Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 118.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Entyvio (vedolizumab)

I. Policy:
Entyvio (vedolizumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Entyvio (vedolizumab)

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:
Entyvio (vedolizumab) is a humanized monoclonal antibody indicated for the treatment of Crohn's Disease and Ulcerative Colitis.

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

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Entyvio (vedolizumab) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

Crohn's Disease

- Prescription written by a gastroenterologist **AND**
- Medical record documentation of age >18 years **AND**
- Medical record documentation of a diagnosis of moderate-to-severe Crohn's disease **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira* OR an infliximab* product.

Ulcerative Colitis

- Prescription written by a gastroenterologist **AND**
- Medical record documentation of age >18 years **AND**
- Medical record documentation of a diagnosis of moderate-to-severe ulcerative colitis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (e.g. 6-mercaptopurine or azathioprine)

AUTHORIZATION DURATION: After the initial 6 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation of coverage will be every 12 months requiring documentation of improvement of signs and symptoms while on Entyvio.

QUANTITY LIMIT:

Initial Authorization:

- Facets RX Count: 1500 (J3380 – Vedolizumab)
- Darwin Quantity Limit: one-time 1-week authorization of 2 vials per 28 days. Remainder of initial 6 month authorization, 1 vial per 56 days

Subsequent Authorizations:

- Facets RX Count: 2100 (J3380 – Vedolizumab)
- Darwin Quantity limit: 1 vial per 56 days

*Prior authorization required

Entyvio (vedolizumab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

Crohn's Disease

- Prescription written by a gastroenterologist **AND**
- Medical record documentation of age >18 years **AND**
- Medical record documentation of a diagnosis of moderate-to-severe Crohn's disease

Ulcerative Colitis

- Prescription written by a gastroenterologist **AND**
- Medical record documentation of age >18 years **AND**
- Medical record documentation of a diagnosis of moderate-to-severe ulcerative colitis

AUTHORIZATION DURATION: After the initial 6 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation of coverage will be every 12 months requiring documentation of improvement of signs and symptoms while on Entyvio.

QUANTITY LIMIT:

Initial Authorization:

- Facets RX Count: 1500 (J3380 – Vedolizumab)
- Quantity Limit: one-time 1-week authorization of 2 vials per 28 days. Remainder of initial 6 month authorization, 1 vial per 56 days

Subsequent Authorizations:

- Facets RX Count: 2100 (J3380 – Vedolizumab)
- Quantity limit: 1 vial per 56 days

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.

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

Devised: 9/16/14

Revised: 11/20/14 (corrected description), 12/30/14 (updated CD formulary alternative criteria), 4/24/18 (per DHS, grandfather), 5/27/20 (updated UC to remove Humira and add azathioprine or 6-MP, added quantity limits), 7/20/21 (update UC 'conventional therapy' language), 5/17/22 (added CD "or an infliximab product"), 5/11/23 (LOB carve out, Medicaid business segment)

Reviewed: 1/20/2015, 3/16, 3/30/17, 3/29/18, 1/30/19, 1/10/20, 5/13/21