Medical Policy Bulletin

Title:
Mirikizumab-mrkz (Omvoh™) for Intravenous Use
Policy #:
MA08.169

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

Mirikizumab-mrkz (Omvoh™), administered via an intravenous (IV) route, is considered medically necessary and, therefore, covered for the treatment of moderately to severely active ulcerative colitis (UC) in adults when **ALL** the following are met:

- Individual has a diagnosis of moderately to severely active UC, as assessed by a validated rating index/scale (e.g., modified Mayo score [MMS])
- Individual is without a current diagnosis of Crohn's disease or inflammatory bowel disease-unclassified (indeterminate colitis)
- Individual has demonstrated an inadequate response to, loss of response, or intolerance to **TWO** advanced therapies (biologic/Janus kinase [JAK] inhibitor therapy) for UC*
- Individual has no prior exposure to anti-interleukin (anti-IL)-12p40 antibodies (e.g., ustekinumab) or anti-IL-23p19 antibodies (e.g., risankizumab, brazikumab, guselkumab, tildrakizumab)
- Three loading doses administered by intravenous infusion at Weeks 0, 4, and 8. (Maintenance doses are administered by subcutaneous injection [may be available through applicable pharmacy benefits] and start at week 12.)

- Mirikizumab-mrkz (Omvoh) is prescribed by, or in consultation with, a licensed gastroenterology professional provider.

*See Description section for specific examples.

EXPERIMENTAL/INVESTIGATIONAL

All other uses for mirikizumab-mrkz (Omvoh) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Guidelines

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable Evidence of Coverage, mirikizumab-mrkz (Omvoh) is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met.

MODIFIED MAYO SCORE (MMS)

The modified Mayo score (MMS) is recommended by the US Food and Drug Administration (FDA) for use in clinical trials in the development of drugs for the treatment of ulcerative colitis (UC). For clinical trials for drugs intended to treat moderately to severely active UC, individuals should have a score of 5 to 9, including an endoscopy subscore of at least 2. Stool frequency and rectal bleeding should be based on a given 24-hour period.

- Stool Frequency*
  - 0: Normal number of stools for this patient
  - 1: 1–2 more stools than normal
  - 2: 3–4 more stools than normal
  - 3: 5 or more stools more than normal
- Rectal Bleeding**
  - 0: No blood seen
  - 1: Stool with streaks of blood
  - 2: Stool with more than streaks of blood
  - 3: Blood alone passed
- Endoscopy
  - 0: Normal appearance of mucosa
  - 1: Mild disease (erythema, decreased vascular pattern), no friability
  - 2: Moderate disease (marked erythema, absent vascular pattern, friability, erosions)
  - 3: Severe disease (spontaneous bleeding, ulcerations)

* Each individual provides their own baseline against which to compare the degree of abnormality in stool frequency.

** Represents the worst bleeding score for that day.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Mirikizumab-mrkz (Omvoh) was approved by the FDA on October 26, 2023, for the treatment of moderately to severely active UC in adults.

PEDIATRIC USE
Mirikizumab-mrkz (Omvoh) is not indicated for use in pediatric individuals less than 18 years of age.

BILLING GUIDELINES

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Description

Ulcerative colitis (UC) is a chronic disease. UC is a type of inflammatory bowel disease (IBD). It is characterized by inflammation and ulcerations of the colon and rectum resulting in the symptoms of abdominal pain, diarrhea, increased stool frequency, increased stool urgency, and rectal bleeding. Outside of the gastrointestinal (GI) tract, symptoms can include eye conditions (redness, irritation), mouth ulcerations, skin conditions (redness, swelling, rashes), and joint conditions (pain, swelling). UC may have a slow onset and worsen over the course of weeks to months, or it may start suddenly. Individuals with UC may experience periods of remission, lasting weeks to years, where the symptoms improve, or they may have periods of mild, moderate, or severe disease activity. Approximately 600,000 to 900,000 individuals in the United States currently have UC. UC is more common in individuals between the ages of 15 and 30 who have a first-degree relative with IBD. Complications of UC can include anemia, dehydration, osteopenia/osteoporosis, delayed growth and development in children, increased risk of colorectal cancer (CRC), intestinal perforation, and fulminant UC or toxic megacolon. There is no cure for UC, so the goal of therapy is the treatment of symptoms and disease remission. Treatment may include medications with or without surgery.

Commonly used medications for the treatment of UC include oral/topical aminosalicylates (e.g., balsalazide, mesalamine, sulfasalazine), oral/topical corticosteroids, immunosuppressants (e.g., methotrexate, 6-mercaptopurine [6-MP], azathioprine), sphingosine-1 phosphate (S1P) receptor modulators (e.g., ozanimod, etrasimod), Janus kinase (JAK) inhibitors (e.g., tofacitinib, upadacitinib), and biologics (e.g., tumor necrosis factor [TNF] blockers [e.g., infliximab, adalimumab, certolizumab, golimumab, natalizumab], integrin receptor blockers [vedolizumab], interleukin [IL]-12 and IL-23 blockers [ustekinumab]).

Mirikizumab-mrkz (Omvoh) is an immunoglobulin G4 (IgG4) monoclonal antibody that is an IL-23 blocker. IL-23 is involved in mucosal inflammation. By blocking IL-23, the treatment can inhibit the release of proinflammatory cytokines and chemokines and thus ameliorate intestinal inflammation.

According to the US Food and Drug Administration (FDA) label, the recommended dosage of mirikizumab-mrkz (Omvoh) is 300 mg administered by intravenous (IV) infusion at weeks 0, 4, and 8 for induction therapy. The recommended maintenance dosage is 200 mg administered by subcutaneous (SC) injection (administered as two injections of 100 mg each) at week 12, then every 4 weeks thereafter.

CLINICAL TRIALS

LUCENT-1
The safety and efficacy of mirikizumab-mrkz (Omvoh), used for induction, was evaluated in a phase III, multicenter, randomized, double-blind, placebo-controlled study (NCT03518086). A total of 1281 individuals with moderate to severe active UC who had an inadequate response to, loss of response, or intolerance to conventional or biologic therapy for UC were randomly assigned in a 3:1 ratio to mirikizumab-mrkz (Omvoh) or placebo. The individuals received treatment at weeks 0, 4, and 8. The primary endpoint was percentage of individuals who achieved clinical remission (defined as achieving a modified Mayo score [MMS] subscore for rectal bleeding of 0, stool frequency of 0 or 1 with 1 point or greater decrease from baseline, and endoscopy of 0 or 1 [excluding friability]) at 12 weeks. Secondary endpoints included percentage of individuals with a clinical response at 12 weeks, percentage of individuals with endoscopic remission at 12 weeks, percentage of individuals with histologic remission at 12 weeks, and percentage of individuals with endoscopic response at 12 weeks.

In the modified intention-to-treat (mITT) population, 868 individuals received mirikizumab-mrkz (Omvoh) and 294 individuals received placebo. At week 12, 24.2 percent of the treatment group versus 13.3 percent of the placebo group achieved clinical remission (99.875 percent confidence interval [CI], 3.2–19.1; *P*<0.001). At week 12, 63.5 percent of the treatment group versus 42.2 percent of the placebo group experienced a clinical response (99.875 percent CI, 10.8–32; *P*<0.001). At week 12, 36.3 percent of the treatment group versus 21.1 percent of the placebo group demonstrated endoscopic remission (99.875 percent CI, 6.3–24.5; *P*<0.001). At the end of 12 weeks, 27.1 percent of the treatment group versus 13.9 percent of the placebo group demonstrated histologic-endoscopic mucosal improvement (99.875 percent CI, 5.5–21.4; *P*<0.001).

LUCENT-2
The safety and efficacy of mirikizumab-mrkz (Omvoh), used for maintenance, was evaluated in a phase III, multicenter, randomized, double-blind, placebo-controlled study (NCT03524092). Individuals who had a clinical response to treatment with mirikizumab-mrkz (Omvoh) by week 12 in LUCENT-1 were randomly assigned again in a 2:1 ratio to receive maintenance therapy with either mirikizumab-mrkz (Omvoh) or placebo, both administered subcutaneously every 4 weeks for 40 weeks. The primary endpoint was percentage of individuals who achieved clinical remission at week 40. Secondary endpoints included percentage of individuals who achieved a glucocorticoid-

free clinical remission, the percentage of individuals who maintained clinical remission, percentage of individuals who demonstrated endoscopic remission at week 40, and percentage of individuals with histologic remission at 40 weeks.

A total of 365 individuals received mirikizumab-mrkz (Omvoh) and 179 individuals received placebo. At week 40, 49.9 percent of the treatment group versus 25.1 percent of the placebo group achieved clinical remission (95 percent CI, 15.2–31.2; *P*<0.001). At week 40, 44.9 percent of the treatment group and 21.8 percent of the placebo group had achieved a glucocorticoid-free clinical remission (95 percent CI, 13.5–29.1; *P*<0.001). At week 40, 63.6 percent of the treatment group and 36.9 percent of the placebo group maintained clinical remission (95 percent CI, 10.4–39.2; *P*<0.001). At week 40, 58.6 percent of the treatment group and 29.1 percent of the placebo group demonstrated endoscopic remission (95 percent CI, 20.2–36.8; *P*<0.001). At week 40, 43.3 percent of the treatment group and 21.8 percent of the placebo group demonstrated histologic-endoscopic mucosal remission (95 percent CI, 12.1–27.6; *P*<0.001).

LUCENT-3
The long-term safety and efficacy of mirikizumab-mrkz (Omvoh) is being evaluated in an ongoing phase III, multicenter, open-label extension study (NCT03519945). Individuals from LUCENT-1 or LUCENT-2 are able to enroll in this long-term (160 weeks) study. The primary endpoint is percentage of individuals who achieve clinical remission at week 52. Secondary endpoints include percentage of individuals who achieve endoscopic remission at week 52, percentage of individuals who achieve corticosteroid-free remission at week 52, percentage of individuals who achieve histologic-endoscopic mucosal remission at week 52, and percentage of individuals who undergo UC surgeries (including colectomy) by week 160.

OFF-LABEL INDICATIONS

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)

N/A

ICD - 10 Procedure Code Number(s)

N/A

ICD - 10 Diagnosis Code Number(s)

K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication
K51.419	Inflammatory polyps of colon with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction

K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications

HCPCS Level II Code Number(s)

J2267 Injection, mirikizumab-mrkz, 1 mg

Revenue Code Number(s)

N/A

Modifiers

THE FOLLOWING MODIFIER IS USED WHEN REPORTING

Mirikizumab-mrkz (Omvoh™) for Injection for Intravenous Use

JA Administered intravenously

Policy History

New policy MA08.169:

12/15/2025	This policy has been reissued in accordance with the Company's annual review process.
12/16/2024	This policy will become effective 12/16/2024.

	This new policy has been developed to communicate the Company's coverage criteria for mirikizumab-mrkz (Omvoh™) for injection for intravenous use.

Version Effective Date:
12/15/2025
Version Issued Date:
12/15/2025
Version Reissued Date:
N/A