BlueCross BlueShield
Federal Employee Program

OMVOH
(mirikizumab-mrkz)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of 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 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)

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

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* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

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

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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* 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

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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)

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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

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Appendix 3 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Crohn's disease (CD)	*must try **TWO** preferred products: Humira** Rinvoq Skyrizi Stelara (SC) Tremfya	Humira
Ulcerative colitis (UC)	*must try **TWO** preferred products: Humira** Rinvoq Skyrizi Stelara (SC) Tremfya	Humira

**Including all preferred biosimilars (see reference product criteria)