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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Biologicals	**Original Policy Date:**	November 24, 2023
Subject:	Omvoh	**Page:**	1 of 9

Last Review Date: December 12, 2025

Omvoh

Description

Omvoh (mirikizumab-mrkz)

Background
Omvoh (mirikizumab-mrkz) is a humanized IgG4 monoclonal antibody that selectively binds to the p19 subunit of human interleukin (IL)-23 cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is involved in mucosal inflammation and affects the differentiation, expansion, and survival of T cell subsets, and innate immune cell subsets, which represent sources of pro-inflammatory cytokines. Research in animal models has shown that pharmacological inhibition of IL-23p19 can ameliorate intestinal inflammation. Omvoh inhibits the release of pro-inflammatory cytokines and chemokines (1).

Regulatory Status
FDA-approved indication: Omvoh is an interleukin-23 antagonist indicated for the treatment of: (1)

- moderately to severely active ulcerative colitis (UC) in adults.
- moderately to severely active Crohn's disease in adults.

Omvoh may increase the risk of infections. Omvoh should not be given to patients with any clinically important active infection until the infection resolves or is adequately treated. If a serious infection develops or an infection is not responding to standard therapy, monitor the patient closely and do not administer Omvoh until the infection resolves (1).

Evaluate patients for tuberculosis infection prior to initiating treatment with Omvoh. Do not administer Omvoh to patients with active tuberculosis. Initiate treatment of latent tuberculosis prior to administering Omvoh. Consider anti-tuberculosis therapy prior to initiation of Omvoh in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving Omvoh should be monitored closely for signs and symptoms of active tuberculosis during and after treatment (1).

Omvoh may cause hepatotoxicity. Liver enzymes and bilirubin should be evaluated at baseline and for at least 24 weeks of treatment. Consider other treatment options in patients with evidence of liver cirrhosis (1).

The safety and effectiveness of Omvoh in pediatric patients less than 18 years of age have not been established (1).

Related policies
Ilumya, Skyrizi, Stelara, Tremfya

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Omvoh may be considered **medically necessary** if the conditions indicated below are met.

Omvoh may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

1. Moderate to severely active ulcerative colitis (UC)
    a. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 1)

b. Prescriber will initiate dosing with three 300 mg intravenous infusions
c. Prescriber will not exceed the FDA labeled maintenance dose of 200 mg SC every 4 weeks
d. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Moderately to severely active Crohn's disease (CD)
   a. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 1)
   b. Prescriber will initiate dosing with three 900 mg intravenous infusions
   c. Prescriber will not exceed the FDA labeled maintenance dose of 300 mg SC every 4 weeks
   d. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following:

1. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
2. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)
4. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports:

1. Ulcerative colitis (UC)
    a. Prescriber will not exceed the FDA labeled maintenance dose of 200 mg SC every 4 weeks
    b. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
2. Crohn's disease (CD)
    a. Prescriber will not exceed the FDA labeled maintenance dose of 300 mg SC every 4 weeks
    b. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following:

1. Condition has improved or stabilized with Omvoh
2. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)
4. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Strength	Quantity
Crohn's disease (CD)	300 mg IV vial 100 mg SC pen/syringe 200 mg SC pen/syringe	9 IV vials (3 doses) + 6 SC pens/syringes per 84 days

Ulcerative colitis (UC)	300 mg IV vial 100 mg SC pen/syringe	3 IV vials (3 doses) + 6 SC pens/syringes per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

Diagnosis	Strength	Quantity
Crohn's disease (CD)	100 mg SC pen/syringe 200 mg SC pen/syringe	6 SC pens/syringes per 84 days
Ulcerative colitis (UC)	100 mg SC pen/syringe	6 SC pens/syringes per 84 days

Duration 18 months

Rationale

Summary

Omvoh is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD) in adults. Omvoh has warnings regarding infections, tuberculosis, hepatotoxicity, and immunizations. The safety and effectiveness of Omvoh in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Omvoh while maintaining optimal therapeutic outcomes.

References

1. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company; January 2025.

Policy History

Date	Action
November 2023	Addition to PA
March 2024	Annual review
February 2025	Per PI update, added indication of CD
December 2025	Annual review. Added documentation requirement. Revised Appendix 3

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

Appendix 1 – List of Conventional Therapies

Conventional Therapy Options for CD
1. Mild to moderate disease – induction of remission: a. Oral budesonide, oral mesalamine b. Alternatives: metronidazole, ciprofloxacin
2. Mild to moderate disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission: a. Prednisone, methylprednisolone intravenously (IV) b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission c. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission d. Azathioprine, mercaptopurine e. Alternative: methotrexate IM

Conventional Therapy Options for UC
1. Mild to moderate disease – induction of remission: a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine b. Rectal mesalamine (e.g., Canasa, Rowasa) c. Rectal hydrocortisone (e.g., Colocort, Cortifoam) d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission: a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission: a. Prednisone, hydrocortisone IV, methylprednisolone IV b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: sulfasalazine
5. Pouchitis: a. Metronidazole, ciprofloxacin b. Alternative: rectal mesalamine

Appendix 2 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name

azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
ixekizumab	Taltz
mirikizumab-mrkz	Omvoh
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR

upadactinib	Rinvoq

Appendix 3 - List of Preferred Products

List of preferred products:
https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_IndicationMedChx.pdf

Refer to formulary documents for confirmation of coverage:
https://www.fepblue.org/pharmacy/prescriptions#drug-lists