Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Entyvio® (Vedolizumab)***
DEPARTMENT: **Clinical Pharmacy Service – Utilization Management**
ORIGINAL DATE: ***July 2014***

Last P & T Committee Approval Date: *December 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Entyvio® (vedolizumab).

Entyvio® (vedolizumab) is indicated for:

- Inducing and maintaining a clinical response,
- Inducing and maintaining a clinical remission,
- Improving the endoscopic appearance of the mucosa, and
- Achieving corticosteroid-free remission in adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulatory; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

Entyvio® (vedolizumab) is indicated for:

- Achieving a clinical response,
- Achieving a clinical remission, and
- Achieving a corticosteroid free remission in adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker

or immunomodulatory; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Entyvio® (vedolizumab), is subject to the prior authorization process.

PROCEDURE

*****Please Note: When coverage of Entyvio is requested through the pharmacy benefit, please refer to policies RX.008.2 Exceptions Due to Medical Necessity and RX.011 Request for Non-Covered Medications. This policy, RX.PA.232.E (B), is for requests for Entyvio on the Medical Benefit only.*****

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Entyvio® are subject to the preferred medical drug list program. This program applies to non-preferred autoimmune products used in the treatment of plaque psoriasis, inflammatory joint related conditions, or inflammatory bowel disease. Coverage for these products (those which are non-preferred and not covered for the prescribed indication) is provided based on clinical circumstances that would exclude the use of the preferred product(s) for the indication. Coverage for non-preferred products will continue in situations where the patient is currently receiving treatment.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Disease-modifying antirheumatic drugs for autoimmune conditions

	Products*
Preferred	• Remicade® **(infliximab)** • Simponi Aria® **(golimumab, intravenous)**
Non-preferred	• Actemra® **(tocilizumab)** • Cimzia® **(certolizumab pegol)** • Entyvio® **(vedolizumab)** • Ilumya® **(tildrakizumab-asmn)** • Inflectra® **(infliximab-dyyb)** • Renflexis® **(infliximab-abda)** • Stelara® **(ustekinumab)** • Orencia® **(abatacept)**

*If applicable for approved indication

Requests for Entyvio® on the Medical Benefit must meet one of the following exception criteria in addition to clinical criteria:

II. *EXCEPTION CRITERIA (Use for Non-Preferred Requests Only)*

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product(s) (as applicable).

Coverage for a non-preferred product is provided when ANY of the following criteria are met:

A. Actemra, Cimzia, Entyvio, Ilumya, Orencia and Stelara
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs
   2. Member has a documented inadequate response or intolerable adverse event with all of the preferred product(s) indicated for the condition being treated, unless there is a documented clinical reason to avoid TNF inhibitors
      i. History of demyelinating disorder
      ii. History of congestive heart failure
      iii. History of hepatitis B virus infection
      iv. Autoantibody formation/lupus-like syndrome
      v. Risk of lymphoma
   3. Requested product is Cimzia and member is currently pregnant or breastfeeding

B. Inflectra and Renflexis
   1. Member has a documented intolerable adverse event with the preferred product, Remicade

III. CLINICAL CRITERIA (*Use for ALL Drug Requests on the Medical Benefit*)

Must meet all of the clinical criteria listed under the respective diagnosis:

1. Ulcerative Colitis:

- Must be prescribed by a gastroenterologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active ulcerative colitis
- Must have tried one of the following therapies:
    - Corticosteroids, with an inadequate response, loss of response, or intolerance as defined as ONE of the following:
        - Persistent active disease despite a history of at least one 4-week induction regimen that included a dose equivalent to prednisone 30mg daily orally for 2 weeks or intravenous corticosteroid for 1 week
        - 2 failed attempts to taper corticosteroids to below a dose equivalent to prednisone 10mg orally daily on 2 separate occasions
        - History of intolerance to corticosteroids (including, but not limited to, Cushing's syndrome, osteopenia/osteoporosis, hyperglycemia, insomnia, and infection)
    - An immunomodulator with an inadequate response, loss of response, or intolerance as defined as ONE of the following:
        - Persistently active disease despite a trial of at least 2 months of oral azathioprine or 6-mercaptorpurine
        - History of intolerance to one or more immunomodulators (including, but not limited to, nausea/vomiting, abdominal pain, pancreatitis, liver function test abnormalities, lymphopenia, thiopurine methyltransferase genetic mutation, and infection)
- Must currently not be using a TNF-blocking agent or other biologic agents in combination with Entyvio
- Member must be brought up to date with all immunizations according to current immunization guidelines prior to starting Entyvio treatment
- Must have no evidence of infection

2. Crohn's Disease:

- Must be prescribed by a gastroenterologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active Crohn's Disease
- Must have tried one of the following therapies:

  - Corticosteroids, with an inadequate response, loss of response, or intolerance as defined as ONE of the following:
    - Persistent active disease despite a history of at least one 4-week induction regimen that included a dose equivalent to prednisone 30mg daily orally for 2 weeks or intravenous corticosteroid for 1 week
    - 2 failed attempts to taper corticosteroids to below a dose equivalent to prednisone 10mg orally daily on 2 separate occasions
    - History of intolerance to corticosteroids (including, but not limited to, Cushing's syndrome, osteopenia/osteoporosis, hyperglycemia, insomnia, and infection)
  - An immunomodulator with an inadequate response, loss of response, or intolerance as defined as ONE of the following:
    - Persistently active disease despite a trial of at least 2 months of oral azathioprine, 6-mercaptorpurine, or methotrexate
    - History of intolerance to one or more immunomodulators (including, but not limited to, nausea/vomiting, abdominal pain, pancreatitis, liver function test abnormalities, lymphopenia, thiopurine methyltransferase genetic mutation, and infection)
- Must currently not be using a TNF-blocking agent or other biologic agents in combination with Entyvio
- Member must be brought up to date with all immunizations according to current immunization guidelines prior to starting Entyvio treatment
- Must have no evidence of infection

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber showing that the member has benefited from therapy as evidenced by documentation of at least one of the following:

- A clinical response
- A clinical remission
- Tapering of corticosteroids
- Improvement in endoscopic appearance of the mucosa

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 4 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2014
2. Feagan BG, Rutgeerts P, Sands BE, et al. Vedolizumab as induction and maintenance therapy for ulcerative colitis. *N Engl J Med* 2013;369:699-710
3. Sandborn WJ, Feagan BG, Rutgeets P, et al. Vedolizumab as induction and maintenance therapy for crohn's disease. *N Engl J Med* 2013;369:711-21
4. D'Haens G, Sandborn WJ, Feagan BG, et al. A review of activity indices and efficacy end points for clinical trials of medical therapy in adults with ulcerative colitis. *Gastroenterol* 2007;132-786
5. Sandborn WJ, Feagan BG, Hanauer SB, et al. A review of activity indices and efficacy endpoints for clinical trials of medical therapy in adults with Crohn's disease. *Gastrolenterol* 2002;122:512- 530
6. Kornbluth A, Sachar DB, et al. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, Practice Parameter Committee. *Am J Gastroenterol* 2010;105:501-523
7. Lichenstein GR, Hanauer SB, Sandborn WJ, et al. Management of crohn's disease in adults. *Am J Gastroenterol* advance online publication, 6 January 2009; doi:10.1038/ajg.2008.168
8. Dassapouls T, Cohen R, Scherl E, et al. Ulcerative colitis clinical care pathway. American Gastroenterological Association, 2015. http://campaigns.gastro.org/algorithms/UlcerativeColitis/index.html. Accessed August 18, 2016.
9. Sandborn W, Binion D, Persley K, et al. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. Gastroenterology 2014;147:702-705.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
Criteria revision	*08/16, 04/17*
Preferred Product Update (effective 4/1/18)	*02/18*
Added procedural clarification	*6/18*
Preferred Product Update	*12/18*