Mirikizumab-mrkz (OMVOH)
Intravenous and Subcutaneous Injection in Ulcerative Colitis
Criteria for Use
March 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for mirikizumab-mrkz.

- ☐ Uncontrolled, active, severe infection including evidence of *C. difficile* and undrained abscess (however, mirikizumab-mrkz may be started / restarted once the infection treatment has been initiated)
- ☐ Untreated latent or active tuberculosis infection.
- ☐ Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis.[1] Mirikizumab-mrkz may be initiated after starting antiviral prophylaxis.[1]
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with mirikizumab-mrkz.
- ☐ Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of mirikizumab-mrkz.[2]
- ☐ Liver cirrhosis unless potential benefits outweigh risks based on shared decision-making.

Inclusion Criteria

ALL of the following must be selected in order to meet criteria:

- ☐ Moderate to severe, active **ulcerative colitis (UC)** confirmed by endoscopy or imaging
- ☐ Prescribed and monitored by a VA / VA Community Care gastroenterologist / hepatologist or locally designated expert in ulcerative colitis
- ☐ Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA]
- ☐ Completed hepatitis B screening (at minimum, HBsAg, total antibody-to-hepatitis-B-core-antigen (anti-HBc) and antibody to hepatitis B surface antigen [anti-HBs])
- ☐ Current or past completion of hepatitis C screening. (Mirikizumab-mrkz may be initiated while waiting for test results.)
- ☐ Obtained liver panel including bilirubin

Additional Inclusion Criteria

ONE of the following must be selected in order to meet criteria:

- ☐ **Tumor necrosis factor inhibitor (TNFI)** is medically inadvisable and **vedolizumab** is medically inadvisable, not tolerated, or not adequate
- ☐ Primary nonresponse, inadequate partial response, or loss of response to TNFI therapy in the presence of adequate TNFI levels.
- ☐ Loss of response (with active disease confirmed by endoscopy or imaging) to **infliximab / biosimilar** (the preferred TNFI in UC) despite TDM-based optimized dosing to address pharmacokinetic failure.[3]
- ☐ Loss of response (with active disease confirmed by endoscopy or imaging) to one TNFI in the presence of adequate TNFI levels.

Additional Inclusion Criteria

ALL of the following must be selected in order to meet criteria:

- ☐ **Tofacitinib** or **upadacitinib** is medically inadvisable, not tolerated or not adequate
- ☐ **Etrasimod** or **ozanimod** is medically inadvisable, not tolerated, or not adequate
- ☐ **Risankizumab-rzaa** is medically inadvisable, not tolerated or not adequate

Additional Inclusion Criteria

Select if appropriate.

- ☐ If HBsAg-negative but anti-HBc-positive: A GI / liver or infectious diseases expert has been consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.
- ☐ For females who can become pregnant and patients with female partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception.

Other Justification

- ☐ _____

Footnotes

1. Antiviral prophylaxis for HBV: Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used.
2. When possible, vaccinations should be updated before the patient initiates mirikizumab-mrkz. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with mirikizumab-mrkz, preferably when dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.
3. TDM, Therapeutic Drug Monitoring. Pharmacokinetic failure resulting in low TNFI levels may be immune-mediated or non–immune-mediated.

Supplemental Information

This supplemental information is provided to assist in adjudication of requests for mirikizumab-mrkz in UC.

Section	Criterion	Issues for Consideration
Inclusion Criteria	Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].	Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered.
	Completed hepatitis B screening (at minimum, HBsAg, total anti-HBc and antibody to hepatitis B surface antigen [anti-HBs]).	Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered. Anti-HBs may help to identify patients who require initial or booster vaccination (anti-HBs titers >= 10 IU/L are generally considered protective) or HBsAg-negative patients without past vaccination who have occult HBV from past infection (anti-HBs positive and lost anti-HBc).
	Current or past completion of hepatitis C screening. (Mirikizumab-mrkz may be initiated while waiting for test results.)	Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered.
	Tofacitinib or upadacitinib is medically inadvisable….	Tofacitinib or upadacitinib may be medically inadvisable for reasons that include but are not limited to ≥ 1 cardiovascular risk factor; presence or history of thrombosis (e.g., pulmonary embolism, deep venous thrombosis, arterial thrombosis); severe hepatic impairment; concurrent use with myelosuppressive agents; history of gastrointestinal perforation; history of chronic or interstitial lung disease.
	Etrasimod or **ozanimod** is medically inadvisable….	Etrasimod or ozanimod may be medically inadvisable for reasons that include but are not limited to the following: (a) In the last 6 months, had a myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, Class III or IV heart failure; (b) History or presence of Mobitz type II second- or third-degree atrioventricular block, sick sinus syndrome, or sinoatrial block (except patients with functioning pacemakers); (c) Infections, bradyarrhythmia and atrioventricular conduction delays, liver disease; macular edema; uncontrolled hypertension; (d) severe untreated sleep apnea (ozanimod); (e) concomitant monoamine oxidase inhibitor (ozanimod)
	Ustekinumab is medically inadvisable….	Ustekinumab may be medically inadvisable for reasons that include but are not limited to history of noninfectious pneumonia (e.g., interstitial pneumonia, eosinophilic pneumonia, cryptogenic organizing pneumonia).
Additional Inclusion Criteria	**Tumor necrosis factor inhibitor (TNFi)** is medically inadvisable….	Infliximab and other TNFis may be medically inadvisable for reasons that include but are not limited to heart failure, demyelinating disease, multiple sclerosis in first-degree relative, lupus, recurrent infections, serious infections, etc.
	Vedolizumab is medically inadvisable….	Vedolizumab may be medically inadvisable for reasons that include but are not limited to liver disease and history of progressive multifocal leukoencephalopathy (PML).

Section	Criterion	Issues for Consideration
	Loss of response (with active disease confirmed by endoscopy or imaging) to **infliximab / biosimila**r (the preferred TNFI in UC) despite TDM-based optimized dosing to address pharmacokinetic failure.	Other options for UC in TNFI-naïve patients are adalimumab and golimumab. Adalimumab is less preferred than vedolizumab and tofacitinib in TNFI-exposed UC patients.
Additional Inclusion Criteria	If HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive, a gastroenterologist / hepatologist or infectious diseases expert has been consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.	In patients who are HBsAg-negative but **anti-HBc-positive**, the presence of antibody to hepatitis B surface antigen (anti-HBs) does not guarantee protection against HBV reactivation, and the available evidence is insufficient to support the use of anti-HBs titers in deciding whether to give antiviral prophylaxis. Management depends on the patient's risk of HBV reactivation. [Reddy K, et al. American Gastroenterological Association Institute Guideline on the Prevention and Treatment of Hepatitis B Virus Reactivation During Immunosuppressive Drug Therapy. Gastroenterology. 2015;148(1):215–219. doi: https://doi.org/10.1053/j.gastro.2014.10.039 Ekpanyapong S, Reddy KR. Hepatitis B Virus Reactivation: What Is the Issue, and How Should It Be Managed? Clin Liver Dis. 2020 Aug;24(3):317-333. doi: 10.1016/j.cld.2020.04.002.]

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