Effective Date: 12/2017
Revised: 12/2018, 7/2019, 8/2020 Reviewed: 12/2017, 12/2018, 7/2019, 8/2020, 12/2020, 5/2021, 3/2022 Scope: Medicaid

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

For all indications:

- Prior Authorization Request is submitted by the Provider's office; AND
- Prior Authorization Request is not submitted by a pharmacy or another third party; AND
- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication

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 with documented moderate to severe active ulcerative colitis.
2. Must be prescribed by, or in consultation with, a specialist in gastroenterology.
3. Patient is free of any active, severe infections.
4. Patient has been screened for tuberculosis according to local practice (if applicable).
5. Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib).
6. Physician has assessed baseline disease severity utilizing an objective measure/tool.
7. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate).
8. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, golimumab, or infliximab.

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 documented moderate to severe disease Crohn's disease.
2. Must be prescribed by, or in consultation with, a specialist in gastroenterology.
3. Patient is free of any active, severe infections.
4. Patient has been screened for tuberculosis according to local practice (if applicable).
5. Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib).
6. Physician has assessed baseline disease severity utilizing an objective measure/tool.
7. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate).
8. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, certolizumab, or infliximab.

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for all members (including new members) who meet the following:

1. ALL initial authorization criteria; AND
2. 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; AND
3. For Crohn's disease:
    a. Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score]; OR
4. For Ulcerative Colitis:
    a. Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, normalization of C-reactive protein (CRP) or fecal calprotectin (FC), and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].

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)

V. REFERENCES

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; August 2021.
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.