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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Biologicals	**Original Policy Date:**	November 24, 2023
Subject:	Omvoh	**Page:**	1 of 7

Last Review Date: March 8, 2024

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 moderately to severely active ulcerative colitis (UC) in adults (1).

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

Diagnosis

Patient must have the following:

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 300mg intravenous infusions
    c. Prescriber will be dosing the patient within 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)

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

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Ulcerative colitis (UC)
   a. Prescriber will be dosing the patient within 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)

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 1)
4. **NOT** given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Strength	Quantity
Ulcerative colitis (UC)	300 mg IV vial 100 mg SC pen	3 IV vials (3 doses) + 6 SC pens per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

Diagnosis	Strength	Quantity
Ulcerative colitis (UC)	100 mg SC pen	6 units 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) 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; October 2023.

Policy History

Date	Action
November 2023	Addition to PA
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 – List of Conventional Therapies

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 DMARDs

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Ulcerative colitis (UC)	*must try **TWO** preferred products: Humira Rinvoq Stelara (SC)	Humira