blue california
Promise Health Plan

vedolizumab (Entyvio)

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

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

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.

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. Meets ONE of the following:
   a. Patient has had an inadequate response or intolerable side effect with infliximab (Avsola, Inflectra, Renflexis)
   b. Patient has had no treatment with infliximab and has a contraindication to infliximab products, Avsola, Inflectra, and Renflexis
3. Not being used in combination with natalizumab, a TNF-blocker, or another targeted immunomodulator
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.
Reauthorizatoin: 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. Meets ONE of the following:
   a. Patient has had an inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra, Renflexis)
   b. Patient has had no treatment with infliximab and has a contraindication to infliximab products, Avsola, Inflectra, and Renflexis

Covered Doses:
300 mg 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. Meets ONE of the following:
   a. Patient has had an inadequate response, intolerable side effect with infliximab (Avsola, Inflectra, or Renflexis),
   b. Patient has had no treatment with infliximab and has a contraindication to Avsola, Inflectra, and Renflexis
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