Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 118.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Entyvio (vedolizumab)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

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 the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. 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

DESCRIPTION:
Entyvio (vedolizumab) is a humanized monoclonal antibody that binds to the alpha4beta7 integrin and blocks the interaction of alpha4beta7 integrin with mucosal addressin cell adhesion molecule-1 (MAdCAM-1) and inhibits the migration of memory T-lymphocytes across the endothelium into inflamed gastrointestinal parenchymal tissue. The interaction of the alpha4beta7 integrin with MAdCAM-1 has been implicated as an important contributor to the chronic inflammation that is a hallmark of ulcerative colitis and Crohn disease.

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 a preferred adalimumab product* 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)
- 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

*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.

REFERENCES:

1. Entyvio [prescribing information]. Lexington, MA: Takeda Pharmaceuticals USA Inc; April 2024.

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), 12/30/23 (references added), 5/10/24 ("Darwin" removed), 5/6/25 (changed Humira [per 11/19/24 P&T], description, removed Medicaid business segment, LOB table, taglines)

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

MA UM Committee approval: 12/31/23, 12/31/24, 6/9/25