SmartHealth

Ascension

Vedolizumab

(Entyvio®) J3380 (1mg)

Covered with prior authorization

Vedolizumab (Entyvio) may be authorized when the following criteria are met:

Moderate to severe Crohn's disease

- Individual is 18 years of age or older; **AND**
- Documented failure or inadequate response, contraindication per FDA label, intolerance, or not a candidate for:
    - a corticosteroid or taken concurrently with a corticosteroid (for example, prednisone, methylprednisolone); **OR**
    - one conventional systemic therapy (for example, azathioprine, 6-mercaptopurine, or methotrexate {MTX}); **OR**
    - Tumor necrosis factor (TNF) blocker or biologic DMARD (such as infliximab, etanercept, adalimumab, certolizumab pegol, or golimumab); **AND**
- Prescribed by, or in consultation with a gastroenterologist or a prescriber who specializes in Crohn's disease; **AND**
- Dose is 300 mg infusion intravenously at zero, two, six weeks and then every eight weeks thereafter.

Ulcerative Colitis

- Individual is 18 years of age or older; **AND**
- Documented failure or inadequate response, contraindication per FDA label, intolerance, or not a candidate for at least ONE conventional therapy (for example, aminosalicylate, corticosteroids, or immunosuppressants);

    ★*Note: An exception to this requirement can be made if the individual has already tried a biologic. These individuals are not required to "step back" and try a conventional agent.*

AND

- Prescribed by or in consultation with a gastroenterologist or a prescriber who specializes in ulcerative colitis; **AND**
- Dose is 300 mg infusion intravenously at zero, two, six weeks and then every eight weeks thereafter

Exclusion criteria:

Requests may not be approved for the following:

- Pediatric individuals (＜18 years of age)
- All other indications not included above;

- Doses, duration, or dosing intervals that exceed FDA maximum limits for any FDA approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use
- Concomitant use with any other biological including all non-tumor necrosis factor (non-TNF) biologics, natalizumab, or oral immunomodulatory agents (for example, Otezla or Xeljanz/Xeljanz XR);
- Active serious infection or a history of recurrent infections;
- New or worsening neurological signs or symptoms of John Cunningham virus (JVC) infection or risk of progessive multifocal leukoencephalopathy (PML);
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.
ENTYVIO is an integrin receptor antagonist indicated in adults for the treatment of:

- moderately to severely active ulcerative colitis
- moderately to severely active Crohn's disease

References:

Bressler B, Marshall JK, Bernstein CN, et al. Clinical practice guidelines for the medical management of nonhospitalized ulcerative colitis: the Toronto consensus. Gastroenterology. 2015;148(5):1035-1058.

Entyvio™ for intravenous injection [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2019.

Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.doi:10.1038/ajg.2018.27.

McEvoy GK, ed. AHFS 2019 Drug Information. Bethesda, MD: American Society of Health-Syst.

Entyvio (vedolizumab) label. (2020, March). Accessdata.fda.gov. Retrieved June 14, 2022 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125476s025s030lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
June 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
July 2022	Criteria for use summary approved by Ascension Gastrointestinal Expert Review Panel
July 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or

email your questions to smarthealthspecialty@ascension.org.