

Medical Policy

Entyvio® (vedolizumab)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-097
CURRENT VERSION EFFECTIVE DATE	1/1/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Entyvio® (vedolizumab) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Entyvio will be provided for 14 weeks initially and may be renewed every 6 months thereafter. Immune Checkpoint Inhibitor-Related Diarrhea/Colitis: 3 doses and may not be renewed.

- Max Units (per dose and over time):
 - o Loading Dose: 300 billable units at weeks 0, 2, & 6
 - o Maintenance Dose: 300 billable units every 8 weeks

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Initial

- A. Patient is 18 years of age or older; **AND**
- B. Provider has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- C. Patient is up to date with all vaccinations, in accordance with current immunization guidelines, prior to initiating therapy; **AND**
- D. Patient has been evaluated and screened for the presence of latent TB (tuberculosis) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- E. Patient does not have an active infection, including clinically important localized infections; **AND**
- F. 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**

Crohn's Disease (CD)

- A. Patient has a documented diagnosis of moderate to severe active disease; **AND**
- B. Patient has a documented trial and 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**
- C. 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 (UC)

- A. Patient has a documented diagnosis of moderate to severe disease; **AND**
- B. Patient has a documented trial and 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**
- C. Patient has a documented trial and 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

- A. Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); **AND**
- B. Patient has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy.

Renewal

- A. Patient continues to meet the Initial criteria; **AND**
- B. 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**

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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 of corticosteroids 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

- 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, 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

- A. May not be renewed

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

- A. ENTYVIO (vedolizumab) for injection, for intravenous use. Initial U.S. Approval: 2014
 - a. ENTYVIO (vedolizumab) for injection is supplied in sterile 20 mL single-dose glass vials, containing 300 mg of vedolizumab as a white to off-white lyophilized cake.

CODING

Applicable NDC Codes	
64764-0300-20	Entyvio 300 mg single use vial

Applicable Procedure Code	
J3380	Injection, vedolizumab, 1 mg; 1 billable unit = 1 mg

Applicable ICD-10 Codes	
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

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Applicable ICD-10 Codes	
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
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

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Applicable ICD-10 Codes	
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
K51.819	Other ulcerative colitis with unspecified complications

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Applicable ICD-10 Codes	
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
K52.1	Toxic gastroenteritis and colitis
R19.7	Diarrhea, unspecified

EVIDENCE BASED REFERENCES

1. Product Information: ENTYVIO(R) intravenous injection, vedolizumab intravenous injection. Takeda Pharmaceuticals America Inc (per FDA), Deerfield, IL, 2020.

POLICY HISTORY

Original Effective Date	1/1/2022
Revised Date	March 1, 2023 - Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
P&T Committee Endorsement	3/21/2022