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

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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 an inflammatory condition that can affect any portion of the gastrointestinal tract from the mouth to the perianal area. Choice of therapy is dependent on the anatomic location of disease, the severity of disease, and whether the treatment goal is to induce remission or maintain remission. The American Gastroenterological Association (AGA) 2021 guideline recommends the following:

- 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
    - Anti-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)

- DMARD therapy:
  - Corticosteroids are suggested over no treatment for the induction of remission, and are recommended against for maintenance of remission
  - 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 2018 American College of Gastroenterology (ACG) guidelines recommend the following:

- Mild to moderately severe disease/low risk disease:
  - Sulfasalazine (in doses of 3-6 grams daily) is effective in colonic and/or ileocolonic CD, but not those with isolated small bowel disease
  - 5-aminosalicylic (ASA) suppositories and enema preparations are effective for induction and maintenance of remission in rectal and sigmoid disease

- Conventional corticosteroids are primarily used for the treatment of flares, and are often used as a bridge until immunomodulators and/or biologic agents become effective
- Controlled ileal release budesonide is effective for induction of remission in ileocecal disease

- Moderate to severe disease/moderate to high risk disease
  - Corticosteroids are effective for short-term use in alleviating signs and symptoms of moderate to severely active CD, but do not induce mucosal healing and should be used sparingly
  - Azathioprine, 6-mercaptopurine, or MTX (15 mg once weekly) may be used in treatment of active disease and as adjunctive therapy for reducing immunogenicity against biologic therapy
  - TNF inhibitors should be used to treat CD that is resistant to treatment with corticosteroids and that is refractory to thiopurines or MTX
  - Vedolizumab with or without an immunomodulator should be considered for induction of symptomatic remission for patients with moderate to severely active CD and objective evidence of active disease
  - Ustekinumab should be used in patients that have failed previous treatment with corticosteroids, thiopurines, MTX, or TNF inhibitors, or in patients with no prior TNF inhibitor exposure
- Severe/fulminant disease:
  - IV corticosteroids should be used
  - TNF inhibitors can be considered
- Maintenance therapy:
  - Thiopurines or methotrexate should be considered once remission is induced with corticosteroids
  - TNF inhibitors, specifically infliximab, adalimumab, and certolizumab pegol, should be used in combination with azathioprine, MTX, or 6-mercaptopurine to maintain remission of TNF induced remission
  - Vedolizumab should be used for maintenance of remission of vedolizumab induced remission
  - Ustekinumab should be used for maintenance of remission of ustekinumab induced remission

Ulcerative Colitis (UC)

Ulcerative colitis (UC) is a chronic immune-mediated inflammatory condition affecting the large intestine associated with inflammation of the rectum, but that can extend to involve additional areas of the colon. The American College of Gastroenterology (ACG) recommends a treat-to-target approach and recommend therapeutic management should be guided by diagnosis (i.e., Montreal classification), assessment of disease activity (i.e., mild, moderate, and severe), and disease prognosis. The ACG treatment recommendations are further broken down into induction therapies and maintenance of remission. The 2019 ACG treatment guidelines recommend the following for therapeutic management of UC:

<u>Induction of remission</u>:

- Mildly active disease:
    - Rectal 5-ASA at a dose of 1 g/day with or without oral 5-ASA at a dose of at least 2 g/day for left-sided UC
    - Rectal 5-ASA at a dose of 1 g/day for ulcerative proctitis
    - Oral 5-ASA at a dose of at least 2 g/day for extensive UC
    - Add oral budesonide multi-matrix (MMX) 9 mg/day for patients that are intolerant or non-responsive to oral and/or rectal and oral 5-ASA at appropriate doses
- Moderately active disease:
    - Oral budesonide multi-matrix (MMX) 9 mg/day for induction of remission
- Moderately to severely active disease:
    - Oral systemic corticosteroids, TNF inhibitors (i.e., adalimumab, golimumab, or infliximab), tofacitinib, or vedolizumab to induce remission
    - Combination of infliximab with thiopurine therapy when using infliximab for induction
    - Switch to tofacitinib or vedolizumab for induction in patients that have failed TNF inhibitors
    - Patients with initial response to TNF inhibitors that lose response should have antibody levels and serum drug levels tested to assess reason for loss of response. If serum levels are adequate, use of another TNF inhibitor is not likely to be of benefit.

<u>Maintenance of remission</u>:

- Previously mildly active disease:
    - Rectal 5-ASA at a dose of 1 g/day in patients with ulcerative proctitis
    - Oral 5-ASA at a dose of at least 2 g/day in patients with left-sided or extensive UC
- Previously moderately to severely active disease:
    - Thiopurines in patients that achieved remission due to corticosteroid induction
    - Continue TNF inhibitors (i.e., adalimumab, golimumab, or infliximab) for remission due to TNF induction
    - Continue vedolizumab for remission due to vedolizumab induction
    - Continue tofacitinib for remission due to tofacitinib induction

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

- Use either standard-dose mesalamine (2-3 g/day) or diazo-bonded 5-ASA for patients with extensive UC for induction of remission and maintenance of remission
- May add rectal mesalamine to oral 5-ASA in patients with extensive or left-sided UC for induction of remission and maintenance of remission

- Use high dose mesalamine (>3 g/day) with rectal mesalamine in patients with suboptimal response to standard-dose mesalamine, diazo-bonded 5-ASA, or with moderate disease activity 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

The American Gastroenterology Association (AGA) published recommendations for the management of moderate to severe UC.

- Standard of care is to continue agents initiated for induction therapy as maintenance therapy, if they are effective (excluding corticosteroids and cyclosporine)
- Adult outpatients with moderate to severe UC:
    - Infliximab, adalimumab, golimumab, vedolizumab, tofacitinib or ustekinumab are strongly recommended over no treatment
    - Biologic naïve patients:
        - infliximab or vedolizumab are conditionally recommended over adalimumab for induction of remission
        - Recommend tofacitinib only be used in the setting of a clinical or registry study
    - Previous exposure to infliximab, particularly those with primary non-response, ustekinumab or tofacitinib are conditionally recommended over vedolizumab or adalimumab for induction of remission
    - Conditionally recommend against use of thiopurine monotherapy for induction, but may be used for maintenance of remission over no treatment

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), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (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 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]

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

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** of the conventional agents used in the treatment of CD **OR** c. The member has an FDA labeled contraindication **ALL** of the conventional agents used in the treatment of CD **OR** d. The member's medication history indicates use of another biologic immunomodulator agent 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** of the following preferred products after at least a 3-month trial: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Stelara (ustekinumab) **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** of the following: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection

	• Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Stelara (ustekinumab) **OR** c. The member has an FDA labeled contraindication to **ALL** of the following: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Stelara (ustekinumab) **OR** d. **ALL** of the following are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Stelara (ustekinumab) **AND** 3. The member has received 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** of the conventional agents used in the treatment of UC **OR** c. The member has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of UC **OR** d. The member's medication history indicates use of another biologic immunomodulator agent 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** of the following preferred products after at least a 3-month trial: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib)

	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** of the following: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) c. The member has an FDA labeled contraindication to **ALL** of the following: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) **OR**

	d. **ALL** of the following are **NOT** clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) **AND** 3. The member has received 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 (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended

release)]; Otezla (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 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]
    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 IV 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 (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla

(apremilast); 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-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** of the conventional agents used in the treatment of CD **OR** c. The member has an FDA labeled contraindication **ALL** of the conventional agents used in the treatment of CD **OR** d. The member's medication history indicates use of another biologic immunomodulator agent 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** of the following preferred products after at least a 3-month trial: • Adalimumab-aaty • Adalimumab-adaz	• 900 mg IV at Weeks 0, 4, and 8 (3 doses total)

	• Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Stelara (ustekinumab) **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** of the following: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Stelara (ustekinumab) **OR** c. The member has an FDA labeled contraindication to **ALL** of the following: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Stelara (ustekinumab) **OR**	

	d. **ALL** of the following are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Stelara (ustekinumab)	
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** of the conventional agents used in the treatment of UC **OR** c. The member has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of UC **OR** d. The member's medication history indicates use of another biologic immunomodulator agent 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:	• 300 mg IV at Weeks 0, 4, and 8 (3 doses total)

	a. The member has tried and had an inadequate response to at least **ONE** of the following preferred products after at least a 3-month trial: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) **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** of the following: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Tremfya (guselkumab)	

	• Xeljanz/Xeljanz XR (tofacitinib) **OR** c. The member has an FDA labeled contraindication to **ALL** of the following: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) **OR** d. **ALL** of the following are **NOT** clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • Adalimumab-aaty • Adalimumab-adaz • Entyvio (vedolizumab) subcutaneous injection • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab)	

	• Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib)	
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 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. A full maintenance dose will require 2 prefilled pens or 2 prefilled syringes given as two consecutive injections, in any order. Before injection, remove prefilled pens or prefilled syringes from the refrigerator and leave at room temperature for 30 minutes if using the carton containing 100 mg/mL + 100 mg/mL or 45 minutes if using the carton containing 200 mg/2 mL + 100 mg/mL. 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 + 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 + 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 02/12/25.

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.