Mass General Brigham
Health Plan

Omvoh (mirikizumab-mrkz)
Effective 04/01/2024

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 is 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 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 criteria is met:

1. Submission of medical records (e.g., chart notes) documenting a 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. Medication is being prescribed by or in consultation with a gastroenterologist.
5. Paid claim or medical charts documenting trial and failure, intolerance, or contraindication to TWO of the following:
    a. Humira, Hadlima, Adalimumab-adaz, Adalimumab-fkjp

b. Simponi
c. Stelara
d. Rinvoq
e. 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

References

1. Omvoh prescribing information. Eli Lilly & Co. Indianapolis, IN. October 2023.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
3. 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.

Review History

3/10/2023: Created and Reviewed at March P&T, Effective 4/1/2024