

Medical Policy Bulletin

Title:

Mirikizumab-mrkz (Omvoh™) for Intravenous Use

Policy #:

MA08.169a

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.

In the absence of coverage criteria from applicable Medicare statutes, regulations, NCDs, LCDs, CMS manuals, or other Medicare coverage documents, this policy uses internal coverage criteria developed by the Company in consideration of peer-reviewed medical literature, clinical practice guidelines, and/or regulatory status.

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

ULCERATIVE COLITIS

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

- Individual has a documented diagnosis of moderately to severely active UC
- Documentation that individual has demonstrated an inadequate response to, or intolerance to, TWO of the following therapies, or that a trial may be inappropriate:
 - Adalimumab (i.e., Humira, adalimumab-adbm, adalimumab-aacf)
 - Ustekinumab (i.e., Yesintek)
 - Upadacitinib (i.e., Rinvoq)
 - Tofacitinib (i.e., Xeljanz, Xeljanz XR)
 - Risankizumab (i.e., Skyrizi)
- No concurrent therapy with any other biologic disease-modifying antirheumatic drug (DMARD) (e.g., tumor necrosis factor antagonist [TNF blocker])
- Three loading doses administered by intravenous infusion at Weeks 0, 4, and 8. (Maintenance doses administered by subcutaneous injection [may be available through applicable pharmacy benefit] start at week 12)

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

CROHN'S DISEASE (CD)

Mirikizumab-mrkz (Omvoh) administered via an intravenous (IV) route as induction therapy, is considered medically necessary and, therefore, covered for the treatment of active CD in adults when ALL the following are met:

- Individual has a documented diagnosis of moderately to severely active CD
- Documentation that individual has demonstrated an inadequate response to, or intolerance to TWO of the following therapies, or that a trial may be inappropriate:
 - Adalimumab (i.e., Humira, adalimumab-adbm, adalimumab-aacf)
 - Ustekinumab (i.e., Yesintek)
 - Risankizumab (i.e., Skyrizi)
 - Upadacitinib (i.e., Rinvoq)
- No concurrent therapy with any other biologic DMARD (e.g., TNF blocker)
- Three loading doses administered by intravenous infusion at Weeks 0, 4, and 8. (Maintenance doses administered by subcutaneous injection [may be available through applicable pharmacy benefit] start at week 12)
- Mirikizumab-mrkz (Omvoh) is prescribed by, or in consultation with, a licensed gastroenterology professional provider

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.

BILLING REQUIREMENTS

For drugs that have more than one method of administration, the appropriate modifier must be appended to indicate the route of administration.

- To report the intravenous route of administration, append the following modifier: JA Administered Intravenously

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

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

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 individual
 - 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.

CROHN'S DISEASE ACTIVITY INDEX

The Crohn's disease activity index (CDAI) is one commonly used tool that the FDA suggests can be used, along with mucosal inflammatory changes, to estimate disease activity in individuals with CD. Clinical remission is defined as a total score of less than 150. Mild disease activity is defined as a total score of 150 to 219. Moderate disease activity is defined as a total score of 220 to 450. Severe disease activity is defined as a total score of greater than 450.

Variable	Multiplier
Number of liquid or soft stools (each day for 7 days)	× 2
Abdominal pain, sum of 7 daily ratings (0=none, 1=mild, 2=moderate, 3=severe)	× 5
General well-being, sum of 7 daily ratings (0=generally well, 1=slightly under par, 2=poor, 3=very poor, 4=terrible)	× 7
Number of complications [1) arthritis or arthralgia, 2) iritis or uveitis, 3) erythema nodosum or pyoderma gangrenosum or aphthous stomatitis, 4) anal fissure or fistula or abscess, 5) other fistula, 6) fever >100°F/37.8°C]	× 20
Use of anti-diarrhea drugs (0=no, 1=yes)	× 30
Abdominal mass (0=no, 2=questionable, 5=definite)	× 10
Hematocrit low (36–51 normal; 0=no, 1=yes)	× 6
Body weight (1-weight/standard weight) × 100 (add or subtract according to sign)	× 1

SIMPLIFIED ENDOSCOPIC ACTIVITY SCORE FOR CROHN'S DISEASE

The simplified endoscopic activity score for CD (SES-CD) is a commonly used tool to measure the amount of mucosal involvement in an individual's colon during a colonoscopy. These variables are measured at five ileocolonic segments: ileum, right colon (including the ileocecal valve or an ileocolonic anastomosis, the cecum, and ascending colon to the hepatic flexure), transverse colon (hepatic flexure to splenic flexure), left colon (splenic flexure to rectosigmoid junction), and the rectum (portion distal to the rectosigmoid junction). Remission is defined as a total score of 0 to 2. Mild activity is defined as a total score of 3 to 6. Moderate activity is defined as a total score of 7 to 15 (or ≥ 4 for individuals with isolated ileal disease). Severe activity is defined as a total score of more than 15.

Variable	0	1	2	3
Size of ulcers	None	Aphthous ulcers (0.1 to 0.5 cm)	Large ulcers (0.5 to 2 cm)	Very large ulcers (>2 cm)
Ulcerated surface (percentage)	None	<10	10 to 30	>30
Affected surface (percentage)	None	<50	50 to 75	>75
Presence of narrowings or stenosis	None	Single, can be passed	Multiple, can be passed	Cannot be passed

US FOOD AND DRUG ADMINISTRATION STATUS

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

Mirikizumab (Omvoh) was approved by the FDA on January 15, 2025, for the treatment of moderately to severely active CD 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

MIRIKIZUMAB-MRKZ (OMVOH)

Mirikizumab-mrkz (Omvoh) is an immunoglobulin G4 (IgG4) monoclonal antibody that is an interleukin (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) for the treatment of ulcerative colitis (UC) 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 consecutive injections of 100 mg each) at week 12, then every 4 weeks thereafter.

According to the FDA label, the recommended dosage of mirikizumab-mrkz (Omvoh) for the treatment of Crohn's disease (CD) is 900 mg administered by IV infusion at weeks 0, 4, and 8 for induction therapy. The recommended maintenance dosage is 300 mg administered by SC injection (administered as two consecutive injections of 100 mg and 200 mg in any order) at week 12 and every 4 weeks thereafter.

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], IL-12 and IL-23 blockers [ustekinumab]).

CLINICAL TRIALS

LUCENT-1

The safety and efficacy of mirikizumab-mrkz (Omvoh), used for induction therapy for individuals with UC, was evaluated in a phase III, multicenter, randomized, double-blind, placebo-controlled study (NCT03518086). A total of 1281 individuals with moderate to severely 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% of the treatment group versus 13.3% of the placebo group achieved clinical remission (99.875% confidence interval [CI], 3.2–19.1; $P < 0.001$). At week 12, 63.5% of the treatment group versus 42.2% of the placebo group experienced a clinical response (99.875% CI, 10.8–32; $P < 0.001$). At week 12, 36.3% of the treatment group versus 21.1% of the placebo group demonstrated endoscopic remission (99.875% CI, 6.3–24.5; $P < 0.001$). At the end of 12 weeks, 27.1% of the treatment group versus 13.9% of the placebo group demonstrated histologic-endoscopic mucosal improvement (99.875% CI, 5.5–21.4; $P < 0.001$).

LUCENT-2

The safety and efficacy of mirikizumab-mrkz (Omvoh), used for maintenance therapy for individuals with UC, 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% of the treatment group versus 25.1% of the placebo group achieved clinical remission (95% CI, 15.2–31.2; $P < 0.001$). At week 40, 44.9% of the treatment group and 21.8% of the placebo group had achieved a glucocorticoid-free clinical remission (95% CI, 13.5–29.1; $P < 0.001$). At week 40, 63.6% of the treatment group and 36.9% of the placebo group maintained clinical remission (95% CI, 10.4–39.2; $P < 0.001$). At week 40, 58.6% of the

treatment group and 29.1% of the placebo group demonstrated endoscopic remission (95% CI, 20.2–36.8; $P<0.001$). At week 40, 43.3% of the treatment group and 21.8% of the placebo group demonstrated histologic-endoscopic mucosal remission (95% CI, 12.1–27.6; $P<0.001$).

LUCENT-3

The long-term safety and efficacy of mirikizumab-mrkz (Omvoh) therapy for individuals with UC 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.

CROHN'S DISEASE

CD is a chronic type of IBD. It is characterized by transmural inflammation in the digestive tract, anywhere from the mouth to anus, but most commonly in the small intestine and the beginning of the large intestine. CD is a relapsing and remitting disease. Individuals may experience flares, when symptoms are present, followed by periods of remission, lasting weeks to years, where the symptoms disappear. The symptoms usually start slowly and can get worse over time. Common symptoms are diarrhea, abdominal pain and cramping, gastrointestinal bleeding with associated anemia, and weight loss. Outside of the GI tract, symptoms can include joint pain or arthritis, painful skin rashes or bumps, eye irritation, the development of kidney stones, inflammation of the lungs that can lead to difficulty breathing, or inflammation of the liver and bile ducts that can cause primary sclerosing cholangitis. It is estimated that 1 million individuals in the United States have CD. CD is more common in individuals between the ages of 13 to 30, have a family member with IBD, smoke cigarettes, or are of Jewish descent. Complications of CD can include anemia, osteoporosis or osteopenia, delayed growth and development, or malnutrition. Serious complications can include intestinal obstruction, the formation of fistulas, or the development of abscesses, anal fissures, or ulcers anywhere along the GI tract. Individuals with CD are also more likely to develop CRC. There is no cure for CD, so the goal of treatment is to maintain remission. Treatments may include medication with or without surgery.

Commonly used medications for the treatment of CD are similar to those used for UC, and can include corticosteroids, immunosuppressants, and biologics. However, not all medications that treat UC can also be used to treat CD. Other medications can include drugs to treat the symptoms, or complications, of the disease. Up to 85% of individuals with CD will eventually require some form of surgery to treat their symptoms or complications.

CLINICAL TRIALS

VIVID-1

The safety and efficacy of mirikizumab-mrkz (Omvoh), used for induction therapy for individuals with CD, was evaluated in a phase III, multicenter, randomized, double-blind, placebo- and active-controlled study (NCT03926130). A total of 1065 individuals from the efficacy population with moderate to severely active CD who had an inadequate response to, loss of response, or intolerance to conventional or biologic therapy for CD were randomly assigned, in a 6:3:2 ratio, to one of three cohorts. Cohort 1 ($n=579$) received mirikizumab-mrkz (Omvoh) IV at weeks 0, 4, and 8, followed by treatment via the SC route every 4 weeks starting at week 12 to week 52. Cohort 2 ($n=287$) received ustekinumab IV at week 0, followed by treatment via the SC route every 8 weeks starting at week 8 onwards. Cohort 3 ($n=199$) received placebo in the same manner as the mirikizumab-mrkz (Omvoh) cohort. At week 12, individuals in Cohort 3 who did respond to placebo, continued on placebo every 4 weeks. At week 12, individuals in Cohort 3 who did not respond to placebo were switched to the mirikizumab-mrkz (Omvoh) regimen starting with three IV doses every 4 weeks followed by SC doses every 4 weeks onwards and their results were included in composite endpoints of individuals who received mirikizumab-mrkz (Omvoh). A total of 80 of 199 participants in Cohort 3 were switched to treatment with mirikizumab-mrkz (Omvoh). The coprimary endpoints were 1) the percentage of participants who achieved clinical response at week 12 and endoscopic response at week 52, and 2) the percentage of participants who achieved clinical response at week 12 and clinical remission at week 52. Key secondary endpoints included endoscopic response at week 12, corticosteroid-free clinical remission at week 52, and endoscopic remission at week 52. These endpoints were assessed in Cohort 1 and Cohort 3. A separate noninferiority endpoint, comparing individuals in Cohort 1 with Cohort 2, assessed clinical remission by CD activity index (CDAI) at week 52. A separate superiority endpoint, comparing individuals in Cohort 1 to Cohort 2, assessed endoscopic response at 52 weeks.

At week 12, 409 of 579 (70.6%) of participants in Cohort 1 versus 103 of 199 (51.8%) of participants in Cohort 3 experienced clinical response (difference, 18.9% [99.5% CI, 7.5–30.3]; $P<0.0001$). At week 52, 280 of 579 (48.4%) of

participants in Cohort 1 versus 18 of 199 (9%) of participants in Cohort 3 experienced endoscopic response (difference, 39.1% [99.5% CI, 31.0–47.2]; $P<0.0001$). At week 52, 313 of 579 (54.1%) of participants in Cohort 1 versus 39 of 199 (19.6%) of participants in Cohort 3 experienced clinical remission by CDAI (difference, 34.6% [99.5% CI, 24.7–44.4]; $P<0.0001$). At week 12, 188 of 579 (32.5%) of participants in Cohort 1 versus 25 of 199 (12.6%) of participants in Cohort 3 achieved endoscopic response (difference, 19.7% [99.5% CI, 11.1–28.2]; $P<0.0001$). By week 52, 253 of 579 (43.7%) of participants in Cohort 1 versus 37 of 199 (18.6%) of participants in Cohort 3 achieved corticosteroid-free clinical remission (difference, 25.0% [99.5% CI, 15.2–34.7]; $P<0.0001$). At week 52, 95 of 579 (15.9%) of participants in Cohort 1 versus four of 199 (2.0%) of participants in Cohort 3 achieved endoscopic remission (difference, 13.8% [99.5% CI, 8.7–18.9]; $P<0.0001$). For the noninferiority endpoint, 313 of 579 (54.1%) of participants in Cohort 1 versus 139 of 287 (48.4%) of participants in Cohort 2 achieved clinical remission by CDQI by week 52 (difference, 5.7% [95% CI, –1.4 to 12.8]. For the superiority endpoint, 280 of 579 (48.4%) of participants in Cohort 2 achieved endoscopic response at week 52 (difference, 2.3% [95% CI, –4.7 to 9.3]; $P=0.51$). In the safety population ($n=1150$) of all participants who received at least one dose of the randomized treatment, most adverse event rates were higher in the Cohort 3 than in Cohort 1. Exceptions of interest were injection site reactions (65/630 [10.8%] vs 7/211 [6.5%]), hypersensitivity reactions (50/630 [7.9%] vs 11/211 [5.2%]), and opportunistic infections (7/630 [1.1%] vs 0/211 [0%]) when comparing Cohort 3 to Cohort 1. There were three deaths in participants in the clinical trial: one individual in Cohort 3 due to a pulmonary embolism, one individual in Cohort 3 who was switched to treatment with mirikizumab-mrkz (Omvo) due to disease worsening, and one individual in Cohort 2 due to *Escherichia coli* sepsis; none were considered to be caused by the study drug or the clinical trial.

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)

Report the most appropriate diagnosis code in support of medically necessary criteria as listed in the policy.

HCPCS Level II Code Number(s)

J2267 Injection, mirikizumab-mrkz, 1 mg

Revenue Code Number(s)

N/A

Modifiers

JA Administered intravenously

Policy History

Revisions From MA08.169a:

06/18/2026	<p>This policy will become effective 06/18/2026.</p> <p>The following indication has been added to this policy:</p> <p>Crohn's disease</p> <p>The following policy criteria have been revised:</p> <p>Ulcerative colitis</p> <p>All ICD-10 codes were removed from the policy.</p> <p>Report the most appropriate diagnosis code in support of medically necessary criteria as listed in the policy.</p>
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New policy MA08.169:

12/15/2025	<p>This policy has been reissued in accordance with the Company's annual review process.</p>
12/16/2024	<p>This policy will become effective 12/16/2024.</p> <p>This new policy has been developed to communicate the Company's coverage criteria for mirikizumab-mrkz (Omvoh™) for injection for intravenous use.</p>

Version Effective Date:

06/18/2026

Version Issued Date:

06/18/2026

Version Reissued Date:

N/A