Entyvio (vedolizumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Entyvio drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits 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)
2. Adult patients with moderately to severely active Crohn’s disease (CD)

Compendial Uses

1. Moderately to severely active ulcerative colitis (UC) in pediatric patients
2. Moderately to severely active Crohn’s disease (CD) in pediatric patients
3. Immune checkpoint inhibitor-related toxicity
4. Acute graft versus host disease

POLICY

Required Documentation

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

A. Ulcerative colitis (UC)

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

B. Crohn's disease (CD)
Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

C. Immune checkpoint inhibitor-related toxicity and acute graft versus host disease
Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy or intolerance to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Prescriber Specialties (initial approvals only)

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
C. Acute graft versus host disease: hematologist or oncologist

Criteria for Initial Approval

A. Ulcerative colitis (UC)
Authorization of 12 months may be granted for members for the treatment of moderately to severely active ulcerative colitis.

B. Crohn's disease (CD)
Authorization of 12 months may be granted for members for the 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 contraindication to systemic corticosteroids or infliximab.

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

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

Continuation of Therapy

A. Ulcerative Colitis

1. 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.
2. 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:
   a. Stool frequency
   b. Rectal bleeding
   c. Urgency of defecation
   d. C-reactive protein (CRP)
   e. Fecal calprotectin (FC)

f. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
g. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

B. Crohn's Disease

1. 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.
2. 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:
   a. Abdominal pain or tenderness
   b. Diarrhea
   c. Body weight
   d. Abdominal mass
   e. Hematocrit
   f. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   g. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

C. 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 initial authorization 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.

Entyvio is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosage and Administration

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

Quantity Limits

Trade Name	Dosage Form	Quantity Limit
Entyvio	Prefilled syringe or pen for subcutaneous injection	**Ulcerative colitis and Crohn's disease** Maintenance (adults): 2 syringes or pens per 28 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3380 - Injection, vedolizumab 1mg

REFERENCES

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POLICY HISTORY

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