# Entyvio® (vedolizumab)
## (Intravenous)

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## I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), unless otherwise specified.
  - Crohn's Disease and Ulcerative Colitis: Prior authorization validity will be provided initially for 14 weeks.
    - Members who will be receiving subcutaneous maintenance doses: Prior authorization validity will be provided for 2 intravenous doses and 4 subcutaneous doses *(see Entyvio SQ policy – Document Number: IC-0733).*
  - Management of Immune Checkpoint Inhibitor-Related Toxicities and Management of CAR T-cell and Lymphocyte Engager-Related Toxicities: Prior authorization validity will be provided for 3 doses total.
- Renewal: Prior authorization validity may be renewed for 12 months (365 days) thereafter, unless otherwise specified.
  - Dose escalation requests for Crohn's Disease and Ulcerative Colitis: Prior authorization validity will be provided for 3 months (90 days) with continued renewal every 12 months (365 days) thereafter (*See Section V for continuation details).*
  - Management of Immune Checkpoint Inhibitor-Related Toxicities and Management of CAR T-cell and Lymphocyte Engager-Related Toxicities: Prior authorization validity may NOT be renewed.
  - Acute Graft Versus Host Disease: Prior authorization validity may be renewed for 6 months (180 days)

## II. Dosing Limits

**Max Units (per dose and over time) [HCPCS Unit]:**

**Crohn's Disease & Ulcerative Colitis:**

- Loading Dose: 300 billable units (300 mg) at weeks 0, 2, & 6
- Maintenance Dose: 300 billable units (300 mg) every 8 weeks

**Management of Immune Checkpoint Inhibitor-Related Toxicities and Management of CAR T-cell and Lymphocyte Engager-Related Toxicities:**

- 300 billable units (300 mg) at weeks 0, 2, & 6

**Acute Graft Versus Host Disease:**

- Loading Dose: 300 billable units (300 mg) at weeks 0, 2, & 6
- Maintenance Dose: 300 billable units (300 mg) every 8 weeks

## III. Initial Approval Criteria [1]

*NOTE: When vedolizumab (Entyvio®) will be self-administered by subcutaneous injection, please refer to applicable pharmacy benefit plan*

Prior authorization validity is provided in the following conditions:

- The prescriber is a specialist in the area of the patient's diagnosis, or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- Member is at least 18 years of age; **AND**
- Provider will confirm that member is up to date with all vaccinations, in accordance with current immunization guidelines, prior to initiating therapy; **AND**

**Universal Criteria [1]**

- Member does not have an active infection, including clinically important localized infections; **AND**
- Member 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**
- Member is not on concurrent treatment with another biologic therapy or targeted synthetic therapy; **AND**

**Crohn's Disease (CD) † [1,2,16,21,25,30,31]**

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- 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.); **OR**
    - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier(e.g., adalimumab, certolizumab, or infliximab); **OR**
    - Member has evidence of high-risk disease for which corticosteroids or immunomodulators are inadequate and biologic therapy is necessary; **OR**
    - Member is already established on a biologic or targeted synthetic therapy for the treatment of CD

* *Three months of corticosteroids are not required if early non-response is confirmed.*

**Ulcerative Colitis (UC) †** [1,12,18-20,32]

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
    - Documented failure or ineffective response to a minimum 3-month* trial of conventional therapy [aminosalicylates, corticosteroids, or immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate, etc.)] at maximum tolerated doses, unless there is a contraindication or intolerance to use; **OR**
    - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier(e.g., adalimumab, golimumab, or infliximab); **OR**
    - Member is already established on a biologic or targeted synthetic therapy for the treatment of UC

* *Three months of corticosteroids are not required if early non-response is confirmed.*

**Management of Immune Checkpoint Inhibitor-Related Toxicities ‡** [13,14]

- Member has been receiving therapy with an immune checkpoint inhibitor; **AND**
    - Member has moderate to severe esophagitis, gastritis, or duodenitis if no improvement on corticosteroids or budesonide; **OR**
    - Member has mild (G1) diarrhea or colitis related to their immunotherapy with persistent or progressive symptoms and a positive lactoferrin/calprotectin; **OR**
    - Member has moderate (G2) to severe (G3-4) diarrhea or colitis related to their immunotherapy if colonoscopy or flexible sigmoidoscopy shows significant ulceration or extensive non-ulcerative inflammation or microscopic colitis on histology

**Acute Graft Versus Host Disease (aGVHD) ‡** [13,22]

- Member has received an allogeneic hematopoietic stem cell transplant; **AND**
- Used for steroid-refractory acute GVHD; **AND**
- Used in combination with systemic corticosteroids as additional therapy following no response to first-line therapies

**Management of CAR T-cell and Lymphocyte Engager-Related Toxicities ‡** [13]

- Member has previously received a BCMA (B-cell maturation antigen)-directed CAR T-cell therapy (e.g., idecabtagene vicieucel, ciltacabtagene autoleucel); **AND**
- Member has Immune Effector Cell-Associated enterocolitis; **AND**
    - Member has steroid-refractory diarrhea; **OR**
    - Member has recurrent diarrhea with steroid taper

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

## IV. Renewal Criteria [1]

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the universal and indication-specific criteria as identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I)*; **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 (CD)** [16,26,27]

- 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 regain, hematocrit, presence of extra intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, improvement in biomarker levels [i.e., fecal calprotectin or serum C-reactive protein (CRP)] and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Harvey-Bradshaw Index score, etc].

**Ulcerative Colitis (UC)** [9-11,20,28]

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, 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.

**Acute Graft Versus Host Disease (aGVHD)** [22-24]

- Response to therapy with an improvement in one or more of the following:
  - Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score, etc.)
  - Member-reported symptoms (e.g., Lee Symptom Scale, etc.)

## V. Dosage/Administration [1,14,17,22-24,33]

| Indication | Dose |
|---|---|
| Crohn's Disease and Ulcerative Colitis | **Induction dose:**<br>• Members who will be receiving intravenous maintenance doses: Administer 300 mg intravenously at weeks 0, 2, & 6 *(see maintenance dosing below)* |

| | |
|---|---|
| | • Members who will be receiving subcutaneous maintenance doses: Administer 300 mg intravenously at weeks 0 and 2 *(see Entyvio SQ policy [Document Number: IC-0733] for maintenance dosing starting at week 6).*<br>**Maintenance dose:**<br>Administer 300 mg intravenously every 8 weeks thereafter<br>***NOTE:*** *Requests for higher intravenous dosing must be reviewed according to the dose escalation information below* |
| Management of Immune Checkpoint Inhibitor-Related Toxicities and Management of CAR T-cell and Lymphocyte Engager-Related Toxicities | Administer 300 mg intravenously at weeks 0, 2, & 6 |
| Acute Graft Versus Host Disease | Administer 300 mg intravenously at weeks 0, 2, & 6, then 300 mg intravenously every 8 weeks |

- Crohn's Disease & Ulcerative Colitis intravenous dose escalation[17] (up to the maximum dose and frequency specified below) may occur upon clinical review on a case-by-case basis provided that the member has:
  - Shown an initial response to therapy; **AND**
  - Received the three loading doses at the dose AND interval specified above; **AND**
  - Received a minimum of one maintenance dose at the dose AND 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
      - ➢ Prior authorization validity 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)**
        - Members who do not regain response should discontinue therapy
        - Members who are responding to therapy may continue with their current dosing**

*Note:

- Request for dose escalation prior to week 14 will be evaluated considering the member'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:
  - vedolizumab trough (if available)** at week 14 is <14 micrograms/mL; **OR**
  - CRP elevation or fecal calprotectin >150

**Vedolizumab trough levels must be obtained (if this is a covered test under the benefit).

- Members whose trough is 14-20 micrograms/mL may continue with 300 mg every 4 weeks.
- Members 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 members demonstrating loss of response may then decrease the interval back to 300 mg every 4 weeks.

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

## VI. Billing Code/Availability Information

HCPCS Code:

- J3380 – Injection, vedolizumab, intravenous, 1 mg; 1 billable unit = 1 mg

NDC:

- Entyvio 300 mg single use vial: 64764-0300-xx

## VII. References


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## Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder

(MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

| Factor | Conclusion |
|---|---|
| Indication | Yes: Consider for PA |
| Safety and efficacy | No: PA not a priority |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug | Yes: Consider for PA |

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---|---|
| D89.810 | Acute graft-versus-host disease |
| D89.812 | Acute on chronic graft-versus-host disease |
| D89.813 | Graft-versus-host disease, unspecified |
| K20.80 | Other esophagitis without bleeding |
| K20.81 | Other esophagitis with bleeding |
| K20.90 | Esophagitis, unspecified without bleeding |
| K20.91 | Esophagitis, unspecified with bleeding |
| K29.00 | Acute gastritis without bleeding |
| K29.01 | Acute gastritis with bleeding |
| K29.80 | Duodenitis without bleeding |
| K29.81 | Duodenitis with bleeding |
| 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 |

| ICD-10 | ICD-10 Description |
|---|---|
| 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 |
| 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 |

| ICD-10 | ICD-10 Description |
|---|---|
| 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 |
| 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 |
| T80.82XA | Complication of immune effector cellular therapy, initial encounter |
| T80.82XS | Complication of immune effector cellular therapy, sequela |
| T80.89XA | Other complications following infusion, transfusion and therapeutic injection, initial encounter |
| T80.89XS | Other complications following infusion, transfusion and therapeutic injection, sequela |
| T86.09 | Other complications of bone marrow transplant |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |