Vedolizumab (Entyvio®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. 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.

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.

II. 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
   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.

III. PRESCRIBER SPECIALTIES

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: gastroenterologist, hematologist, or oncologist

IV. 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 the member has experienced an inadequate response, intolerance, or contradiction to systemic corticosteroids or infliximab.

V. 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.

VI. OTHER

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

VII. DOSAGE AND ADMINISTRATION

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

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Entyvio (Vedolizumab)	Crohn's Disease	Route of Administration: Intravenous ≥18 Years Initial: 300mg on weeks 0, 2, and 6, followed by Maintenance: 300mg every 8 weeks
Entyvio (Vedolizumab)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Intravenous 300mg on weeks 0, 2, and 6, then every 8 weeks
Entyvio (Vedolizumab)	Ulcerative Colitis	Route of Administration: Intravenous ≥18 Years Initial: 300mg intravenously on weeks 0, 2, and 6, followed by Maintenance: 300mg intravenously every 8 weeks
Entyvio (Vedolizumab)	Ulcerative Colitis	Route of Administration: Intravenous/subcutaneous ≥18 Years Initial: 300mg intravenously on weeks 0, 2, followed by Maintenance beginning week 6: 108mg subcutaneously every 2 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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EFFECTIVE DATE 10/31/2024

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