Mass General Brigham
Health Plan

Omvoh (mirikizumab-mrkz)
Effective 01/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	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 all the following diagnosis-specific criteria have been met:

<u>Ulcerative Colitis</u>
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)

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

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:

Drug Name and Dosage Form	Quantity Limit
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. Effective 12/1/2024: updated language for trial with biologics remove requirement for documentation of medical records to demonstrate trial. Effective 1/1/2025: removed biologic step through requirement and updated reauthorization criteria to require documentation of clinical response to therapy.