mirikizumab-mrkz (Omvoh™)

Policy # 00871
Original Effective Date: 04/08/2024
Current Effective Date: 04/08/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider mirikizumab-mrkz (Omvoh™)‡ for the treatment of moderately to severely active ulcerative colitis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for mirikizumab-mrkz (Omvoh) will be considered when the following criteria are met:

- Initial
    - Patient has a diagnosis of moderately to severely active ulcerative colitis; AND
    - Patient is greater than or equal to 18 years of age; AND
    - Patient has failed treatment with conventional therapies such as corticosteroids, azathioprine, or 6-mercaptopurine (6-MP) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
      *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
    - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: a preferred adalimumab product (i.e. Humira®, adalimumab-adbm)‡, ustekinumab (Stelara®)‡, upadacitinib (Rinvoq®)‡, golimumab (Simponi®)‡, or tofacitinib (Xeljanz®/ Xeljanz XR®)‡; AND
      *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

  - Omvoh will NOT be used in combination with biologic DMARDs for the treatment of ulcerative colitis, such as adalimumab (Humira, adalimumab-adbm), ustekinumab (Stelara), infliximab (Remicade®, biosimilar) ‡, or vedolizumab (Entyvio®)‡; AND
  - Patient has a negative TB test (e.g., purified protein derivative [PPD] or blood test); AND
  - For Omvoh intravenous requests ONLY: Dose will not exceed 3 induction doses of 300mg each
- Continuation
  - Patient has received an initial authorization for Omvoh; AND
  - Patient has experienced improvement on therapy as evidenced by improvement in at least one objective measure OR improvement in at least one symptom compared to baseline
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of mirikizumab-mrkz (Omvoh) when any of the following criteria are not met to be **not medically necessary.****

- For initial requests:
  - Patient has failed the pre-requisite medications listed in the patient selection criteria.
- For continuation requests:
  - Patient has experienced improvement on therapy as evidenced by improvement in at least one objective measure OR improvement in at least one symptom compared to baseline

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of mirikizumab-mrkz (Omvoh) when the patient selection criteria are not met (with the exception of those denoted above as **not medically necessary****) to be **investigational.***

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Background/Overview

Omvoh is a humanized IgG4 monoclonal antibody indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults. Omvoh is the first ulcerative colitis treatment that selectively targets the p19 subunit of the IL-23 cytokine, which inhibits its interaction with the IL-23 receptor. IL-23 is involved in mucosal inflammation and affects the differentiation, expansion, and survival of T cell subsets and innate immune cell subsets, which represent sources of proinflammatory cytokines. Research has shown that pharmacologic inhibition of IL-23p19 can improve intestinal inflammation. The dosing of Omvoh includes an induction and maintenance phase. Omvoh is administered as three 300 mg intravenous infusions at Weeks 0, 4, and 8, followed by 200 mg subcutaneous self-injections (administered as two consecutive injections of 100 mg each) starting at Week 12, and administered every 4 weeks thereafter.

Ulcerative Colitis

Ulcerative colitis is a chronic, episodic, inflammatory disease of the large intestine and rectum characterized by bloody diarrhea. This disease usually begins in the rectal area and may eventually extend through the entire large intestine. Repeated episodes of inflammation lead to thickening of the wall of the intestine and rectum with scar tissue. Death of colon tissue or sepsis may occur with severe disease. The goals of treatment are to control the acute attacks, prevent recurrent attacks and promote healing of the colon. Hospitalization is often required for severe attacks. There are several drug classes available for the management of moderate to severe UC including conventional therapies (thiopurines and corticosteroids) and advanced therapies (i.e. tumor necrosis factor (TNF) antagonists, interleukin 12/23 antagonists, Janus kinase (JAK) inhibitors, and sphingosine-1-phosphate modulators). In general, most drugs that are used to induce remission are continued chronically as maintenance therapy, if they are effective.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In October 2023, the FDA approved Omvoh for the treatment of moderately to severely active ulcerative colitis in adults.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The safety and efficacy of Omvoh was evaluated in two randomized, double-blind, placebo-controlled, Phase 3 clinical trials consisting of a 12-week induction study (LUCENT-1) and a 40-week maintenance study (LUCENT-2). The trials enrolled over 1,000 adult patients with moderately to severely active UC who had inadequate response, loss of response, or failed to tolerate any of the following: corticosteroids, 6-mercaptopurine, azathioprine, biologic therapy (TNF blocker, vedolizumab), or tofacitinib. The primary endpoints of the trials were the proportion of patients achieving clinical remission at week 12 and week 40. At Week 12, 24% of patients achieved clinical remission compared to 15% in the placebo group in the LUCENT-1 trial. Patients with clinical response to Omvoh induction treatment in LUCENT-1 were randomized 2:1 to receive Omvoh 200 mg SC or placebo every 4 weeks for 40 weeks (total 52 weeks of treatment). Of the patients in LUCENT-2 who were treated with Omvoh for 52 weeks, 51% achieved clinical remission compared to 27% in the placebo group and 50% of patients achieved steroid-free clinical remission at 1 year compared to 27% in the placebo group.

References

1. Omvoh [package insert]. Eli Lily and Company. Indianapolis, Indiana. October 2023.
2. Omvoh (mirikizumab-mrkz) New Drug Review. IPD Analytics. December 2023.

Policy History

Original Effective Date: 04/08/2024
Current Effective Date: 04/08/2024
03/07/2024 Medical Policy Committee review
03/13/2024 Medical Policy Implementation Committee approval. New policy.
03/26/2024 Coding update
Next Scheduled Review Date: 03/2025

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	C9168, C9399, J3590
ICD-10 Diagnosis	All related diagnoses

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.