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 ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. 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)
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 check point inhibitor toxicity
    - Management of moderate (G2) to severe (G3-4) immunotherapy-related diarrhea or colitis that is refractory to systemic corticosteroids and infliximab

POLICY

Required Documentation

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

A. Ulcerative colitis

1. Initial requests

a. 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.
b. Chart notes or medical record documentation of hospitalization due to acute, severe ulcerative colitis (if applicable)

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

B. Crohn's disease

1. Initial requests
   a. 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.
   b. Chart notes or medical record documentation supporting diagnosis of fistulizing Crohn's disease (if applicable)
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

C. Immune checkpoint inhibitor-related toxicity

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.

Criteria for Initial Approval

A. Moderately to severely active ulcerative colitis (UC)

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active ulcerative colitis.

2. Authorization of 12 months may be granted for the treatment of moderately to severely active UC for members who had an inadequate response, intolerance or contraindication to at least ONE conventional therapy option (See Appendix A).

3. Authorization of 12 months may be granted for members who have been hospitalized for acute, severe UC (e.g., continuous bleeding, severe toxic symptoms, including fever and anorexia).

B. Moderately to severely active Crohn's disease (CD)

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for the treatment of moderately to severely active Crohn's disease.

2. Authorization of 12 months may be granted for the treatment of moderately to severely active Crohn's disease in members who had an inadequate response, intolerance or contraindication to at least ONE conventional therapy option (See Appendix B).

3. Authorization of 12 months may be granted for the treatment of fistulizing CD.

C. Immune Checkpoint Inhibitor Toxicity

1. Authorization of 1 month may be granted for the management of immunotherapy-releated diarrhea or colitis when the following criteria are met:
   a. Member has a diagnosis of moderate (Grade 2) or severe (Grade 3-4) immunotherapy-related diarrhea or colitis
   b. Member has recently received treatment with immune checkpoint inhibitor therapy (e.g., ipilimumab, nivolumab, pembrolizumab, atezolizumab, avelumab, darvalumab)
   c. Member has experienced an inadequate response, intolerance, or contraindication to an adequate trial of systemic corticosteroid treatment
   d. Member has experienced an inadequate response, intolerance, or contraindication to infliximab; OR member also has immune-related hepatitis

Continuation of Therapy

A. Moderately to Severely Active 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. Endoscopic appearance of the mucosa
    g. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

B. Moderately to Severely Active 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. Endoscopic appearance of the mucosa
    g. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

C. Immune Checkpoint Inhibitor Toxicity

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.

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

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

Appendix A: Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:
   a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine
   b. Rectal mesalamine (e.g., Canasa, Rowasa)
   c. Rectal hydrocortisone (e.g., Colocort, Cortifoam)
   d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
   a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine
   b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
   a. Prednisone, hydrocortisone IV, methylprednisolone IV
   b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: sulfasalazine

Appendix B: Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
   a. Oral budesonide
   b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternatives: oral budesonide, methotrexate intramuscularly (IM) or subcutaneously (SC), sulfasalazine
3. Moderate to severe disease – induction of remission:
   a. Prednisone, methylprednisolone intravenously (IV)
   b. Alternatives: methotrexate IM or SC
4. Moderate to severe disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: methotrexate IM or SC
5. Perianal and fistulizing disease – induction of remission
   a. Metronidazole ± ciprofloxacin, tacrolimus
6. Perianal and fistulizing disease – maintenance of remission
   a. Azathioprine, mercaptopurine
   b. Alternative: methotrexate IM or SC

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

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*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.02.08
Reviewed: April 2022
Revised: April 2021
Current Effective Date: July 16, 2021