AETNA BETTER HEALTH® Coverage Policy/Guideline				
Name:	Entyvio		Page:	1 of 5
Effective Date:	5/1/2024		Last Review Date:	11/2023, 3/2024
Applies to:	☐Illinois ☒New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☐Virginia	☒Florida Kids ☐Michigan ☒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:
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.

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
   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
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-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

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