

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

## Entyvio (vedolizumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 Year

Medications	Quantity Limit
Entyvio (vedolizumab) 300mg/vial*	1 vial per 56 days (8 weeks)

\*Initiation of therapy for both Crohn's Disease (CD) and Ulcerative Colitis (UC): May approve up to 2 (two) additional single-use vials (300mg/vial) in the first 6 weeks (42 days) of treatment

### **APPROVAL CRITERIA**

Requests for Entyvio (vedolizumab) may be approved for the following:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to ONE (1) preferred biologic agent [Current preferred biologic includes – Humira (adalimumab), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda)] unless the following is met:
  - A. Individual has been receiving and is maintained on a stable dose of the Entyvio (vedolizumab); **OR**
  - B. The preferred agent(s) are not acceptable due to concomitant clinical conditions, including but not limited to any of the following:
    1. Known hypersensitivity to any active or inactive component which is not also associated with Entyvio (vedolizumab); **OR**
    2. Pregnant or planning on becoming pregnant; **OR**
    3. Serious infections or concurrent sepsis; **OR**
  - C. Individual has any of the following concomitant clinical conditions:
    1. Demyelinating disease; **OR**
    2. Heart failure with documented left ventricular dysfunction; **OR**
    3. Malignancy [including but not limited to, solid or hematologic cancers and excluding superficial skin cancers (such as basal and squamous cell)]; **OR**
    4. Tuberculosis infection;

### **AND**

- II. Crohn's disease (CD) when each of the following are met:

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- A. Individual is 6 years of age or older (Conrad 2016, Singh 2016) with moderate to severe CD; **AND**
- B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants) or a tumor necrosis factor (TNF) antagonist;

**OR**

- III. Ulcerative colitis (UC) when each of the following are met:
  - A. Individual is 6 years of age or older (Conrad 2016, Singh 2016) with moderate to severe UC; **AND**
  - B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants) or a TNF antagonist.

Requests for Entyvio (vedolizumab) may **not** be approved for of the following:

- I. All other indications not included above; **OR**
- II. In combination with apremilast, JAK inhibitors, or other biologic drugs (such as TNF antagonists or natalizumab); **OR**
- III. Active, serious infection or a history of recurrent infections; **OR**
- IV. New or worsening neurological signs or symptoms of John Cunningham virus (JCV) infection or risk of progressive multifocal leukoencephalopathy (PML).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 14, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. American Gastroenterological Association. Identification, assessment and initial medical treatment of ulcerative colitis Clinical Care Pathway. Available at <https://gastro.org/guidelines/ibd-and-bowel-disorders>. Accessed on: October 6, 2019.
6. American Gastroenterological Association. Identification, assessment and initial medical treatment of Crohn's disease Clinical Care Pathway. Available at <https://gastro.org/guidelines/ibd-and-bowel-disorders>. Accessed on: October 6, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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7. Lichtenstein GR, Loftus EV, Isaacs KL et al. 2018 American College of Gastroenterology Guideline for the management of Crohn's disease in adults. *Am J Gastroenterol* 2018; 113:481–517.
8. Rubin DT, Ananthakrishnan AN, Siegel CA et al. American College of Gastroenterology Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol* 2019; 114:384-413.
9. Conrad MA, Stein RE, Maxwell EC, et al. Vedolizumab therapy in severe pediatric inflammatory bowel disease. *Inflamm Bowel Dis.* 2016; 22(10):2425-2431.
10. Singh N, Rabizadeh S, Jossen J, et al. Multi-center experience of vedolizumab effectiveness in pediatric inflammatory bowel disease. *Inflamm Bowel Dis.* 2016; 22(9):2121-2126.

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