Mass General Brigham
Health Plan

Omvoh (mirikizumab-mrkz)
Effective 07/01/2025

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
- Moderately to severely active Crohn's disease 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>Moderately to Severely Active Ulcerative Colitis</u>

1. Diagnosis of moderately to severely active ulcerative colitis.
2. ONE of the following:
    a. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
        i. 6-mercaptopurine
        ii. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
        iii. Azathioprine
        iv. Corticosteroids (e.g., prednisone)
    b. Disease severity warrants systemic biologic as first-line therapy

<u>Moderately to Severely Active Crohn's Disease</u>

1. Diagnosis of moderately to severely active Crohn's disease
2. ONE of the following:
    a. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:

i. 6-mercaptopurine
ii. Azathioprine
iii. Corticosteroids (e.g., prednisone)
iv. Methotrexate

b. Disease severity warrants systemic biologic as first-line therapy

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 for Omvoh IV will be granted for 12 weeks
2. Initial and reauthorization approvals for Omvoh SC will be granted for 24 months
    a. Reauthorizations will not be granted for Omvoh IV
3. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limit
UC pack: Omvoh 100 mg/mL autoinjector	2 autoinjectors per 28 days
UC pack: Omvoh 100 mg/mL prefilled syringe	2 prefilled syringes per 28 days
CD pack: Omvoh 100 mg/mL autoinjector + Omvoh 200 mg/2mL autoinjector	2 autoinjectors per 28 days
CD pack: Omvoh 100 mg/mL prefilled syringe + Omvoh 200 mg/2 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 (mirikizumab-mrkz) [prescribing information]. Indianapolis, IN: Eli Lilly; January 2025.
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.
05/14/2025 – Reviewed and updated at May P&T. Added criteria for supplemental indication of Crohn's disease. Updated criteria for ulcerative colitis to remove disease characteristic requirement and allow for approval if

disease severity warrants systemic biologic as first-line therapy. Updated approval length to 24 months for SC injection. Updated Limitations section to reflect quantity limits for Crohn's disease packs. Effective 7/1/2025.