RX.PA.008.MPC *Entyvio® (Vedolizumab)*

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.

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

PROCEDURE

A. <u>Initial Authorization Criteria:</u>

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

For all diagnoses:

- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling.

I. 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 have an adequate trial of Renflexis (infliximab-abda) or Inflectra (infliximab-dyyb) with an inadequate response, loss of response, or intolerance
- Must have a documented inadequate treatment response (trial of at least 3 months) or intolerance to Humira (adalimumab)
- 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 vedolizumab (Entyvio) treatment
- Must have no evidence of infection

II. 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 have an adequate trial of Renflexis (infliximab-abda) or Inflectra (infliximab-dyyb) with an inadequate response, loss of response, or intolerance
- Must have a documented inadequate treatment response (trial of at least 3 months) or intolerance to Humira (adalimumab)
- 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

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Entyvio will be considered investigational or experimental for any other use and coverage may be provided if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, DrugDex, Lexi-Drug, etc…) or at least two published peer-reviewed randomized controlled trials for the treatment of the diagnosis(es) for which it is prescribed. Abstracts (including meeting abstracts) are excluded from review consideration. These requests will be reviewed on a case by case basis to determine medical necessity.

D. <u>Reauthorization Criteria:</u>

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 all of the following:

- MPC Renewal:
    - Chart documentation confirming positive response to therapy as evidenced by a documented improvement by the prescriber
    - Must be prescribed by a gastroenterologist

- Prescriber attests that Entyvio is not prescribed concurrently with TNF-blocking medications or other biologic medications

- Non- MPC Renewal:
  - Members who have previously been taking Entyvio and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria).
  - Member has not been receiving medication samples for Entyvio; AND
  - Provider has a documented clinical response of the member's improvement on treatment from baseline.

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, if required for the plan and level of request.

HCPCS Code(s):

Code	Description
J3380	Injection, vedolizumab, 1 mg

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Addition of Humira to the initial review criteria. Expanded the reauthorization criteria to include MPC vs Non-MPC continuation of therapy reviews	*10/2022*
Update to off-label restrictions	*04/2022*
Annual review	*02/2022*
Addition of dosing requirements	*12/2021*
Addition of Inflectra as a preferred formulary alternative	*11/2021*
Addition of Renflexis as a preferred formulary alternative	*08/2021*

P&T Review	*11/2020*

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