Vedolizumab, IV (Entyvio®)	Place of Service Infusion Center Administration Home Infusion Administration Office Administration Outpatient Facility Infusion Administration* [*Prior authorization required – see section (1)] HCPCS: J3380 per 1 mg

Conditions listed in policy (*see criteria for details*)

- Crohn's disease
- Immunotherapy-related diarrhea or colitis secondary to immune-checkpoint inhibitor therapy
- Ulcerative colitis

AHFS therapeutic class: GI drug, monoclonal antibody

Mechanism of action: Integrin receptor antagonist

(1) Special Instructions and Pertinent Information

Entyvio, given as a subcutaneous (SC) injection: Refer to the "Self-Administered Drugs" medical benefit drug policy for commercial plans.

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

Members with the following plan: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage/HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG™ Care Guidelines, 19th edition, 2015

ADMINISTRATION OF ENTYVIO IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. **Patient is receiving their first 3 induction infusions of Entyvio or is being re-initiated on Entyvio after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

   Or

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event on Entyvio based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events on Entyvio based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. **Patient is physically or cognitively unstable based on documentation submitted.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Entyvio® (vedolizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Crohn's disease

1. Patient age greater than or equal to 18 years, **AND**
2. Not being used in combination with natalizumab, a TNF-blocker, or another targeted immunomodulator, **AND**
3. Inadequate response or intolerable side effect with two BSC-preferred agents [Hadlima, Humira, infliximab (Avsola or Inflectra), Rinvoq, Skyrizi, and Stelara], or contraindication to all preferred agents

Covered Doses

Initial induction dosing: 300 mg IV at Weeks 0, 2, and 6

Maintenance: Beginning at Week 14, 300mg IV every 8 weeks.

Coverage Period

Initial induction phase: 14 weeks

Reauthorization: Indefinite (if patient had clinical benefit by week 14 & drug given at an approved site of service)

ICD-10:

K50.00-K50.119, K50.80-K50.919

Immunotherapy-related diarrhea or colitis secondary to immune-checkpoint inhibitor therapy

1. Treatment of moderate or severe diarrhea or colitis secondary to immune-checkpoint inhibitor therapy, **AND**
2. Prior treatment with corticosteroids was ineffective, **AND**

3. Inadequate response, intolerable side effect, or contraindication to infliximab (Avsola or Inflectra)

Covered Doses
300 mg IV at Weeks 0, 2, and 6
Coverage Period
Cover up to 3 doses

ICD-10:
K52.1, R19.7

Ulcerative colitis

1. Patient age greater than or equal to 18 years, **AND**
2. Not being used in combination with natalizumab, a TNF-blocker, or another targeted immunomodulator, **AND**
3. Either of the following:
    a. ***Effective through 3/31/2024***: Inadequate response or intolerable side effect with a BSC-preferred agent [Hadlima, Humira, infliximab (Avsola or Inflectra), Rinvoq, Stelara, Xeljanz/Xeljanz XR], or contraindication to all preferred drugs, OR
    b. ***Effective 4/1/2024***: Inadequate response or intolerable side effect with BSC-preferred agent [infliximab (Avsola or Inflectra)], or contraindication to the preferred agent

Covered Doses
Initial induction dosing: 300 mg IV at Weeks 0, 2, and 6
Maintenance: Beginning at Week 14, 300 mg IV every 8 weeks. Entyvio can also be self-injected subcutaneously for maintenance. The subcutaneous form can be requested from the patient's Pharmacy Benefit.

Coverage Period
Initial induction phase: 14 weeks
Reauthorization: Indefinite (if patient had clinical benefit by week 14 & drug given at an approved site of service)

ICD-10:
K51.0-K51.319, K51.5-K51.519, K51.80-K51.919

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Entyvio® (vedolizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- Sterile 20 mL single-use glass vials, containing 300 mg of vedolizumab

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Entyvio (vedolizumab) [Prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; 6/2022.
- Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158: 1450-1461.
- Lichtenstein GR, Loftus EV, Isaacs KL, et al. American College of Gastroenterology Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol 2018; 113:481-517.
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
- National Comprehensive Cancer Network. Management of Immunotherapy-Related Toxicities (Version 2.2023). Available at: www.nccn.org.
- Sands B, Dubinsky M, Vermeire S, et al. P-098 Effects of increased vedolizumab dosing frequency on clinical remission and response in ulcerative colitis and Crohn's disease. Inflammatory Bowel Diseases. Dec 2014; volume 2. Clinical poster presentations, Abstract. *http://journals.lww.com/ibdjournal/Abstract/2014/12001/P_098_Effects_of_Increased_Vedolizumab_Dosing.136.aspx*
- Rubin DT, Ananthakrishnan AN, Siegel CA, et al. American College of Gastroenterology Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019; 114:384-413.
- Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-alpha biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. Gastroenterology 2013; 145:1459-63.

(7) Policy Update

Date of last revision: 1Q2024
Date of next review: 3Q2024
Changes from previous policy version:

- Section (2): Ulcerative colitis – ***Effective 4/1/2024***, infliximab (Avsola or Inflectra)] will be the preferred drug.
  Rationale: Selection of preferred drugs is supported by similar safety and efficacy and are guideline supported agents

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee