



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Entyvio

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Effective Date: 11/15/2023

Last Review Date: 10/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> 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:

A. FDA-Approved Indications

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

B. Compendial Uses

Immune checkpoint inhibitor-related toxicity

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

Applicable Drug List:

Entyvio

Policy/Guideline:

Documentation for all indications:

The patient is unable to take THREE preferred products, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation:

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

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

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

B. Immune checkpoint inhibitor-related toxicity (initial requests only)

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.



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Prescriber Specialty:

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

- A. Crohn's disease and ulcerative colitis: gastroenterologist
- B. Immune checkpoint inhibitor-related toxicity: hematologist or oncologist

Criteria for Initial Approval:

A. Ulcerative colitis (UC)

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

B. Crohn's disease (CD)

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

C. Immune checkpoint inhibitor-related toxicity

Authorization of 6 months may be granted for the treatment of immune checkpoint inhibitor-related diarrhea or colitis when either of the following criteria is met:

- 1. Member has had an inadequate response, intolerance, or contraindication to systemic corticosteroids or infliximab.
- 2. Member has moderate or severe diarrhea or colitis.

Continuation of Therapy:

A. Ulcerative colitis (UC)

- 1. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.
- 2. Authorization of 12 months may be granted for all adult 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:
 - i. Stool frequency
 - ii. Rectal bleeding
 - iii. Urgency of defecation
 - iv. C-reactive protein (CRP)
 - v. Fecal calprotectin (FC)
 - vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound



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vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

B. Crohn's disease (CD)

1. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.
2. Authorization of 12 months may be granted for all adult 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:
 - i. Abdominal pain or tenderness
 - ii. Diarrhea
 - iii. Body weight
 - iv. Abdominal mass
 - v. Hematocrit
 - vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
 - vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

C. Immune checkpoint inhibitor-related toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Other Criteria:

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.

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease



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2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

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-use vial	1 vial every 56 days	3 vials per 43 days	<ul style="list-style-type: none"> • Loading doses: 300 mg at weeks 0, 2, and 6 • Maintenance dose: 300 mg every 8 weeks thereafter

*Exception limits apply to loading doses.

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5. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed January 16, 2023.
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