Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 317.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Omvoh (mirikizumab-mrkz)

I. Policy:
Omvoh (mirikizumab-mrkz)

II. Purpose/Objective:
To provide a policy of coverage regarding Omvoh (mirikizumab-mrkz)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Omvoh (mirikizumab-mrkz) 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 proinflammatory cytokines. Research in animal models has shown that pharmacologic inhibition of IL-23p19 can ameliorate intestinal inflammation. Mirikizumab-mrkz inhibits the release of pro-inflammatory cytokines and chemokines.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Omvoh (mirikizumab-mrkz) will be considered medically necessary for the Commercial, Exchange, and CHIP lines of business when ALL of the following criteria are met:

- Medical record documentation that Omvoh is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Omvoh is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) preferred formulary biologics for the treatment of ulcerative colitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on Entyvio* **AND** infliximab* **AND**
- Medical record documentation that Omvoh 300 mg vials as intravenous (IV) infusion are being used for induction therapy

Note: Plan preferred formulary biologics include: Humira*, adalimumab-fkjp*, Hadlima*, Yusimry*, Rinvoq*, Simponi*, Xeljanz/XR*

*Prior authorization required

AUTHORIZATION DURATION: 6 Months

QUANTITY LIMIT: One time authorization of 900mg of Omvoh IV (300mg IV at weeks 0, 4, and 8)
- Darwin Quantity Limit: 45 mL per 56 days GPI 14 for Omvoh 300 mg/15 mL vial
- Darwin Quantity limit: 2mL per 28 days GPI 14 for Omvoh 100 mg/mL Prefilled Pen
  (Facets Rx Count: will convert to Facets count when Jcode becomes available)

Omvoh (mirikizumab-mrkz) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:
- Medical record documentation that Omvoh is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Omvoh is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that Omvoh 300 mg vials as intravenous (IV) infusion are being used for induction therapy

AUTHORIZATION DURATION: One time 6 month authorization of Omvoh IV (300mg IV at weeks 0, 4, and 8)

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Omvoh [Prescribing Information]. Indianopolis IN. Eli Lilly and Company. October 2023.
2. IPD Analytics. Omvoh for the Treatment of Ulcerative Colitis. New Drug Approval Review. December 15, 2023. Accessed January 29, 2024. https://www.ipdanalytics.com

This policy will be revised as necessary and reviewed no less than annually.

Devised: 4/19/24

Revised:

Reviewed:

MA UM Committee approval: 5/22/24