Reference number
2666-A

STANDARD MEDICARE PART B 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.

A. FDA-Approved Indications
   1. Ulcerative colitis (UC)
      Adult patients with moderately to severely active UC
   2. Crohn's disease (CD)
      Adult patients with moderately to severely active CD

B. Compendial Uses
   Immune checkpoint inhibitor-related toxicity

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Moderately to severely active ulcerative colitis (UC)
Authorization of 24 months may be granted for treatment of moderately to severely active ulcerative colitis.

B. Moderately to severely active Crohn's disease (CD)
Authorization of 24 months may be granted for treatment of moderately to severely active Crohn's disease.

C. Immune checkpoint inhibitor-related toxicity
Authorization of 1 month may be granted for the treatment of immune checkpoint inhibitor-related diarrhea or colitis in members who have had an inadequate response to systemic corticosteroids or who have a clinical reason to avoid these medications.

III. CONTINUATION OF THERAPY

A. Immune checkpoint inhibitor-related toxicity
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

B. All other indications
All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 24 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with Entyvio
2. Entyvio is being used to treat an indication enumerated in Section II
3. The member is receiving benefit from therapy

IV. REFERENCES

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; March 2020.
2. Kornbluth A, Sachar D, 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 January 25, 2017.
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 January 26, 2017.
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.
5. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 05, 2020.
6. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450