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

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

3. **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.**

4. **<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 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, 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
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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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
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