Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Mirikizumab-mrkz (Omvoh®)	MP-RX-FP-125-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of Mirikizumab-mrkz (Omvoh®), an interleukin-23 antagonist approved by the Food and Drug Administration (FDA) for the treatment of moderately to severely active ulcerative colitis in adults.

Background Information

Mirikizumab is a monoclonal antibody that selectively bind to the specific protein p19 subunit of human IL-23 cytokine and inhibits the IL-23 pathway indicated for the treatment of moderately to severely active ulcerative colitis in adults.

Ulcerative Colitis

For those with moderately to severely active disease, the American College of Gastroenterology (ACG) guidelines strongly recommend induction of remission using oral budesonide MMX, oral systemic corticosteroids, TNFi, tofacitinib or vedolizumab (moderate to high quality evidence). The American Gastroenterological Association (AGA) guidelines define moderate to severe UC as those who are dependent on or refractory to corticosteroids, have severe endoscopic disease activity, or are at high risk of colectomy. AGA strongly recommends biologics (TNFi, vedolizumab, or ustekinumab) or tofacitinib over no treatment in induction and maintenance of remission (moderate quality of evidence). For biologic-naïve individuals, Infliximab or vedolizumab are conditionally recommended over adalimumab for induction of remission (moderate quality evidence). Guidelines precede FDA approval of mirikizumab for UC.

Approved Indications

Omvoh is approved by the FDA for the treatment of moderately to severely active ulcerative colitis in adults.

Other Uses

None

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J3590	Unclassified biologics [Omvoh] (mirikizumab-mrkz)

ICD-10	Description
K51	Ulcerative colitis
K51.8	Other ulcerative colitis
K51.9	Ulcerative colitis, unspecified

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Mirikizumab-mrkz (Omvoh®)

A. Criteria For Initial Approval

i. Ulcerative colitis (UC) when the following criteria are met:

A. For individuals requesting intravenous induction doses:

1. Individual is 18 years of age or older with moderate to severe UC; **AND**
2. Individual has had an inadequate response to or is intolerant of conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); **OR**
3. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

OR

B. For individuals requesting subcutaneous maintenance therapy:

1. Individual is 18 years of age or older with moderate to severe UC; **AND**
2. Individual has completed the intravenous induction doses with Omvoh and will be using subcutaneous Omvoh for maintenance therapy.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Mirikizumab-mrkz (Omvoh®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) if the following information is provided:

A. Documentation that the patient has been receiving and is maintained on a stable dose of Omvoh; **AND**

B. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

C. Authorization Duration

i. Initial Approval Duration: Up to 12 months

ii. Reauthorization Approval Duration: Up to 12 months

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D. **Conditions Not Covered**

Any other use is considered experimental, investigational, or unproven, and may not be approved including the following (this list may not be all inclusive):

i. In combination with topical or oral JAK inhibitors, apremilast, deucravacitinib, ozanimod, etrasimod, or any of the following biologic immunomodulators: TNF antagonists, other IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL- 1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
ii. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
iii. If initiating therapy, Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention - recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors);**OR**
iv. When the above criteria are not met and for all other indications.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

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Mirikizumab-mrkz (Omvoh®)	MP-RX-FP-125-24	☒ MMM MA ☒ MMM Multihealth

	Recommended Dosing Schedule
Induction dosage	300 mg administered by intravenous infusion at weeks 0, 4 and 8.
Maintenance dosage	200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter.
Exceptions	
• Patients should be evaluated for tuberculosis (TB) infection prior to initiating treatment with Omvoh. • Liver enzymes and bilirubin levels should be monitored at baseline and for at least 24 weeks of treatment.	

Reference Information

1. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 18, 2016. Accessed October 15, 2023.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 27, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Feuerstein JD, Ho EY, Shmidt E et al. American Gastroenterological Association Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology 2021; 160:2496-2508.
5. Feuerstein JD, Issacs KL, Schneider Y, et al. American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450-1461.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
7. Lichtenstein GR, Loftus EV, Isaacs KL et al. 2018 American College of Gastroenterology Guideline for the management of Crohn's disease in adults. *Am J Gastroenterol* 2018; 113:481–517.
8. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019; 80: 1029-72.
9. Rubin DT, Ananthakrishnan AN, Siegel CA et al. American College of Gastroenterology Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019; 114:384-413.
10. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2019; 71(1): 5-32.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption	N/A	6/28/2024

Revised: 01/29/2024