Reference number(s)
2004-A

Specialty Guideline Management
Entyvio

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Entyvio	vedolizumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

- Adult patients with moderately to severely active ulcerative colitis (UC)
- Adult patients with moderately to severely active Crohn's disease (CD)

Compendial Uses[5-7,10-11]

- Immune checkpoint inhibitor-related toxicity
- Acute graft versus host disease
- Chimeric antigen receptor (CAR) T-cell-related toxicity

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Ulcerative colitis (UC) and Crohn's disease (CD)

Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Immune checkpoint inhibitor-related toxicity and acute graft versus host disease

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Crohn's disease and ulcerative colitis: gastroenterologist
- Immune checkpoint inhibitor-related toxicity, acute graft versus host disease, and CAR T-cell-related toxicity: gastroenterologist, hematologist, or oncologist

Coverage Criteria

Ulcerative colitis (UC)[1,2,4,8]

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

Crohn's disease (CD)[1,3,9]

Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

Immune checkpoint inhibitor-related toxicity[5-7]

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when any of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.
- Member has immune checkpoint inhibitor-related diarrhea or colitis.

Acute graft versus host disease[5,10]

Authorization of 12 months may be granted for treatment of acute graft versus host disease when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.

CAR T-cell-related toxicity[11]

Authorization of 6 months may be granted for adjunctive or steroid-sparing treatment of immune effector cell (IEC)-associated enterocolitis when the member has steroid-refractory diarrhea or recurrent diarrhea with steroid taper.

Continuation of Therapy

Ulcerative colitis (UC)[1,2,4,8]

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Stool frequency
- Rectal bleeding
- Urgency of defecation
- C-reactive protein (CRP)
- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Crohn's disease (CD)[1,3,9]

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Abdominal pain or tenderness
- Diarrhea
- Body weight
- Abdominal mass
- Hematocrit
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Immune checkpoint inhibitor-related toxicity, acute graft versus host disease, and CAR T-cell-related toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

1. Entyvio [package insert]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; February 2026.
2. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1):S2-S25.
3. Lichtenstein GR, Loftus EV, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2025;120:1225-1264.

4. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol. 2025;120:1187-1224.
5. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 14, 2026.
6. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Management of Immune Checkpoint-Related Toxicities. Version 1.2026. Available at: www.nccn.org. Accessed January 14, 2026.
7. Schneider BJ, Naidoo J, Santomasso BD, et al. Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy: American Society of Clinical Oncology Guideline Update. J Clin Oncol. 2021;39(36):4073-4126.
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.
9. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease. Gastroenterology. 2025;169(7):1397-1448.
10. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Hematopoietic Cell Transplantation (HCT). Version 3.2025. Available at: www.nccn.org. Accessed January 14, 2026.
11. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Management of CAR T-Cell and Lymphocyte Engager-Related Toxicities. Version 2.2026. Available at: www.nccn.org. Accessed January 14, 2026.