

Clinical Policy Title:	mirikizumab-mrkz
Policy Number:	RxA.813
Drug(s) Applied:	OmvoH
Original Policy Date:	09/12/2024
Last Review Date:	03/12/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Ulcerative Colitis (must meet all):

1. Diagnosis of moderate to severe active ulcerative colitis (UC);
2. Member meets one of the following (a or b):
 - a. Trial and failure of ≥ 3 months of at least one (1) conventional agent (azathioprine, 6-mercaptopurine, aminosalicylate);
 - b. Trial and failure of at least one (1) corticosteroid (e.g., prednisone, budesonide, methylprednisolone);
3. Trial and failure of at least two (2) of the following agents: adalimumab (Abrilada™, Hadlima™, Yuflyma, or adalimumab-aaty), Rinvoq, ustekinumab (Yesintek, Steqeyma), Simponi, or Xeljanz/XR.

Approval duration

All Lines of Business (except Medicare): 12 months

B. Crohn's Disease (must meet all):

1. Diagnosis of moderate to severe active Crohn's disease;
2. Member meets one of the following (a or b):
 - a. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]), unless contraindicated or clinically significant adverse effects are experienced;
 - b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide), unless contraindicated or significant adverse effects experienced;
3. Trial and failure of one preferred TNF inhibitor: adalimumab (Abrilada™, Yuflyma, Hadlima™, or adalimumab-aaty), or Cimzia, unless contraindicated or significant adverse effects experienced.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications:

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

Approval duration

All Lines of Business (except Medicare): 12 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

References

1. Omvoh. Package insert. Eli Lilly; 2024. Available at: <https://pi.lilly.com/us/omvoh-uspi.pdf?s=pi>. Accessed August 23, 2024.
2. D’Haens GR, Dubinsky M, Kobayashi T, et al. Mirikizumab as Induction and Maintenance Therapy for UC. New England Journal of Medicine. 2023. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa2207940>. Accessed August 23, 2024.
3. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn’s Disease. Feuerstein, Joseph D.Sultan, Shahnaz et al. Gastroenterology, Volume 160, Issue 7, 2496 – 2508. Available at: [https://www.gastrojournal.org/article/S0016-5085\(21\)00645-4/fulltext](https://www.gastrojournal.org/article/S0016-5085(21)00645-4/fulltext). Accessed March 13, 2025.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	8/23/2024	09/12/2024
Policy was reviewed: 1. Update Humira biosims to covered formulary alternatives: Abrilada, Hadlima, adalimumab-aaty	2/13/2025	
Policy was reviewed: 1. New FDA approved indication added to criteria: Chron’s Disease 2. References updated	3/12/2025	