AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Entyvio	Page:	1 of 5
Effective Date:	5/23/2025	Last Review Date:	4/2025

Applies to:	☐Illinois	☐Florida	☒Florida Kids
	☒New Jersey	☒Maryland	☐Michigan
	☒Pennsylvania Kids	☐Virginia	☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Entyvio under the patient's prescription drug benefit.

Description:

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[5-7,11]

- Immune checkpoint hibitor-related toxicity
- Acute graft versus host disease

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

Applicable Drug List:

Entyvio

Policy/Guideline:

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: gastroenterologist, hematologist, or oncologist
- Acute graft versus host disease: 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 diarrhea or colitis when the member has experienced an inadequate response, intolerance, or has a contraindication to systemic corticosteroids or infliximab.

Acute graft versus host disease[5,11]

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.

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

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.

Dosage and Administration

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

Approval Duration and Quantity Restrictions:

Approval:

Initial Approval:

- 12 months for UC and CD, 6 months for Immune checkpoint inhibitor-related toxicity

Renewal Approval:

- 12 months for UC and CD, 6 months for Immune checkpoint inhibitor-related toxicity

Quantity Level Limit:

Medication	Standard Limit	Exception Limit*	FDA-recommended dosing
Entyvio (vedolizumab) 300 mg per 20 mL single-dose vial	1 vial every 56 days	3 vials per 42 days	**CD, UC intravenous** • Loading doses: 300 mg at weeks 0, 2, and 6 • Maintenance dose: 300 mg every 8 weeks thereafter
Entyvio (vedolizumab) 108 mg/0.68 mL single-dose prefilled syringe/pen	2 syringes/pens every 28 days	N/A	**UC maintenance** • After initial intravenous doses at week 0 and 2, can transition to subcutaneous 108 mg every 2 weeks starting at week 6.

Abbreviations: CD = Crohn's disease, UC = ulcerative colitis

*Coverage up to the exception limits may be provided with prior authorization

References:

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8. 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.
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10. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486.
11. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Hematopoietic Cell Transplantation (HCT). Version 2.2024. Available at: www.nccn.org. Accessed January 22, 2025.