MVP Health Care Medical Policy

Medicare Part B: ENTYVIO (vedolizumab)

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**01/01/2024**
Approval Date:	**10/01/2025**
Effective Date:	**12/01/2025**

Related Policies:

Inflammatory Biologic Drug Therapy

Experimental or Investigational Procedures

Infliximab

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Drugs Requiring Prior Authorization (covered under the medical benefit)

J3380 Entyvio (vedolizumab, injection 1mg)

Overview/Summary of Evidence

ENTYVIO is an integrin receptor antagonist indicated for adult ulcerative colitis and adult Crohn's disease. Prior to initiating treatment with ENTYVIO, all members should be brought up to date with all immunizations according to current immunization guidelines. ENTYVIO is not recommended in members with active, severe infections until the infections are controlled. Providers should consider withholding treatment in members who develop a severe infection while on treatment with ENTYVIO. Providers should perform screening for tuberculosis (TB) according to the local practice.

Indications/Criteria

Coverage is provided in the following conditions:

Universal Criteria:

- Member is at least 18 years of age; AND

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND

- Member is not on concurrent treatment with another TNF-inhibitor, biologic response modifier, natalizumab products or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.);

- Coverage duration (unless otherwise specified for applicable indication)
    - **Initial coverage up to 6 months**
    - **Continuation of coverage 12 months**

For the treatment of **Crohn's disease**:

- Documented moderate to severe active disease; AND 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

Continuation of therapy will require documentation of:

- 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].

For the treatment of **Ulcerative Colitis**:

- Documented moderate to severe active disease; AND 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); OR 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
- Requests for members with moderately severe UC, who are naïve to biologic therapies will be reviewed on a case-by-case basis consistent with the AGA guidelines.

Continuation of therapy will require documentation of:

- 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, 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].

Management of **Immune Checkpoint Inhibitor-Related Diarrhea/Colitis/Pneumonitis**:

- Member has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND

- Member has moderate (grade 2) to severe (grade 3-4) diarrhea, colitis, or pneumonitis related to their immunotherapy; AND

- Documented failure, contraindication, or ineffective response to systemic corticosteroids or infliximab.

Continuation of therapy will require documentation of: May not be renewed for Immune Checkpoint Inhibitor-Related Diarrhea/Colitis/Pneumonitis

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Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

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References

1. Entyvio [package insert]. Lexington, MA 02421; Takeda Pharmaceuticals America, Inc; Approved 2014. Revised 04/2024.
2. 2. Lichtenstein GR, Loftus EV, Isaacs K, et al. American College of Gastroenterology Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113: 481-517. doi: 10.1038/ajg.2018.27; published online 27 March 2018.
3. 3. Kornbluth A, Sachar DB; Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2010 Mar;105(3):501-23.
4. 4. Dignass A, Lindsay JO, Sturm A, et al. Second European evidence-based consensus on the diagnosis and management of ulcerative colitis part 2: current management. J Crohns Colitis. 2012 Dec;6(10):991-1030.
5. 5. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. Gastroenterology. 2013 Dec;145(6):1459-63. doi: 10.1053/j.gastro.2013.10.047.
6. 6. Gomollón F, Dignass A, Annese V, et al. EUROPEAN Evidence-based consensus on the diagnosis and management of Crohn's disease 2016: Part 1: Diagnosis and medical management. J Crohns Colitis. 2016 Sep 22. pii: jjw168.
7. 7. Harbord M, Eliakim R, Bettenworth D, et al. Third European Evidence-based Consensus on Diagnosis and Management of Ulcerative Colitis. Part 2: Current Management. J Crohns Colitis. 2017 Jan 28. doi: 10.1093/ecco-jcc/jjx009.
8. 8. National Institute for Health and Care Excellence. NICE 2012. Crohn's Disease: Management. Published 10 October 2012. Clinical Guideline [CG152]. https://www.nice.org.uk/guidance/cg152/resources/crohns-disease-management-pdf-35109627942085.
9. 9. Lewis JD, Chuai S, Nessel L, et al. Use of the Non-invasive Components of the Mayo Score to Assess Clinical Response in Ulcerative Colitis. Inflamm Bowel Dis. 2008 Dec; 14(12): 1660–1666. doi: 10.1002/ibd.20520
10. 10. Paine ER. Colonoscopic evaluation in ulcerative colitis. Gastroenterol Rep (Oxf). 2014 Aug; 2(3): 161–168.

11. 11. Walsh AJ, Bryant RV, Travis SPL. Current best practice for disease activity assessment in IBD. Nature Reviews Gastroenterology & Hepatology 13, 567–579 (2016) doi:10.1038/nrgastro.2016.128
12. 12. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019 Mar;114(3):384-413.
13. 13. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) vedolizumab. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL
14. ACG Clinical Guidline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi: 10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)
15. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis Singh, Siddharth et al. Gastroenterology, Volume 167, Issue 7, 1307 – 1343. December 2024.