Neighborhood Health Plan OF RHODE ISLAND

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 who have previously received Entyvio or any other biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active ulcerative colitis.
2. Authorization of 4 months may be granted for treatment of moderately to severely active UC in members who are 18 years of age or older 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. Inflectra/Renflexis/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 who have previously received Entyvio or any other biologic indicated for the treatment of Crohn's disease.

2. Authorization of 4 months may be granted for treatment of moderately to severely active CD in members who are 18 years of age or older 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. Inflectra/Renflexis/Remicade (infliximab)

III. CONTINUATION OF THERAPY

Authorization of 6 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.

Quantity Limit to both Initial Approval and Continuation of Therapy: FDA Guidance

Initial Approval Quantity Limit: Weeks 0, 2, 6 and every 8 thereafter (#4 EA / 4 months)

Continuation of Therapy: Every 8 weeks (#3 EA / 6 months)

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.