

Corporate Medical Policy: Mirikizumab-mrkz (Omvo[®]) “**Notification**” **POLICY EFFECTIVE JULY 1, 2026**

Restricted Product(s):

- mirikizumab-mrkz (Omvo[®]) intravenous infusion for administration by a healthcare professional

FDA Approved Use:

- For the treatment of moderately to severely active Crohn's disease in adults
- For the treatment of moderately to severely active ulcerative colitis in adults

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient has a diagnosis of moderately to severely active **Crohn's disease (CD); AND**
 - a. The patient is 18 years of age or older; **AND**
 - b. **ONE** of the following:
 - i. The patient has moderately to severely active disease, as evidenced by **ONE** of the following:
 1. The patient has **BOTH** of the following:
 - a. Symptoms consistent with active CD (e.g., diarrhea, abdominal pain, significant weight loss, fatigue, fever, anemia, vitamin or mineral deficiencies, intermittent nausea or vomiting, etc.) **[medical record documentation required]; AND**
 - b. Evidence of active inflammation, confirmed by **ONE** of the following **[medical record documentation required]:**
 - i. Active inflammatory disease on cross-sectional imaging (MRE, CTE), intestinal ultrasound, or pelvic MRI for perianal disease (e.g., bowel wall thickening, ulceration, hyperenhancement, fistula, abscess); **OR**
 - ii. Biomarker evidence indicative of inflammation (e.g., elevated fecal calprotectin [FC], elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate [ESR], low serum albumin); **OR**
 2. Significant extent of disease or upper GI involvement identified on radiographic or endoscopic assessment (e.g., large or deep mucosal lesions, fistulas or perianal abscesses, intestinal strictures, extensive disease [ileal involvement >40 cm or pancolitis], prior bowel resection, etc.) **[medical record documentation required]; OR**
 3. Corticosteroid-dependence, or refractory to oral corticosteroids **[medical record documentation required]; OR**

- ii. The patient is currently established on a biologic or systemic immunomodulator agent that is NOT the requested agent and is FDA approved for the treatment of CD (excluding sample use) **[medical record documentation required]; AND**
 1. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]; AND**
 - c. ONE of the following:
 - i. The patient has tried and had an inadequate response to ONE of the following agents used in the treatment of CD for at least 3-months: an adalimumab product, an ustekinumab product, risankizumab-rzaa (Skyrizi[®]), vedolizumab (Entyvio[®]), upadacitinib (Rinvoq[®]) **[medical record documentation required]; OR**
 - ii. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE of the following agents used in the treatment of CD: an adalimumab product, an ustekinumab product, risankizumab-rzaa (Skyrizi[®]), vedolizumab (Entyvio[®]), upadacitinib (Rinvoq[®]) **[medical record documentation required]; OR**
 - iii. The patient has an FDA labeled contraindication to ALL of the following agents used in the treatment of CD: an adalimumab product, an ustekinumab product, risankizumab-rzaa (Skyrizi[®]), vedolizumab (Entyvio[®]), upadacitinib (Rinvoq[®]) **[medical record documentation required]; OR**
 - iv. BOTH of the following:
 1. The prescriber has provided information indicating why ALL of the following agents for treatment of CD are not clinically appropriate for the patient: an adalimumab product, an ustekinumab product, risankizumab-rzaa (Skyrizi[®]), vedolizumab (Entyvio[®]), upadacitinib (Rinvoq[®]) **[medical record documentation required]; AND**
 2. The prescriber has provided a complete list of previously tried agents for the requested indication **[medical record documentation required]; AND**
 - d. The request is for initiation of Omvoh (mirikizumab) therapy, and an initial intravenous infusion of Omvoh (mirikizumab) will be administered; **AND**
 - e. The patient will NOT be treated with the 100 mg and 200 mg dose subcutaneous injections; **OR**
2. The patient has a diagnosis of moderately to severely active **ulcerative colitis (UC); AND**
 - a. The patient is 18 years of age or older; **AND**
 - b. ONE of the following:
 - i. The patient has moderately to severely active disease, as evidenced by ONE of the following:
 1. The patient has BOTH of the following:
 - a. Symptoms consistent with active UC (e.g., increased stool frequency, rectal bleeding, bowel urgency, nocturnal symptoms, abdominal pain and/or cramping, extraintestinal manifestations, significant weight loss, etc.) **[medical record documentation required]; AND**

- b. Evidence of active inflammation or high-risk disease, confirmed by ONE of the following **[medical record documentation required]**:
 - i. Moderate to severe disease activity on a lower gastrointestinal endoscopy using a validated endoscopic assessment tool (e.g., Mayo Endoscopic Subscore [MES], Ulcerative Colitis Endoscopic Index of Severity [UCEIS] or equivalent); **OR**
 - ii. Evidence of active inflammatory disease on intestinal ultrasound (IUS), including findings consistent with active colitis (e.g., increased bowel wall thickness, hyperemia); **OR**
 - iii. Biomarker evidence indicative of inflammation (e.g., elevated fecal calprotectin [FC], elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate [ESR], low serum albumin); **OR**
 - iv. Presence of at least one poor prognostic factor (e.g., age younger than 40 years at diagnosis, extensive colitis, hospitalization for colitis) **[medical record documentation required]; OR**
 - 2. Corticosteroid-dependence, or refractory to oral corticosteroids **[medical record documentation required]; OR**
 - ii. The patient is currently established on a biologic or systemic immunomodulator agent that is NOT the requested agent and is FDA approved for the treatment of UC (excluding sample use) **[medical record documentation required]; AND**
 - 1. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]; AND**
- c. ONE of the following:
- i. The patient has tried and had an inadequate response to ONE of the following agents used in the treatment of UC for at least 3-months: an adalimumab product, an ustekinumab product, risankizumab-rzaa (Skyrizi[®]), guselkumab (Tremfya[®]), vedolizumab (Entyvio[®]), upadacitinib (Rinvoq[®]), tofacitinib (Xeljanz[®]/Xeljanz XR[®]) **[medical record documentation required]; OR**
 - ii. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE of the following agents used in the treatment of UC: an adalimumab product, an ustekinumab product, risankizumab-rzaa (Skyrizi[®]), guselkumab (Tremfya[®]), vedolizumab (Entyvio[®]), upadacitinib (Rinvoq[®]), tofacitinib (Xeljanz[®]/Xeljanz XR[®]) **[medical record documentation required]; OR**
 - iii. The patient has an FDA labeled contraindication to ALL of the following agents used in the treatment of UC: an adalimumab product, an ustekinumab product, risankizumab-rzaa (Skyrizi[®]), guselkumab (Tremfya[®]), vedolizumab (Entyvio[®]), upadacitinib (Rinvoq[®]), tofacitinib (Xeljanz[®]/Xeljanz XR[®]) **[medical record documentation required]; OR**
 - iv. BOTH of the following:
 - 1. The prescriber has provided information indicating why ALL of the following agents for treatment of UC are not clinically appropriate for the patient: an adalimumab product, an ustekinumab product, risankizumab-rzaa (Skyrizi[®]),

- guselkumab (Tremfya®), vedolizumab (Entyvio®), upadacitinib (Rinvoq®), tofacitinib (Xeljanz®/Xeljanz XR®) **[medical record documentation required]; AND**
2. The prescriber has provided a complete list of previously tried agents for the requested indication **[medical record documentation required]; AND**
 - d. The request is for initiation of Omvoh (mirikizumab) therapy, and an initial intravenous infusion of Omvoh (mirikizumab) will be administered; **AND**
 - e. The patient will NOT be treated with the 100 mg dose subcutaneous injection; **AND**
 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist for CD, UC) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
 4. The patient will NOT be using mirikizumab-mrkz (Omvoh®) in combination with another biologic immunomodulator agent or Zeposia®; **AND**
 5. The patient does NOT have any FDA labeled contraindications to mirikizumab-mrkz (Omvoh®); **AND**
 6. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB; **AND**
 7. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below).

Duration of Approval: Crohn's disease or ulcerative colitis induction (IV): 90 days

FDA Label Reference				
Medication	Indication	Dosing	HCPCS	Maximum Units*
mirikizumab-mrkz (Omvoh®) intravenous (IV) infusion	CD in patients \geq 18 years old	Induction: 900 mg IV at week 0, week 4, and week 8	J2267	CD: 2,700 UC: 900

FDA Label Reference				
Medication	Indication	Dosing	HCPCS	Maximum Units*
	UC in patients \geq 18 years old	Induction: 300 mg IV at week 0, week 4, and week 8		

*Maximum units allowed for duration of approval

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Lichtenstein GR, Loftus EV Jr, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol.* 2025;120(6):1225-1264.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2025 Jun 3;120(6):1187-1224.
3. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease. *Gastroenterology.* 2025;169(7):1397-1448.
4. Singh S, Loftus EV, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology.* 2024;167(7):1307-1343.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

July 2026: Criteria change: For CD: Removed required trial and failure of conventional therapy; Replaced allowance for severely active disease with required demonstration of moderately to severely active disease by documented presence of symptoms of active disease plus evidence of active inflammation OR significant extent of disease or upper GI involvement on radiographic or endoscopic assessment OR corticosteroid-dependence or refractory to oral corticosteroids; Changes made to align with updated clinical guidelines. For UC: Removed required trial and failure of conventional therapy; Replaced allowance for severely active disease with required demonstration of moderately to severely active disease by documented presence of symptoms of active disease plus evidence of active inflammation or high-risk disease (with associated confirmatory criteria) OR corticosteroid-dependence or refractory to oral corticosteroids; Changes made to align with

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updated clinical guidelines. For CD and UC: Added allowance for patients currently established on a biologic or systemic immunomodulator agent that is NOT the requested agent and is FDA approved for treatment of the requested indication for those who have had positive clinical benefit from use of the biologic or systemic immunomodulator agent. Other minor formatting changes made throughout policy for clarity with no change to intent. **Policy notification given 5/1/2026 for effective date 7/1/2026.**

August 2025: Criteria change: For CD: Updated policy to allow bypassing conventional agents for severely active Crohn's disease. Updated list of preferred biologic agents throughout policy to remove listed examples of ustekinumab products for clarity.

February 2025: Criteria change: Added newly approved indication for moderately to severely active Crohn's disease in adults with associated criteria, and added associated dosing to FDA label reference table.

January 2025: Criteria change: Changed trial and failure requirements from two biologic immunomodulator products to ONE biologic immunomodulator product, added Tremfya and Entyvio as options within trial and failure requirements, and removed Simponi as an option within trial and failure requirements.

July 2024: Criteria change: Changed trial and failure requirements from three biologic immunomodulator products to two biologic immunomodulator products, and added Skyrizi and Simponi as options within trial and failure requirements. Adjusted duration of approval from 56 days to 90 days to allow time to schedule all induction doses after authorization approval.

July 2024: Coding change: Added HCPCS code J2267 to dosing reference table effective 7/1/2024; deleted C9168, J3490, and J3590 termed 6/30/2024.

April 2024: Coding change: Added HCPCS code for C9168 to dosing reference table effective 4/1/2024; deleted C9399 termed 3/31/2024.

November 2023: Original medical policy criteria issued.