



Medical Pharmacy Drug Prior Authorization Criteria

Drug Trade Name:	Entyvio®	Drug Generic Name:	Vedolizumab
J Code:	J3380	1 billable unit =	1 mg
Original Date of Review:	12/7/2022	Last Reviewed:	9/10/2025
Revision Date History	12/7/2022, 3/15/2023, 8/30/2023, 12/13/2023, 9/11/2024		

Vedolizumab reduces chronically inflamed gastrointestinal parenchymal tissue associated with ulcerative colitis and Crohn disease by binding specifically to the alpha-4-beta-7-integrin receptor and blocking its interaction with mucosal addressing cell adhesion molecule-1. This inhibits the movement of memory T-lymphocytes across the endothelium into inflamed gastrointestinal tissue.

Criteria:

- **Length of authorization:**
 - Initial: 14 weeks
 - Renewal: Up to 12 months
 - Immune Checkpoint Inhibitor-Related Diarrhea/Colitis: 3 doses and may not be renewed
- **Age:** see below for product specific requirements
- **Diagnoses [including ICD-10 codes]:** see below
- **Quantity Limit:**
 - Loading Dose:
 - Entyvio® 300 mg single use vial: 1 vial IV at weeks 0, 2, & 6 (3 vials total per 42 days)
 - Maintenance Dose:
 - Entyvio® 300 mg single use vial: 1 vial IV every 8 weeks (56 days)
- **Maximum Units:**

Indication	Billable Units	Per Number of Days
All Loading Dose	900	42
All Maintenance	300	56

- **Initial Approval Criteria**
 - **Universal Criteria [if applicable]**
 - Coverage is provided in the following conditions:
 - Patient is at least 18 years of age; **AND**
 - Patient is up to date with all vaccinations, in accordance with current immunization guidelines, prior to initiating therapy; **AND**
 - Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**

- Provider attests that the patient will be screened for active infection, including clinically important localized infections, prior to each administration of this medication; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); **AND**
- **Indication Specific Criteria [if applicable]**
 - **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 of corticosteroids or immunomodulators (e.g., azathioprine, 6- mercaptopurine, or methotrexate, etc.); **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
 - **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
 - **Management of Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**
 - Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); **AND**
 - Patient has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy
- **Renewal Criteria**
 - Coverage may be renewed based upon the following criteria:
 - Patient continues to meet universal and indication-specific criteria as identified in Initial Approval Criteria; **AND**
 - Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: anaphylaxis or other serious allergic, severe infusion-related or hypersensitivity reactions, severe infections, progressive multifocal leukoencephalopathy (PML), jaundice or other evidence of significant liver injury, etc.; **AND**
 - **Crohn's Disease**
 - 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].
 - **Ulcerative Colitis**

- 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**
 - May not be renewed

• **Dosage/Administration**

Entyvio®	
Indication	Dose
Ulcerative Colitis and Crohn's Disease	<p><u>Loading dose:</u> Administer 300 mg intravenously at weeks 0, 2, & 6</p> <p><u>Maintenance dose:</u> Administer 300 mg intravenously every 8 weeks thereafter <i>Requests for higher dosing must be reviewed according to the information below</i></p>
Immune Checkpoint Inhibitor-Related Diarrhea/Colitis	Administer 300 mg intravenously at weeks 0, 2, & 6
<ul style="list-style-type: none"> • Dose escalation (up to the maximum dose and frequency specified below) may occur upon clinical review on a case-by-case basis provided that the patient has: <ul style="list-style-type: none"> ○ Shown an initial response to therapy; AND ○ Received the three loading doses at the dose <u>AND</u> interval specified above; AND ○ Received a minimum of one maintenance dose at the dose <u>AND</u> interval specified above; AND ○ Responded to therapy (by treatment week 14) with subsequent loss of response; AND ○ Dose escalation must not exceed the following limits: 300 mg every 4 weeks <ul style="list-style-type: none"> ➢ Coverage will be provided for 3 months with continued approval (as specified in Sections I & IV) contingent upon demonstration of clinical improvement and vedolizumab levels (if available) <ul style="list-style-type: none"> • Patients who do not regain response should discontinue therapy • Patients who are responding to therapy may continue with their current dosing 	
<p><u>Note:</u></p> <ul style="list-style-type: none"> • Request for dose escalation prior to week 14 will be evaluated considering the patient's clinical picture regarding severity of inflammation, factors which may result in subtherapeutic response to standard dosing (e.g., obesity, hypoalbuminemia, prior TNF-I exposure), timing of response and breakthrough/loss of response, AND one of the following: <ul style="list-style-type: none"> ○ vedolizumab trough (if available) at week 14 is <14 micrograms/mL; OR CRP elevation or calprotectin >150 	
<p>Vedolizumab trough levels must be obtained (if this is a covered test under the benefit).</p> <ul style="list-style-type: none"> • Patients whose trough is 14-20 micrograms/mL may continue with 300 mg every 4 weeks. • Patients with a trough >20 micrograms/mL must increase the interval between administrations from 4 weeks to 6 weeks. Response should be assessed after receipt of 3 doses at this every 6-week interval. Those patients demonstrating loss of response may then decrease the interval back 	

to 300 mg every 4 weeks.

- Patients whose trough is <14 micrograms/mL are candidates to decrease the interval between administrations from 8 weeks to 4 weeks

NDC:

- Entyvio® 300 mg single use vial: 67464-0300-20

References:

1. Entyvio® [package insert]. Lexington, MA 02421; Takeda Pharmaceuticals America, Inc; August 2021. Accessed March 2022.
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. 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. 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. 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. 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. 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. 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. 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. Paine ER. Colonoscopic evaluation in ulcerative colitis. *Gastroenterol Rep (Oxf).* 2014 Aug; 2(3): 161–168.
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. 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. 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 COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2021.
14. Bergqvist, V, Hertervig E, Gedeon P, et al. Vedolizumab treatment for immune checkpoint inhibitor-induced enterocolitis. *Cancer Immunology Immunotherapy* 66: 581-592, No. 5, May 2017.

15. Torres J, Bonovas S, Doherty G, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. *J Crohn's Colitis*. 2020 Jan 1;14(1):4-22. doi: 10.1093/ecco-jcc/jjz180. PMID: 31711158.
16. National Institute for Health and Care Excellence. NICE 2019. Crohn's Disease: Management. Published 03 May 2019. Clinical Guideline [NG129].
<https://www.nice.org.uk/guidance/ng129/resources/crohns-disease-management-pdf-66141667282885>.
17. Vermeire S, Loftus EV, Colombel JF, et al. Long-term Efficacy of Vedolizumab for Crohn's Disease, *Journal of Crohn's and Colitis*, Volume 11, Issue 4, 1 April 2017, Pages 412–424, <https://doi.org/10.1093/ecco-jcc/jjw176>.

Covered Diagnosis Codes

ICD-10	ICD-10 Description
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess

K50.918	Crohn's disease, unspecified, with other complication
ICD-10	ICD-10 Description
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess

K51.818	Other ulcerative colitis with other complication
ICD-10	ICD-10 Description
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications