

## **SPECIALTY GUIDELINE MANAGEMENT**

### **ENTYVIO (vedolizumab)**

#### **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.

##### FDA-Approved Indications

1. Moderately to severely active ulcerative colitis (UC)
2. Moderately to severely active Crohn's disease (CD)

All other indications are considered experimental/investigational and are not a covered benefit.

##### **II. CRITERIA FOR INITIAL APPROVAL**

###### **A. Moderately to severely active ulcerative colitis (UC)**

1. Authorization of 4 months may be granted for members who are 18 years of age or older and have received Entyvio or any other biologic indicated for the treatment of ulcerative colitis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Entyvio.
2. Authorization of 4 months may be granted for members who are 18 years of age or older and who had an inadequate response, intolerance or contraindication to EITHER of the following:
  - a. At least ONE conventional therapy option (See Appendix A)
  - b. At least ONE TNF-alpha inhibitor indicated for UC:
    - i. Humira (adalimumab)
    - ii. Remicade (infliximab)
    - iii. Simponi (golimumab)

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

1. Authorization of 4 months may be granted for members who are 18 years of age or older and have received Entyvio or any other biologic indicated for the treatment of Crohn's disease in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Entyvio.
2. Authorization of 4 months may be granted for members who are 18 years of age and older and who had an inadequate response, intolerance or contraindication to EITHER of the following:
  - a. At least ONE conventional therapy option (See Appendix B)
  - b. At least ONE TNF-alpha inhibitor indicated for CD:
    - i. Cimzia (certolizumab)
    - ii. Humira (adalimumab)
    - iii. Remicade (infliximab)

##### **III. CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for all members (including new members) who meet ALL initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Entyvio as evidenced by low disease activity or improvement in signs and symptoms of the condition.

**IV. APPENDICES****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
5. Pouchitis: Metronidazole, ciprofloxacin
  - a. Alternative: rectal mesalamine

**Appendix B: Examples of Conventional Therapy Options for CD**

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

**V. REFERENCES**

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2014.
2. Kornbluth A, Sachar DB, and the Practice Parameters Committee of the American College of Gastroenterology. Ulcerative Colitis Practice Guidelines in Adults. *Am J Gastroenterol*. 2010; 105:501–523. Available at <http://s3.gi.org/physicians/guidelines/UlcerativeColitis.pdf>. Accessed September 6, 2016.
3. Lichtenstein GR, Hanauer SB, Sandborn WJ, and the Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's disease in adults. *Am J Gastroenterol*. 2009. Available at <http://s3.gi.org/physicians/guidelines/CrohnsDiseaseinAdults2009.pdf>. Accessed September 6, 2016.
4. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.