vedolizumab (Entyvio)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: binds to the alpha-4-beta-7-integrin receptor and blocking its interaction with mucosal addressin cell adhesion molecule-1 and inhibits the migration of memory T-lymphocytes across the endothelium
HCPCS:
J3380:Injection, vedolizumab, intravenous, 1 mg
How Supplied:
300 mg vedolizumab in a single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Crohn's Disease, moderate to severe
- Immunotherapy-Related Diarrhea or Colitis Secondary to Immune-Checkpoint Inhibitor Therapy
- Ulcerative Colitis, moderate to severe

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Entyvio given as an intravenous injection is managed under the Medical Benefit. Entyvio given as a subcutaneous injection can be obtained through the patient's pharmacy benefit. Please refer to the "Self-Administered Drugs" medical benefit drug policy for more information.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** 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 THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating therapy (allowed for the first 2 induction infusions) with 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.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Crohn's Disease, moderate to severe
Meets medical necessity if all the following are met:
Initial

1. Age is consistent with the FDA-approved indication
2. Not being used in combination with natalizumab, a TNF-blocker, or another targeted immunomodulator
3. Inadequate response or intolerable side effect with BSC-preferred agent [infliximab (Avsola or Inflectra)] or contraindication to preferred agent
4. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a gastroenterologist

Reauthorization

1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Covered Doses:
Initial induction and 1st maintenance dose: 300 mg given intravenously at Weeks 0, 2, 6 and 14. Entyvio may be switched to subcutaneous injection starting at Week 6. The subcutaneous form can be requested from the patient's Pharmacy Benefit.

Reauthorization: 300 mg given intravenously 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: 14 weeks
Reauthorization: Yearly, based on continued response to therapy

ICD-10:
K50.00-K50.119, K50.80-K50.919

Immunotherapy-Related Diarrhea or Colitis Secondary to Immune-Checkpoint Inhibitor Therapy
Meets medical necessity if all the following are met:
1. Treatment of moderate or severe diarrhea or colitis secondary to immune-checkpoint inhibitor therapy
2. Prior treatment with corticosteroids was ineffective
3. Inadequate response, intolerable side effect, or contraindication to infliximab (Avsola or Inflectra)

Covered Doses:
300 mg given intravenously at Weeks 0, 2, and 6

Coverage Period:
Cover up to 3 doses

ICD-10:
K52.1, R19.7

Ulcerative Colitis, moderate to severe
Meets medical necessity if all the following are met:
Initial
1. Age is consistent with the FDA-approved indication
2. Not being used in combination with natalizumab, a TNF-blocker, or another targeted immunomodulator,
3. Inadequate response or intolerable side effect with BSC-preferred agent [infliximab (Avsola or Inflectra)] or contraindication to the preferred agent
4. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a gastroenterologist

Reauthorization
1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Covered Doses:
Initial induction and 1st maintenance dose: 300 mg given intravenously at Weeks 0, 2, 6 and 14. Entyvio may be switched to subcutaneous injection starting at Week 6. The subcutaneous form can be requested from the patient's Pharmacy Benefit.

Reauthorization: 300 mg given intravenously 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: 14 weeks
Reauthorization: Yearly, based on continued response to therapy

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

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Entyvio (vedolizumab) Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; April 2024.
4. 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.
5. 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.
6. MCG Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
7. National Comprehensive Cancer Network. Management of Immunotherapy-Related Toxicities (Version 1.2025). Available at: www.nccn.org.
8. 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.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- Added specialist requirement for Crohn's disease and ulcerative colitis

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee