for 12 months.
  - a. Reauthorizations will not be granted for Omvoh IV
- 3. The following quantity limitations apply:

<b>Drug Name and Dosage Form</b>	<b>Quantity Limit</b>
Omvoh 100 mg/mL autoinjector	2 autoinjectors per 28 days
Omvoh 100 mg/mL prefilled syringe	2 prefilled syringes per 28 days

**References**

- 1. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterol.* 2020;158:1450-1461.
- 2. Omvoh [prescribing information]. Indianapolis, IN: Eli Lilly; April 2024.
- 3. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol.* 2019;114:384-413.

**Review History**

3/10/2024 - Created and Reviewed at March P&T, Effective 4/1/2024

09/11/2024 – Reviewed and updated at September P&T. Updated criteria for ulcerative colitis to include Skyrizi as a step through agent. Removed specialist prescriber requirement. Administrative update to add quantity limits to the Limitations section. Effective 12/01/2024.

10/09/2024 – Reviewed and updated at October P&T. Updated language for trial with biologics remove requirement for documentation of medical records to demonstrate trial. Effective 12/1/2024.

