

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Entyvio (vedolizumab)
BENEFIT TYPE	Medical or pharmacy
STATUS	Prior Authorization Required

Entyvio is an integrin receptor antagonist indicated in adults for the treatment of moderately to severely active ulcerative colitis (UC) or moderately to severely active Crohn's disease (CD). It targets the immune system of the gut and has a favorable safety profile.

CD and UC are inflammatory bowel diseases. CD can affect any part of the GI tract whereas UC only affects the large intestine (colon and rectum). CD can affect the entire thickness of the bowel wall whereas UC only affects the inner-most lining.

Entyvio (vedolizumab) will be considered for coverage when the following criteria are met:

Crohn's Disease (CD)

For initial authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a documented diagnosis of moderately to severely active CD; AND
4. **Dosage allowed/Quantity limit:**
 - a) IV: administer 300 mg IV infusion at 0, 2, and 6 weeks, and every 8 weeks thereafter. Quantity limit: 1 vial per 56 days following induction.
 - b) SubQ: administer 300 mg IV infusion at week 0 and 2. Then at week 6, administer 108 mg subq every 2 weeks. Quantity limit: 2 syringes/pens per 28 days following induction.

Note: Therapy should be discontinued if no evidence of therapeutic benefit by week 14.

If all the above requirements are met, the medication will be approved for 4 months.

For reauthorization:

1. Chart notes have been provided showing improvement in signs and symptoms of CD such as mucosal healing, fewer flare-ups, ability to taper off steroids, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Ulcerative Colitis (UC)

For initial authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a documented diagnosis of moderately to severely active UC; AND
4. Member must have a documented trial and inadequate response with ONE of the following:
 - a) 6-mercaptopurine or azathioprine;
 - b) Corticosteroid (e.g., budesonide, prednisone, methylprednisolone);
 - c) 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.).

5. Dosage allowed/Quantity limit:

- a) IV: administer 300 mg IV infusion at 0, 2, and 6 weeks, and every 8 weeks thereafter. Quantity limit: 1 vial per 56 days following induction.
- b) SubQ: administer 300 mg IV infusion at week 0 and 2. Then at week 6, administer 108 mg subq every 2 weeks. Quantity limit: 2 syringes/pens per 28 days following induction.

Note: Therapy should be discontinued if no evidence of therapeutic benefit by week 14.

If all the above requirements are met, the medication will be approved for 4 months.

For reauthorization:

1. Chart notes have been provided showing improvement in signs and symptoms of UC such as clinical remission, decrease in rectal bleeding, decreased corticosteroid use, improved endoscopic appearance of the mucosa, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Entyvio (vedolizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/08/2017	New policy for Entyvio created. Policy SRx-0041 archived. For both diagnoses CD and UC: TNF inhibitor Humira was listed as required trial. List of diagnoses considered not medically necessary was added.
02/26/2019	Humira removed from required trials. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Initial authorization length increased to 12 months. Inadequate response to trial agents combined under member's history; CDAI and Mayo scoring requirement added; severity factors for CD removed from requirements.
11/23/2020	Replaced list of excluded diagnoses with the generic statement. Updated references. Removed TB requirements (not necessary for this drug). CD: Removed CDAI score requirement. Specified length of trials for conventional therapies, previously not specified. Added a trial of TNF inhibitor in accordance with guidelines. Reduced initial auth approval to 4 months (must discontinue if no benefit observed after 14 weeks). UC: Removed Mayo score and endoscopy subscore requirements. Specified length of trials for conventional therapies. Reduced initial auth approval to 4 months (must discontinue if no benefit observed after 14 weeks).
08/09/2022	Transferred policy to new template. Added QL. Crohn's: Added reference. Removed requirement for trial of conventional therapy. Added ability to taper off steroids as an option to meet renewal criteria. UC: Added improved endoscopic appearance as option for renewal criteria.
11/06/2023	Added pharmacy benefit option; added subq dosing and quantity limit; updated references; removed TNF trial for CD.
05/17/2024	Added subq dosing for Crohn's disease.
08/18/2025	Updated references. UC: Removed duration from trials

References:

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; 2024.

2. Raine T, Bonovas S, Burisch J, et al. ECCO Guidelines on Therapeutics in Ulcerative Colitis: Medical Treatment. *J Crohns Colitis*. 2022;16(1):2-17. doi:10.1093/ecco-jcc/jjab178
3. 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.
4. Sands, BE, Feagan, BG, Rutgeerts, P, et al. Effects of Vedolizumab Induction Therapy for Patients With Crohn's Disease in Whom Tumor Necrosis Factor Antagonist Treatment Had Failed. *Gastroenterology*. 2014 May 21.
5. Sandborn, WJ, Feagan, BG, Rutgeerts, P, et al. Vedolizumab as induction and maintenance therapy for Crohn's disease. *N Engl J Med* 2013; 369(8):711-21.
6. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology*. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022
7. Lichtenstein GR, Loftus EV, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2025;120(6):1225-1264. Published 2025 Jun 3. doi:10.14309/ajg.0000000000003465
8. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024;167(7):1307-1343. doi:10.1053/j.gastro.2024.10.001
9. Rubin D, Ananthakrishnan A, Siegel C, et al. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *The American Journal of Gastroenterology* 120(6):p 1187-1224, June 2025. | DOI: 10.14309/ajg.0000000000000003
10. Gordon H, Minozzi S, Kopylov U, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. *J Crohns Colitis*. 2024;18(10):1531-1555. doi:10.1093/ecco-jcc/jjae091

Effective date: 01/01/2026

Revised date: 08/18/2025