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

<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.

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 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)

      AND
    - 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

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 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)

    AND

    - 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

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, if required for the plan and level of request.

HCPCS Code(s):

Code	Description
J3380	Injection, vedolizumab, 1 mg

REFERENCES

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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
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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.

<u>Date of Change</u>	<u>Documented Change</u>
09/16/2021	Update of additional preferred TNF-Inhibitor: Inflectra
08/2021	Update of preferred TNF-Inhibitor: Renflexis
04/06/2021	Update of preferred TNF-Inhibitor
11/2021	Policy review by P&T