RX.PA.008.CCH ENTYVIO® (VEDOLIZUMAB)

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

Entyvio® (vedolizumab) is indicated for:

- Treatment of moderately to severely active ulcerative colitis in adults
- Treatment of moderately to severely active Crohn's disease in adults

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 Medical Policy Committee.

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

PROCEDURE
Initial Authorization Criteria:
Must meet all 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.
- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.*TB* test (T-Spot)]
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast))
- Must have no evidence of infection
- Member must be brought up to date with all immunizations according to current immunization guidelines prior to starting vedolizumab (Entyvio) treatment

1. Ulcerative Colitis:

- Must be prescribed by or in consultation with a gastroenterologist
- Must be age 18 years or older
- Must have a diagnosis of moderately to severely active ulcerative colitis
- Must have an adequate trial of conventional therapy including corticosteroids, 5-ASA agents (e.g., sulfasalazine, mesalamine), OR immunosuppressants (e.g., azathioprine, 6-mercaptopurine) (see Appendix 1) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must have an adequate trial (of at least 3 months) and failure of at least 1 preferred tumor necrosis factor (TNF)-alpha inhibitor with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies
    - Preferred self-injectable alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/

2. Crohn's Disease:

- Must be prescribed by or in consultation with a gastroenterologist
- Must be age 18 years or older
- Must have a diagnosis of moderately to severely active Crohn's Disease
- Must have an adequate trial on a therapeutically effective dose of conventional therapy including corticosteroids OR immunosuppressants (e.g., azathioprine, 6-mercaptopurine) (See Appendix 2) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must have an adequate trial (of at least 3 months) and failure of at least 1 preferred tumor necrosis factor (TNF)-alpha inhibitor with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies
    - Preferred self-injectable alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/

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:

- Member must be prescribed a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast))

- Member must have achieved clinical remission by treatment week 14 (after initial approval) and maintained positive clinical response thereafter as evidenced by low disease activity or improvement in signs and symptoms of UC or Crohn's disease.
    - Note: according to the prescribing information, therapy must be discontinued in patients who show no evidence of therapeutic benefit by week 14.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

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.

APPENDIX 1

Examples of Conventional Therapy Options for UC
Mild to moderate disease – induction of remission: Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine Rectal mesalamine (e.g., Canasa, Rowasa) Rectal hydrocortisone (e.g., Colocort, Cortifoam) Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine Mild to moderate disease – maintenance of remission: Oral mesalamine, balsalazide, olsalazine, rectal mesalamine Alternatives: azathioprine, mercaptopurine, sulfasalazine Severe disease – induction of remission: Prednisone, hydrocortisone IV, methylprednisolone IV Alternatives: cyclosporine IV, tacrolimus, sulfasalazine Severe disease – maintenance of remission: Azathioprine, mercaptopurine Alternative: sulfasalazine <u>Pouchitis</u> Metronidazole, ciprofloxacin Alternative: rectal mesalamine

APPENDIX 2

Examples of Conventional Therapy Options for CD
Mild to moderate disease – induction of remission: Oral budesonide Alternatives: metronidazole, ciprofloxacin, rifaximin Mild to moderate disease – maintenance of remission: Azathioprine, mercaptopurine Alternatives: oral budesonide, methotrexate intramuscularly (IM) or subcutaneously (SC), sulfasalazine Moderate to severe disease – induction of remission: Prednisone, methylprednisolone intravenously (IV) Alternatives: methotrexate IM or SC Moderate to severe disease – maintenance of remission: Azathioprine, mercaptopurine Alternative: methotrexate IM or SC Perianal and fistulizing disease – induction of remission No trial is needed Perianal and fistulizing disease – maintenance of remission No trial is needed

HCPCS Code(s):

Code	Description
J3380	INJECTION, VEDOLIZUMAB, 1 MG

REFERENCES

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; August 2021
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. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology*. 2020;158(5):1450-1461
7. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. *Am J Gastroenterol*. 2018;113(4):481-517

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
Initial review	3/22
Updated approval duration to 1 year	2/23