Blue Cross Blue Shield Blue Care Network of Michigan

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Effective Date: 10/03/2024

Omvoh™ IV (mirikizumab-mrkz)

HCPCS: J2267

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved indication
   b. FDA approved age
   c. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated
   d. Not to be used in combination with biologic therapies or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication
   e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: Align with FDA recommended dosing
   b. Initial Authorization Period: One year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

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Background Information:

- Omvoh is an interleukin (IL)-23 antagonist that selectively binds the p19 subunit of IL-23, and is indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

- UC and Crohn's disease (CD) are two of the most common forms of inflammatory bowel disease (IBD). Both UC and CD are chronic, relapsing, remitting, inflammatory conditions of the gastrointestinal (GI) tract. UC only involves the large intestine as opposed to CD, which can affect any part of the GI tract from mouth to anus. CD can also affect the entire thickness of the bowel wall, while UC only involves the innermost lining of the large intestine. UC can present with symptoms of abdominal discomfort or loose bowel movements, including blood. The cause of UC or CD is not fully understood; however, research suggests that an interplay between environmental factors, genetics, and intestinal microbiota may contribute to the development of UC or CD. UC has an incidence of 9 to 20 cases per 100,000 persons per year. Its prevalence is 156 to 291 cases per 100,000 persons per year.

- The 2019 American College of Gastroenterology guidelines and the 2020 American Gastroenterology Association guidelines state therapeutic management in UC should be guided by the specific diagnosis, an assessment of disease activity, and disease prognosis. Treatment selection should be based not only on inflammatory activity but also on disease prognosis. Remission can be induced using a variety of medications, including oral 5-aminosalycylic acid (5-ASA), corticosteroids, or biologic agents. Thiopurines, such as azathioprine and mercaptopurine, can be used to maintain remission. The tumor necrosis factos (TNF) inhibitor agents infliximab, adalimumab, and golimumab are effective for treatment of patients with UC. Treatment guidelines do not recommend the use of one agent over another as there have been no head-to-head trials comparing the agents to one another. Vedolizumab is another guideline recommended option in patients with moderately to severely active UC for induction of remission, and in patients with moderately to severely active UC who have previously failed anti-TNF therapy, for induction of remission. Sphingosine 1-phosphate (S1P) receptor modulators have not been included in these guidelines.

- The efficacy of Omvoh was based on results from the LUCENT program, which included two randomized, double-blind, placebo-controlled Phase III clinical trials consisting of one 12-week induction study (UC-1) and one 40-week maintenance study (UC-2) for 52 weeks of continuous treatment. All patients in the LUCENT program were required to have had an inadequate response to, loss of response to, or inability to take one or more glucocorticoids or immunomodulators for the treatment of UC (i.e., conventional treatment failure), or biologic therapy or a Janus kinase (JAK) inhibitor for the treatment of UC (i.e., treatment failure with biologic agent or tofacitinib). Patients were allowed to receive oral 5-ASA, oral glucocorticoids, azathioprine, 6-mercaptopurine, or methotrexate at stable doses throughout the trial.

    - The primary endpoint of UC-1 and UC-2 was clinical remission at Week 12 and Week 52, respectively. The secondary endpoints of UC-1 were clinical response, endoscopic improvement, and histologic-endoscopic mucosal improvement (HEMI) at 12 weeks. The secondary endpoints of UC-2 were endoscopic improvement, maintenance of clinical remission in subjects who achieved clinical remission at 12 weeks, corticosteroid-free clinical remission, and HEMI at 40 weeks (a total of 52 weeks of treatment).

        - Of patients treated with Omvoh at 12 weeks in UC-1:

            - 24% achieved clinical remission compared to 15% with placebo ($p<0.001$).

            - 65% achieved a clinical response compared to 43% with placebo ($p<0.001$).

            - 34% achieved endoscopic improvement compared to 21% with placebo ($p<0.001$).

            - 25% achieved histologic-endoscopic mucosal improvement compared to 14% with placebo ($p<0.001$).

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- Of patients treated with Omvoh at 40 weeks (a total of 52 weeks of treatment) in UC-2:
    - 51% achieved clinical remission compared to 27% with placebo (p<0.001).
    - 50% achieved corticosteroid-free clinical remission compared to 27% with placebo (p<0.001). Patients in steroid-free remission stopped using corticosteroids for at least the previous 12 weeks prior to the one-year assessment.
    - 58% achieved endoscopic improvement compared to 30% with placebo (p<0.001).
    - 66% achieved maintenance of clinical remission in patients who achieved clinical remission at Week 12 compared to 40% with placebo (p<0.001).
    - 43% achieved histologic-endoscopic mucosal improvement compared to 22% with placebo (p<0.001).
- Clinical trials have not evaluated the safety and efficacy of Omvoh when used in combination with other biologics or targeted DMARDs.

References:

1. Omvoh [prescribing information] Indianapolis, IN: Eli Lilly. October 2023.
2. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158: 1450 - 61.
3. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019; 114: 384–413.
4. Lynch WD, Hsu R. Ulcerative Colitis. [Updated 2023 Jun 5]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK459282/

Policy History		
#	Date	Change Description
1.3	Effective Date: 10/03/2024	Added “for the same indication” to the not to be used in combination with other biologics or targeted DMARDs criteria
1.2	Effective Date: 03/01/2024	UM medical management system removal for MAPPO and BCNA for Omvoh SQ
1.1	Effective Date: 02/12/2024	UM medical management system update for MAPPO and BCNA for Omvoh IV and SQ
1.0	Effective Date: 12/14/2023	New policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

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