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Subject: Mirikizumab-mrkz (Omvoh®) Injection and Infusion

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Dosage/ Administration	Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions
Related Guidelines	Other	References	Updates		

DESCRIPTION:

Mirikizumab (Omvoh) is an injectable monoclonal antibody and interleukin 23 (IL-23) antagonist that was first approved by the US Food and Drug Administration (FDA) in November 2023 for “the treatment of moderately to severely active ulcerative colitis (UC) in adults”. It is the third IL-23 specific antagonist to be approved by the FDA, the second to be approved for an inflammatory bowel disease (IBD), and the first to be approved for UC. In January 2025, the FDA approved a second indication for “the treatment of moderately to severely active Crohn’s disease (CD) in adults”. The other IL-23 specific antagonists include guselkumab (Tremfya), first approved in July 2017 and currently approved for plaque psoriasis (2017), psoriatic arthritis (2020), UC (2024), CD(2025) and risankizumab (Skyrizi), first approved in April 2019, and currently approved for plaque psoriasis (2019), psoriatic arthritis (2022), CD (2022), and UC (2024). Intravenous (IV) risankizumab was launched in June 2022 with the approval for CD. Ustekinumab (Stelara) also targets IL-23; however, it targets both IL-12 and IL-23. Mirikizumab is a humanized IgG4 monoclonal antibody that selectively binds to the p19 subunit of human 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 pharmacologic inhibition of IL-23p19 can ameliorate intestinal inflammation. Mirikizumab inhibits the release of pro-inflammatory cytokines and chemokines. Treatment with mirikizumab requires three intravenous (IV) loading doses prior to converting to subcutaneous (SC) maintenance dosing every 4 weeks. Higher induction and maintenance dosing is required for CD as compared to UC.

In two randomized controlled trials in adults with moderate to severe active UC, which lead to the initial FDA approval, mirikizumab was associated with a significantly greater proportion of patients achieving clinical remission vs. placebo. Clinical remission was defined as stool frequency subscore of 0 or 1, rectal bleeding subscore of 0, and endoscopy score of 1 or less (excluding friability) on the modified Mayo score (mMS). In study UC-1, patients were randomized 3:1 at week 0 to receive 300 mg mirikizumab or placebo by IV infusion at week 0, week 4, and week 8. Of the patients treated with mirikizumab (n=795), 24% achieved clinical remission at week 12 vs.15% in patients who received placebo (n=267). Study UC-2 included patients (n=506) where those who achieved clinical response at week 12 in study UC-1. They were randomized 2:1 to receive mirikizumab 200 mg or placebo SQ every 4 weeks for 40 weeks, for a

total of 52 weeks of treatment. Significantly more patients achieved clinical remission at week 40 with mirikizumab vs. placebo (51% vs. 27%).

The expanded approval for CD was based on data from the randomized, double-blind, placebo-controlled, Phase 3 VIVID-1 study. A total of 679 adult patients with moderately to severely active CD who had an inadequate response, loss of response, or intolerance to corticosteroids, immunomodulators, and/or biologics were randomized to receive mirikizumab, placebo, or ustekinumab. Patients on mirikizumab were given 900 mg via IV infusion at Weeks 0, 4, and 8, followed by 300 mg via SC injection at Week 12 then every 4 weeks for 40 weeks. Clinical remission was achieved by 53% of patients on mirikizumab vs. 36% of patients receiving placebo at Week 52. Endoscopic response, defined as >50% reduction from the baseline in Simple Endoscopic Score for Crohn's Disease (SES-CD) total score, was achieved by 46% of patients on mirikizumab vs. 23% of patients receiving placebo at Week 52. Mirikizumab demonstrated noninferiority to ustekinumab in clinical remission at Week 52. In biologic failure patients, mirikizumab achieved greater numerical response rates for clinical remission and endoscopic response compared to ustekinumab; however, these results did not reach statistical significance.

INFLAMMATORY BOWEL DISEASE

Crohn's Disease (CD)

Crohn's disease (CD) is a chronic inflammatory bowel disease with genetic, immunologic, and environmental influences. It can affect any portion of the gastrointestinal tract but involves the small intestine and proximal colon most often. The most common symptom is diarrhea, but abdominal pain, fatigue, fever, weight loss, and vomiting are also prevalent. Symptoms typically occur as a chronic, intermittent course, with only a minority of patients having continuously active symptomatic disease or a prolonged remission. In most cases, CD is a chronic, progressive, destructive disease. Early diagnosis and management of CD can lead to better outcomes and less negative impact on quality of life.

Patients are considered to have moderate to severe disease if they have failed to respond to treatment for mild to moderate disease, or if they present with more prominent symptoms of CD. Inflammation-related biomarkers are more likely to be abnormal, and greater endoscopic disease burden is typical. This includes larger or deeper ulcers, strictures, or extensive areas of disease and/or evidence of stricturing, penetrating, or perianal disease. The International Organization for the Study of Inflammatory Bowel Diseases characterizes patients with severe disease as having at least 10 loose stools per day, daily abdominal pain, presence of anorectal symptoms, systemic corticosteroid use within the prior year, lack of symptomatic improvement despite prior exposure to biologics and/or immunosuppressive agents, or significant impact of the disease on activities of daily living. They are also at a high risk for adverse disease-related complications, including surgery, hospitalization, and disability, based on a combination of structural damage, inflammatory burden, and impact of quality of life. Patients with severe disease may have large or deep mucosal lesions on endoscopy or imaging, presence of fistula and/or perianal abscess, presence of strictures, prior intestinal resections, presence of a stoma, and/or extensive disease (e.g., involvement of long bowel segments, pancolitis).

The choice of therapy in CD is dependent on the anatomic location of the disease, the severity of disease, and whether the treatment is needed to induce remission or maintain remission. The goal of treatment for induction of remission is to achieve clinical response and control of inflammation within 3 months of treatment initiation. After inducing clinical remission, patients should be transitioned to steroid-sparing maintenance therapy. In the absence of immunomodulator or biologic treatment, corticosteroid dependency and/or resistance occurs in up to half of patients. In general, the drug(s) used for induction of remission should be continued as maintenance therapy, with the exception of corticosteroids.

The American Gastroenterological Association (AGA) 2021 guideline provides the following recommendations and guidance:

- Biologic therapy:

- The AGA suggest early introduction with a biologic, with or without an immunomodulator, rather than delaying their use until after failure of 5-aminosalicylates and/or corticosteroids (Conditional recommendation, low certainty of evidence)
    - Earlier therapy with a biologic may result in overtreating some patients and potentially exposing them to treatment-related risks and costs with limited benefit. However, step-up therapy comes with a potential risk of harm from disease progression related to inadequate disease therapy.
- Anti-tumor necrosis factor (TNF) (i.e., infliximab or adalimumab) and ustekinumab are recommended over no treatment for the induction and maintenance of remission
- Vedolizumab is suggested over no treatment for the induction and maintenance of remission
- AGA suggests against the use of natalizumab over no treatment for the induction and maintenance of remission
- Patients naïve to biologic therapy, the AGA recommends infliximab, adalimumab, or ustekinumab over certolizumab pegol and suggests the use of vedolizumab over certolizumab pegol for the induction of remission
- Patients with primary non-response to anti-TNF, the AGA recommends ustekinumab and suggests vedolizumab for induction of remission
- Patients with secondary non-response to infliximab, the AGA recommends use of adalimumab or ustekinumab and suggests the use of vedolizumab for the induction of remission (if adalimumab was the first line drug, there is indirect evidence to suggest using infliximab as a second-line agent)

- Corticosteroid therapy:
    - Corticosteroids are suggested over no treatment for the induction of remission, and are recommended against for maintenance of remission
        - In patients with CD involving the distal ileum and/or ascending colon who are more concerned about systemic corticosteroids and less concerned about the lower efficacy, they may reasonably choose budesonide over systematic corticosteroids for inducing remission
- Disease modifying antirheumatic drug (DMARD) therapy:
    - Patients in corticosteroid induced remission or with quiescent moderate to severe CD, the AGA suggests thiopurines for maintenance of remission
    - Subcutaneous or intramuscular methotrexate are suggested over no treatment for the induction and maintenance of remission
    - The AGA recommends against the use of 5-aminosalicylates or sulfasalazine over no treatment for the induction or maintenance of remission
    - The AGA suggests against the use of thiopurines over no treatment for achieving remission and recommends biologic drug monotherapy over thiopurine monotherapy for induction of remission
    - The AGA suggests against the use of oral methotrexate monotherapy over no treatment for the induction and maintenance of remission
- Combination therapy:
    - Patients that are naïve to biologics and immunomodulators, the AGA suggest use of infliximab in combination with thiopurines over infliximab monotherapy for the induction and maintenance of remission (combination infliximab with methotrexate may be more effective over infliximab monotherapy)
    - Patients that are naïve to biologics and immunomodulators, the AGA suggest use of adalimumab in combination with thiopurines over adalimumab monotherapy for the induction and maintenance

of remission (combination adalimumab with methotrexate may be more effective over adalimumab monotherapy)

- No recommendations are being made regarding the use of ustekinumab or vedolizumab in combination with thiopurines or methotrexate over biologic monotherapy for induction or maintenance or remission

The American College of Gastroenterology (ACG) 2025 guideline provides the following recommendations and guidance:

- Biologic therapy:
  - Biologic agents are effective for treating patients with active CD and previous inadequate response to corticosteroids, thiopurines, and/or methotrexate
  - Suggest against requiring failure of conventional therapy before initiation of advanced therapy for the management of CD (conditional recommendation, low level of evidence)
    - The risk of adverse effects and high cost of biologic agents may not be justifiable in a lower risk population
  - Recommend the following drugs for induction and maintenance of remission for moderately to severely active CD:
    - Anti-TNF agents (i.e., infliximab, adalimumab, certolizumab), vedolizumab, ustekinumab, risankizumab, mirikizumab, guselkumab
  - Recommend combination therapy of intravenous infliximab with immunomodulators (thiopurines) as compared with treatment with either immunomodulators alone or intravenous infliximab alone in patients with CD who are naïve to those agents
  - Recommend the use of risankizumab as compared with ustekinumab in patients with moderate to severe CD and prior exposure to anti-TNF therapy
  - Biosimilar infliximab, adalimumab, and ustekinumab are effective treatments for patients with moderate-to-severe CD and can be used for de novo induction and maintenance therapy
  - There are data to support the safety and efficacy of transitioning or switching to biosimilar infliximab or adalimumab for patients with CD in stable disease maintenance
- Janus kinase (JAK) inhibitor therapy:
  - Recommend upadacitinib use for induction and maintenance of remission for patients with moderate-to-severe CD who have previously been exposed to anti-TNF agents
- Corticosteroid therapy:
  - Recommend oral corticosteroids for short-term induction of remission in patients with moderately to severely active CD
    - Recommend controlled ileal release budesonide at a dose of 9 mg daily for induction of symptomatic remission in patients with mildly to moderately active ileocecal CD
  - Corticosteroids should not be used for maintaining remission, and their use should not exceed 3 continuous months without attempting to introduce a steroid-sparing agent (such as an immunomodulator)
- DMARD therapy:
  - Recommend against azathioprine or 6-mercaptopurine for induction of remission in moderately to severely active CD
    - Due to their slow onset of action of 8 to 12 weeks, thiopurines are not effective agents for induction of remission

- Suggest azathioprine or 6-mercaptopurine for maintenance of remission in patients with moderately to severely active CD who had induction of remission with corticosteroids
- Suggest methotrexate (up to 25 mg once weekly intramuscular or subcutaneous) for maintenance of remission in patients with moderately to severely active CD who had induction of remission with corticosteroids
- Azathioprine, 6-mercaptopurine, or methotrexate may be used in the treatment of active CD and as adjunctive therapy for reducing immunogenicity associated with anti-TNF therapy

Ulcerative Colitis (UC)

Ulcerative colitis (UC) is a chronic inflammatory bowel disease affecting the large intestine. It typically starts with inflammation of the rectum, but often extends proximally to involve additional areas of the colon. The most common symptom is bloody diarrhea, but urgency, tenesmus, abdominal pain, malaise, weight loss, and fever can also be associated. UC commonly has a gradual onset and will present with periods of spontaneous remission and subsequent relapses.

Disease severity is based on patient-reported outcomes (e.g., bleeding, bowel habits, bowel urgency), inflammatory burden (e.g., endoscopic assessment, inflammatory markers), disease course, and disease impact. Commonly assessed symptoms include frequency and timing of bowel movements, rectal bleeding, bowel urgency, abdominal pain, bowel cramping, and weight loss. Poor prognostic factors include less than 40 years of age at diagnosis, extensive colitis, severe endoscopic disease, hospitalization for colitis, elevated C-reactive protein (CRP), and low serum albumin. Therapeutic management in UC should be guided by the extent of bowel involvement, assessment of disease activity (i.e., quiescent, mild, moderate, or severe), and disease prognosis. Treatment response should be evaluated 12 weeks after initiation of therapy to confirm efficacy and safety.

The American College of Gastroenterology (ACG) published recommendations and guidance (2025) for the management of moderate-to-severe UC:

<u>General treatment information</u>:

- Patients with mildly to moderately active UC and a number of prognostic factors associated with an increased risk of hospitalization or surgery should be treated with therapies for moderate-to-severe disease
- Patients with mildly to moderately active UC who are not responsive (or are intolerant) to 5-aminosalicylate (5-ASA) therapies (e.g., balsalazide, mesalamine, sulfasalazine) should be treated as patients with moderate-to-severe disease

<u>Corticosteroid therapy</u>:

- In patients with moderately active UC, recommend oral budesonide multi-matrix system (MMX) for induction of remission
  - In patients with moderately active UC, consider nonsystemic corticosteroids such as budesonide MMX before the use of systemic therapy
- Recommend oral systemic corticosteroids to induce remission in UC of any extent
  - In patients with severely active UC, consider systemic corticosteroids rather than topical corticosteroids
- Recommend against systemic, budesonide MMX, or topical corticosteroids for maintenance of remission

<u>Disease modifying antirheumatic drug (DMARD) therapy</u>:

- Recommend against monotherapy with thiopurines or methotrexate for induction of remission
- 5-ASA therapy could be used as monotherapy for induction of moderately but not severely active UC

- 5-ASA therapy for maintenance of remission is likely not as effective in prior severely active UC as compared with prior moderately active UC
- Suggest thiopurines for maintenance of remission in patients now in remission due to corticosteroid induction
- Suggest against using methotrexate for maintenance of remission

Biologic/advanced therapy:

- Recommend the following drugs for induction of remission and continuing the same drug for maintenance of remission:
    - Anti-tumor necrosis factor (TNF) agents (e.g., infliximab, adalimumab, golimumab), ustekinumab, guselkumab, mirikizumab, risankizumab, vedolizumab, tofacitinib, upadacitinib, sphingosine-1-phosphate (S1P) receptor modulators (e.g., ozanimod, etrasimod)
    - Most clinical trials and available data demonstrate a benefit of using the steroid-sparing therapy that induces remission to maintain that remission
- When infliximab is used as induction therapy, recommend combination therapy with a thiopurine
    - Data on combination anti-TNF and immunomodulators in moderately to severely active UC only exist for infliximab and thiopurines
- Infliximab is the preferred anti-TNF therapy for patients with moderately to severely active UC
- Recommend vedolizumab as compared to adalimumab for induction and maintenance of remission
- Patients who are primary nonresponders to an anti-TNF (defined as lack of therapeutic benefit after induction and despite sufficient serum drug concentrations) should be evaluated and considered for alternative mechanisms of disease control (e.g., in a different class of therapy) rather than cycling to another drug within the anti-TNF class
- Biosimilars to anti-TNF therapies and to ustekinumab are acceptable substitutes for originator therapies. Delays in switching should not occur and patients and clinicians should be notified about such changes

The American Gastroenterology Association (AGA) published recommendations and guidance (2018) for the management of mild-to-moderate UC:

- In patients with moderate disease activity, suggest using high dose mesalamine (greater than 3 g/day) with rectal mesalamine for induction of remission and maintenance of remission
- Add either oral prednisone or budesonide MMX in patients that are refractory to optimized oral and rectal 5-ASA, regardless of disease extent
- If progression to moderate-to-severe disease activity occurs, or if the patient is at high risk for colectomy despite therapy, consider escalating to treatment for moderate-to-severe disease with immunomodulators and/or biologics

The American Gastroenterology Association (AGA) published recommendations and guidance (2024) for the management of moderate-to-severe UC:

General treatment information:

- Suggest early use of advanced therapy (e.g., biologics, ozanimod, etrasimod), with or without immunomodulator therapy (e.g., thiopurines), rather than treatment with 5-ASA and a gradual step up to biologic/immunomodulator therapy after 5-ASA treatment failure (conditional recommendation, very low certainty of evidence)
    - Patients with less severe disease or those who place a higher value on the safety of 5-ASA therapy over the efficacy of immunosuppressives may reasonably choose gradual step therapy with 5-ASA therapy

DMARD therapy:

- Suggest against using thiopurine monotherapy for inducing remission
- Suggest thiopurine monotherapy may be used for maintaining remission typically induced with corticosteroids
- Suggest against using methotrexate monotherapy for inducing or maintaining remission

Advanced therapy:

- Recommend using one of the following advanced therapies over no treatment:
    - Infliximab, golimumab, vedolizumab, tofacitinib, upadacitinib, ustekinumab, ozanimod, etrasimod, risankizumab, guselkumab
- Suggest using one of the following advanced therapies over no treatment:
    - Adalimumab, filgotinib*, mirikizumab (*not currently approved by the Food and Drug Administration)
- Biosimilars of infliximab, adalimumab, and ustekinumab can be considered equivalent to their originator drug in their efficacy
- Suggest the use of infliximab in combination with an immunomodulator over infliximab or an immunomodulator alone
- Suggest the use of adalimumab or golimumab in combination with an immunomodulator over adalimumab, golimumab or immunomodulator monotherapy

Advanced therapy-naïve patients (first-line therapy):

- Suggest that a higher or intermediate efficacy medication be used rather than a lower efficacy medication
    - Higher efficacy: infliximab, vedolizumab, ozanimod, etrasimod, upadacitinib, risankizumab, guselkumab
    - Intermediate efficacy: golimumab, ustekinumab, tofacitinib, filgotinib, mirikizumab
    - Lower efficacy: adalimumab

Prior exposure to one or more advanced therapies, particularly TNF antagonists:

- Suggest that a higher or intermediate efficacy medication be used rather than a lower efficacy medication
    - Higher efficacy: tofacitinib, upadacitinib, ustekinumab
    - Intermediate efficacy: filgotinib, mirikizumab, risankizumab, guselkumab
    - Lower efficacy: adalimumab, vedolizumab, ozanimod, etrasimod

POSITION STATEMENT:

Comparative Effectiveness

The Food and Drug Administration has deemed the subcutaneous formulations of the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) of the subcutaneous formulations in certain provider-administered setting such as an outpatient hospital, ambulatory surgical suite, or emergency facility is not considered medically necessary.

NOTE: The list of self-administered products with prerequisites for certain indications can be found at Preferred Agents and Drug List.

SUBCUTANEOUS OMVOH (PHARMACY BENEFIT)

Initiation of subcutaneous mirikizumab (Omvoh) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "5"):

1. **ONE** of the following ("a", "b", or "c"):
    a. The member has been treated with subcutaneous mirikizumab (starting on samples is not approvable) within the past 90 days
    b. The prescriber states the member has been treated with subcutaneous mirikizumab (starting on samples is not approvable) within the past 90 days **AND** is at risk if therapy is changed
    c. **BOTH** of the following ("i" and ii"):
        i. Subcutaneous mirikizumab will be used for the treatment of an indication listed in Table 1, and **ALL** of the indication-specific criteria are met
        ii. E**ITHER** of the following if the member has an FDA-approved indication ("I" or "II"):
            I. The member's age is within FDA labeling for the requested indication for subcutaneous mirikizumab
            II. The prescriber has provided information in support of using subcutaneous mirikizumab for the member's age for the requested indication
2. The prescriber is a specialist in the area of the member's diagnosis (e.g., gastroenterologist for CD and UC) or the prescriber has consulted with a specialist in the area of the member's diagnosis
3. Member does **NOT** have any FDA labeled contraindications to subcutaneous mirikizumab
4. Member will **NOT** be using subcutaneous mirikizumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
5. **ANY** of the following ("a", "b", "c", or "d"):
    a. The dosage does not exceed the following based on the indication for use:
        i. Crohn's disease (CD) - 300 mg subcutaneously (given as two consecutive injections of 100 mg and 200 mg in any order) every 4 weeks (28 days) [to be started 4 weeks after the last loading dose of IV mirikizumab (i.e., Week 12)]
            - QL: 100 mg/1 mL autoinjector/pen - 1 autoinjector/pen (1 mL)/28 days [included in a single carton of 200 mg/2 mL + 100 mg/mL co-packaged]
            - QL: 100 mg/1 mL prefilled syringe - 1 syringe (1 mL)/28 days [included in a single carton of 200 mg/2 mL + 100 mg/mL co-packaged]
            - QL: 200 mg/1 mL autoinjector/pen - 1 autoinjector/pen (2 mL)/28 days [included in a single carton of 200 mg/2 mL + 100 mg/mL co-packaged]
            - QL: 200 mg/1 mL prefilled syringe - 1 syringe (2 mL)/28 days [included in a single carton of 200 mg/2 mL + 100 mg/mL co-packaged]
        ii. Ulcerative colitis (UC) - 200 mg subcutaneously (given as either one injection of 200 mg or two consecutive injections of 100 mg each) every 4 weeks (28 days) [to be started 4 weeks after the last loading dose of IV mirikizumab (i.e., Week 12)]
            - QL: 100 mg/1 mL autoinjector/pen - 2 autoinjectors/pens (2 mL)/28 days [one carton of 100 mg/mL + 100 mg/mL]

- QL: 100 mg/1 mL prefilled syringe - 2 syringes (2 mL)/28 days [one carton of 100 mg/mL + 100 mg/mL]
- QL: 200 mg/1 mL autoinjector/pen - 1 autoinjector/pen (2 mL)/28 days
- QL: 200 mg/1 mL prefilled syringe - 1 syringe (2 mL)/28 days

b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

   i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

   ii. **ALL** of the following ("1", "2", and "3"):

      1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
      2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
      3. **EITHER** of the following ("a" or "b"):
         a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit
         b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

   i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

   ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

   i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

   ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration: 12 months; the start date will depend on the number of Omvoh IV loading doses already received

Table 1

Diagnosis	Criteria
Moderately to severely active Crohn's disease (CD)	**ALL** of the following ("1", "2", and "3"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of CD **OR** c. The member has an FDA labeled contraindication **ALL** conventional agents used in the treatment of CD **OR** d. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of CD **AND** 2. **ANY** of the following: a. The member has tried and had an inadequate response to at least **ONE** preferred product after at least a 3-month trial **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **ONE** preferred product **OR** c. The member has an FDA labeled contraindication to **ALL** preferred products **OR** d. **ALL** preferred product are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred CD products are:** • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd)

	• Humira (adalimumab) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Yesintek (ustekinumab-kfce) **AND** 3. The member has received or will receive IV mirikizumab (Omvoh) for induction therapy
Moderately to severely active ulcerative colitis (UC)	**ALL** of the following ("1", "2", and "3"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of UC **OR** c. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of UC **OR** d. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of UC **AND** 2. **ANY** of the following: a. The member has tried and had an inadequate response to at least **ONE** preferred product after at least a 3-month trial **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **ONE** preferred product **OR** c. The member has an FDA labeled contraindication to **ALL** preferred products **OR**

	d. **ALL** preferred product are **NOT** clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred UC products are:** • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) • Yesintek (ustekinumab-kfce) **AND** 3. The member has received or will receive IV mirikizumab (Omvoh) for induction therapy
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a

Continuation of subcutaneous mirikizumab (Omvoh) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for subcutaneous mirikizumab has been previously approved by Florida Blue [Note: members not previously approved for the requested agent will require initial evaluation review]
2. Member has had clinical benefit with subcutaneous mirikizumab therapy
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., gastroenterologist for CD and UC) or the prescriber has consulted with a specialist in the area of the member's diagnosis
4. Member does **NOT** have any FDA-labeled contraindications to subcutaneous mirikizumab
5. Member will **NOT** be using subcutaneous mirikizumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **ANY** of the following ("a", "b", "c", or "d"):
    a. The dosage does not exceed the following based on the indication for use:

i. Crohn's disease (CD) - 300 mg subcutaneously (given as two consecutive injections of 100 mg and 200 mg in any order) every 4 weeks (28 days) [to be started 4 weeks after the last loading dose of IV mirikizumab (i.e., Week 12)]

- QL: 100 mg/1 mL autoinjector/pen - 1 autoinjector/pen (1 mL)/28 days [included in a single carton of 200 mg/2 mL + 100 mg/mL co-packaged]
- QL: 100 mg/1 mL prefilled syringe - 1 syringe (1 mL)/28 days [included in a single carton of 200 mg/2 mL + 100 mg/mL co-packaged]
- QL: 200 mg/1 mL autoinjector/pen - 1 autoinjector/pen (2 mL)/28 days [included in a single carton of 200 mg/2 mL + 100 mg/mL co-packaged]
- QL: 200 mg/1 mL prefilled syringe - 1 syringe (2 mL)/28 days [included in a single carton of 200 mg/2 mL + 100 mg/mL co-packaged]

ii. Ulcerative colitis (UC) - 200 mg subcutaneously (given as either one injection of 200 mg or two consecutive injections of 100 mg each) every 4 weeks (28 days)

- QL: 100 mg/1 mL autoinjector/pen - 2 autoinjectors/pens (2 mL)/28 days [one carton of 100 mg/mL + 100 mg/mL]
- QL: 100 mg/1 mL prefilled syringe - 2 syringes (2 mL)/28 days [one carton of 100 mg/mL + 100 mg/mL]
- QL: 200 mg/1 mL autoinjector/pen - 1 autoinjector/pen (2 mL)/28 days
- QL: 200 mg/1 mL prefilled syringe - 1 syringe (2 mL)/28 days

b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. **ALL** of the following ("1", "2", and "3"):

1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
3. **EITHER** of the following ("a" or "b"):
    a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit
    b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration: 12 months

INTRAVENOUS OMVOH (MEDICAL BENEFIT)

Initiation of intravenous (IV) mirikizumab (Omvoh) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "6"):

1. Intravenous mirikizumab will be used for the treatment of an indication listed in Table 2, and **ALL** of the indication-specific and maximum-allowable dose criteria are met
2. **EITHER** of the following if the member has an FDA-approved indication ("a" or "b"):
   a. The member's age is within FDA labeling for the requested indication for intravenous mirikizumab
   b. The prescriber has provided information in support of using intravenous mirikizumab for the member's age for the requested indication
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., gastroenterologist for CD and UC) or the prescriber has consulted with a specialist in the area of the member's diagnosis
4. Member does **NOT** have any FDA labeled contraindications to IV mirikizumab
5. Member will **NOT** be using intravenous mirikizumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. Member has not received a previous dose of mirikizumab (IV or SC) in the past 6 months

Approval duration:

- CD and UC - 3 months (to allow for 3 doses total)
- Other indications – 12 months

Table 2

Indication	Criteria	Max Allowable Dosage
Moderately to severely active Crohn's disease (CD)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-	• 900 mg IV at Weeks 0, 4, and 8 (3 doses total)

	mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of CD **OR** c. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of CD **OR** d. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of CD **AND** 2. **ANY** of the following: a. The member has tried and had an inadequate response to at least **ONE** preferred product after at least a 3-month trial **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **ONE** preferred product **OR** c. The member has an FDA labeled contraindication to **ALL** preferred products **OR** d. **ALL** preferred products are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred CD products are:** • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd)	

	• Humira (adalimumab) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Yesintek (ustekinumab-kfce)	
Moderately to severely active ulcerative colitis (UC)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of UC **OR** c. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of UC **OR** d. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of UC **AND** 2. **ANY** of the following: a. The member has tried and had an inadequate response to at least **ONE** preferred product after at least a 3-month trial **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **ONE** preferred product **OR**	• 300 mg IV at Weeks 0, 4, and 8 (3 doses total)

	c. The member has an FDA labeled contraindication to **ALL** preferred products **OR** e. **ALL** preferred product are **NOT** clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred UC products are:** • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) • Yesintek (ustekinumab-kfce)	
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a	Maximum dose supported by the FDA labeled indication or maximum dose supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved:

- Indicated for the treatment of: (1) moderately to severely active ulcerative colitis (UC) in adults, and (2) moderately to severely active Crohn's disease in adults.

- For UC - The recommended induction dosage is 300 mg administered by IV infusion over at least 30 minutes at Week 0, Week 4, and Week 8. The recommended maintenance dosage is 200 mg administered by SQ injection (given as either one injection of 200 mg or two consecutive injections of 100 mg each) at Week 12, and every 4 weeks thereafter.
- For CD - The recommended induction dosage is 900 mg administered by IV infusion over at least 90 minutes at Week 0, Week 4, and Week 8. The recommended maintenance dosage is 300 mg administered by SQ injection (given as two consecutive injections of 100 mg and 200 mg in any order each) at Week 12, and every 4 weeks thereafter.

- Omvoh for IV use is intended for administration by a healthcare provider using aseptic technique. Each vial is for single use only. Administer the infusion over at least 30 minutes for a 300 mg dose, and at least 90 minutes for a 900 mg dose. Refer to the product labeling for preparation and administration instructions.
- Omvoh for SC use is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject after training in SQ injection technique. Before injection, remove prefilled pens or prefilled syringes from the refrigerator and leave at room temperature for 45 minutes. Do not shake the prefilled pens or prefilled syringes from. Sites for injection include the abdomen, thigh, and back of the upper arm. Instruct patients to inject in a different location every time. For example, if the first injection was in the abdomen, administer the second injection (to complete a full dose) in another area of the abdomen, or upper arm, or thigh. Administration in the back of upper arm may only be performed by another person.

Dose Adjustment:

- No specific guidelines for dosage adjustments for renal or hepatic impairment are available. It appears that no dosage adjustments are needed.

Drug Availability:

- IV infusion
  - 300 mg/15 mL (20 mg/mL) solution in a single-dose vial
- Subcutaneous use:
  - Single-dose Prefilled Pen
    - 100 mg/mL + 100 mg/mL (for UC) - carton of 2
    - 200 mg/2 mL (for UC) – carton of 1
    - 200 mg/2 mL + 100 mg/mL (for CD) - carton of 2 (1 of each)
  - Single-dose Prefilled Syringe
    - 100 mg/mL + 100 mg/mL (for UC) - carton of 2
    - 200 mg/2 mL (for UC) – carton of 1
    - 200 mg/2 mL + 100 mg/mL (for CD) - carton of 2 (1 of each)
- Note to Pharmacist: The entire carton of 2 prefilled pen or 2 prefilled syringes are to be dispensed as a unit.
- Store refrigerated at 2°C to 8°C (36°F to 46°F). Do not freeze. Do not use Omvoh if it has been frozen. Do not shake. Keep in the original carton to protect from light until the time of use. Omvoh is sterile and preservative-free. Discard any unused portion. If needed, the prefilled pen may be stored at room temperature up to 30°C (86°F) for up to 2 weeks in the original carton to protect from light. Once Omvoh has been stored at room temperature, do not return to the refrigerator. If these conditions are exceeded, Omvoh must be discarded. The vial and prefilled pen are not made with dry natural rubber latex.

PRECAUTIONS:

Boxed Warning:

- None

Contraindication:

- Patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.

Precautions/Warnings

- **Hypersensitivity Reactions**: Serious hypersensitivity reactions, including anaphylaxis and infusion-related reactions, have been reported. If a severe hypersensitivity reaction occurs, discontinue and initiate appropriate treatment.
- **Infections**: Omvoh may increase the risk of infection. Do not initiate treatment with Omvoh in patients with a clinically important active infection until the infection resolves or is adequately treated. If a serious infection develops, do not administer Omvoh until the infection resolves.
- **Tuberculosis**: Do not administer Omvoh to patients with active TB infection. Monitor patients receiving Omvoh for signs and symptoms of active TB during and after treatment.
- **Hepatotoxicity**: Drug-induced liver injury has been reported. Monitor liver enzymes and bilirubin levels at baseline and for at least 24 weeks of treatment and thereafter according to routine patient management. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded.
- **Immunizations**: Avoid use of live vaccines.

BILLING/CODING INFORMATION:

HCPCS Coding:

C9168	Injection, mirikizumab-mrkz, 1 mg [IV formulation, hospital outpatient use only]
J3590	Unclassified biologicals

ICD-10 Diagnosis Codes That Support Medical Necessity of Intravenous Injection (C9168, J3590, NDC):

K50.00 – K50.919	Crohn's disease [regional enteritis]
K51.00 – K51.919	Ulcerative colitis

ICD-10 Diagnosis Codes That Support Medical Necessity of Subcutaneous Injection (J3590, NDC):

K50.00 – K50.919	Crohn's disease [regional enteritis]
K51.00 – K51.919	Ulcerative colitis

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Bacillus Calmette-Guérin (BCG): a vaccine against tuberculosis that is prepared from a strain of the attenuated (weakened) live bovine tuberculosis bacillus, Mycobacterium bovis.

DMARDs: An acronym for disease-modifying antirheumatic drugs. These are drugs that modify the rheumatic disease processes, and slow or inhibit structural damage to cartilage and bone. These drugs are unlike symptomatic treatments such as NSAIDs that do not alter disease progression. DMARDs can be further subcategorized. With the release of biologic agents (e.g., anti-TNF drugs), DMARDs were divided into either: (1) conventional, traditional, synthetic, or non-biological DMARDs; or as (2) biological DMARDs. However, with the release of newer targeted non-biologic drugs and biosimilars, DMARDs are now best categorized as: (1) conventional synthetic DMARDs (csDMARD) (e.g., MTX, sulfasalazine), (2) targeted synthetic DMARDs (tsDMARD) (e.g., baricitinib, tofacitinib, apremilast), and (3) biological DMARDs (bDMARD), which can be either a biosimilar DMARD (bsDMARD) or biological originator DMARD (boDMARD).

RELATED GUIDELINES:

Adalimumab Products, 09-J0000-46
Certolizumab Pegol (Cimzia), 09-J0000-77
Etrasimod (Velsipity) Tablet, 09-J4000-72
Golimumab (Simponi, Simponi Aria), 09-J1000-11
Guselkumab (Tremfya), 09-J2000-87
Infliximab Products, 09-J0000-39
Natalizumab (Tysabri) Injection, 09-J0000-73
Ozanimod (Zeposia) Capsules, 09-J3000-70
Risankizumab (Skyrizi), 09-J3000-45
Tofacitinib (Xeljanz, Xeljanz XR) Oral Solution, Tablet and Extended-Release Tablet, 09-J1000-86
Upadacitinib (Rinvoq), 09-J3000-51
Ustekinumab (Stelara), 09-J1000-16
Vedolizumab (Entyvio), 09-J2000-18

OTHER:

NOTE: The list of biologic immunomodulator agents not permitted as concomitant therapy can be found at Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

Table 3: Conventional Synthetic DMARDs

Generic Name	Brand Name
Auranofin (oral gold)	Ridaura
Azathioprine	Imuran
Cyclosporine	Neoral, Sandimmune

Hydroxychloroquine	Plaquenil
Leflunomide	Arava
Methotrexate	Rheumatrex, Trexall
Sulfasalazine	Azulfidine, Azulfidine EN-Tabs

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 11/12/25.

GUIDELINE UPDATE INFORMATION:

04/01/24	New Medical Coverage Guideline.
07/01/24	Revision to guideline consisting of updating the position statement, related guidelines, and other section. Amjevita low concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
10/01/24	Revision to guideline consisting of updating the position statement. Omvoh moved from a Step 3c agent to a Steb 3b agent.
11/15/24	Revision to guideline consisting of updating the position statement and other section. Tremfya added as Step 1a agent for UC and clarified that the age requirement that exists for subcutaneous Omvoh also applies to intravenous Omvoh.
01/01/25	Review and revision to guideline consisting of updating the position statement, other section, and references. Omvoh moved from a Step 3b agent (double step) to a Step 2 agent (single step). Adalimumab-aaty, Adalimumab-adaz, and Entyvio SC added among the prerequisite therapies for UC. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
04/01/25	Revision to guideline consisting of updating the description section, position statement, dosage/administration section, billing/coding information, and references based on a new FDA approved indication for CD. Omvoh is a Step 2 agent (single step) for CD.
05/15/25	Revision. Tremfya added among the preferred agents for CD.
07/01/25	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for CD and UC.
01/01/26	Review and revision to guideline consisting of updating the description, position statement, dosage/administration, and references.
05/15/26	Revision to guideline consisting of clarifying the approval duration and start date for Omvoh subcutaneous injection following Omvoh IV induction.
07/01/26	Revision: Modified the prerequisite requirement that bypasses the conventional agent step to exclude sample use and include systemic targeted synthetic small molecule drugs as an option. Removed Selarsdi as a preferred agent for CD and UC.
10/01/26	Revision: Clarified wording regarding IV induction therapy prior to subcutaneous maintenance therapy.