



Entyvio™ (vedolizumab) (Intravenous)

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I. Length of Authorization

- Coverage 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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

Loading Dose:

- Entyvio 300 mg single use vial: 1 vial at weeks 0, 2, & 6 (3 vials total per 42 days)

Maintenance Dose:

- Entyvio 300 mg single use vial: 1 vial every 8 weeks (56 days)

B. Max Units (per dose and over time) [Medical Benefit]:

Loading Dose:

- 300 billable units at weeks 0, 2, & 6

Maintenance Dose:

- 300 billable units every 8 weeks

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; **AND**
- Patient aged 18 years or older; **AND**
- Patient is free of any active, severe infections; **AND**
- Patient has been screened for tuberculosis according to local practice (if applicable); **AND**
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**

Crohn's disease †

- Documented moderate to severe 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 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); **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, 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, etc.); **AND**
- Patient has severe (grade 3-4) diarrhea or colitis related to their immunotherapy; **AND**
- Patient's condition is refractory to infliximab.

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Patient is receiving ongoing monitoring for presence of TB or other active infections; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: anaphylaxis or other serious allergic 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, normalization of C-reactive protein (CRP) or fecal calprotectin (FC), 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

V. Dosage/Administration

| Indication | Dose |
|--|---|
| Ulcerative Colitis and Crohn’s Disease | <u>Loading dose:</u> 300 mg, intravenously, at weeks 0, 2, & 6 |
| | <u>Maintenance dose:</u> 300 mg, intravenously, every 8 weeks thereafter |
| Immune Checkpoint Inhibitor related diarrhea/colitis | 300 mg, intravenously, at weeks 0, 2, & 6 |

VI. Billing Code/Availability Information

Jcode:

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

NDC:

- Entyvio 300 mg single use vial: 67464-0300-xx

VII. References

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13. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) vedolizumab. National Comprehensive Cancer Network, 2019. 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 2019.
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Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|--------|--|
| K50.00 | Crohn's disease of small intestine without complications |

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

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

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| ICD-10 | ICD-10 Description |
|--------|-----------------------|
| R19.7 | Diarrhea, unspecified |

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

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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): 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, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| 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 |