Entyvio (vedolizumab)

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

Medications	Quantity Limit
Entyvio (vedolizumab) 300mg/vial*^ Intravenous Infusion	1 vial per 56 days (8 weeks)
Entyvio (vedolizumab) 108mg/0.68mL pen/syringe Subcutaneous Injection	1 pen/syringe every 2 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

^For CD or UC, may approve increased dosing, up to 1 vial (300 mg) every 4 weeks if the following criteria are met:

I. Individual has been treated with standard maintenance dosing (i.e. every 8 weeks) for *at least* 2 doses or 16 weeks; **AND**
II. The increased dosing is being prescribed by or in consultation with a gastroenterologist; **AND**
III. Individual initially achieved an adequate response to standard maintenance dosing but has subsequently lost response, as determined by the prescriber; **OR**
IV. Individual partially responded but had an inadequate response to standard maintenance dosing as determined by the prescriber; **AND**
V. Symptoms, if present, are not due to active infections or any other gastrointestinal disorder other than the primary disease; **AND**
VI. Requested dosing does not exceed up to one vial (300 mg) every 4 weeks.

Initial approval duration for increased dosing for CD or UC: 16 weeks

^Requests for continued escalated dosing for CD or UC may be approved if the following criteria are met:

I. Requested dosing does not exceed up to one vial (300 mg) every 4 weeks; **AND**
II. Individual has subsequently regained response or achieved adequate response following increased dosing, as shown by improvement in signs and symptoms of the disease (including but not limited to reduction in stool frequency/bloody stools, improvement abdominal pain, or endoscopic response); **AND**
III. Individual is not experiencing unacceptable adverse effects from increased dosing; **AND**
IV. Individual will be assessed regularly for dose de-escalation.

Continued approval duration for increased dosing for CD or UC: 6 months

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^For CD or UC, Increased dosing may not be approved for the following:

I. Individual has had no response to Entyvio at standard maintenance dosing (i.e. every 8 weeks); **OR**

II. Individual is requesting dose escalation in absence of signs and symptoms of the disease (for example, requesting based on results of therapeutic drug level or anti-drug antibody testing alone).

APPROVAL CRITERIA

Initial requests for Entyvio (vedolizumab) Intravenous Infusion may be approved for the following:

I. Crohn's disease (CD) when the following criteria are met:
   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 or is intolerant of conventional therapy (such as systemic corticosteroids, or immunosuppressants [such as thiopurines or methotrexate]); **OR**
   C. Individual has a contraindication to systemic corticosteroids or thiopurines or methotrexate; **AND**
   D. Individual has had a trial and inadequate response or intolerance to ONE (1) preferred biologic agent [Current preferred biologics include – adalimumab-adbm, Humira (adalimumab) unless the following is met. Medication samples/coupons/discount cards are excluded from consideration as a trial.:
      1. Individual has been receiving and is maintained on a stable dose of the Entyvio (vedolizumab);

OR

II. Ulcerative colitis (UC) when the following criteria 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 or is intolerant of conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); **OR**
   C. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines; **AND**
   D. Individual has had a trial and inadequate response or intolerance to ONE (1) preferred biologic agent [Current preferred biologics include – adalimumab-adbm, Humira (adalimumab), or Simponi (golibumab)] unless the following is met. Medication samples/coupons/discount cards are excluded from consideration as a trial.:
      1. Individual has been receiving and is maintained on a stable dose of the Entyvio (vedolizumab).

OR

III. Immunotherapy-related toxicities when each of the following criteria are met (NCCN 2A):
   A. Individual is undergoing immune checkpoint inhibitor therapy for a cancer diagnosis; **AND**

B. Individual is experiencing moderate to severe diarrhea or colitis as a result of immune checkpoint inhibitor treatment; **AND**
C. Symptoms persist despite treatment with steroids.

Initial requests for Entyvio (vedolizumab) subcutaneous injection may be approved for the following:

I. Ulcerative colitis (UC) when the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe UC;
AND
B. Individual has completed intravenous induction doses with Entyvio and is using subcutaneous Entyvio for maintenance therapy; **OR**
AND
C. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Humira (adalimumab), Simponi (golimumab), or Stelara (ustekinumab)]*. Medication samples/coupons/discount cards are excluded from consideration as a trial.:
AND
1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
OR
2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;
OR
D. Documentation is provided that individual has been receiving and is maintained on a stable dose of Entyvio (vedolizumab). Medication samples/coupons/discount cards are excluded from consideration as a trial.;
OR
E. Documentation is provided that individual has had a trial of Stelara AND has the following concomitant clinical conditions:
3. Demyelinating disease; **OR**
2. Heart failure with documented left ventricular dysfunction;
OR
G. Documentation is provided that individual has concomitant malignancy or latent tuberculosis infection;
OR
H. Documentation is provided that individual requires Entyvio subcutaneous injection due to clinical attributes such as selectivity.

*Note: Rinvoq is the preferred Janus Kinase (JAK) inhibitor(s). JAK inhibitor clinical criteria require a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents.

Continuation requests for Entyvio (vedolizumab) [intravenous subcutaneous] may be approved if the following criteria are met:

I. Documentation is provided that individual has been receiving and is maintained on a stable dose of Entyvio. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Requests for Entyvio (vedolizumab) intravenous infusion and subcutaneous injection may **not** be approved for the following:

I. In combination with oral or topical JAK inhibitors, ozanimod, etrasimod, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, ustekinumab, abatacept, rituximab, or natalizumab; **OR**
II. Active, serious infection or a history of recurrent infections; **OR**
III. New or worsening neurological signs or symptoms of John Cunningham virus (JCV) infection or risk of progressive multifocal leukoencephalopathy (PML) OR
IV. When the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 29, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. Feuerstein JD, Ho EY, Shmidt E et al. American Gastroenterological Association Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology 2021; 160:2496-2508.
5. Feuerstein JD, Issacs KL, Schneider Y, et al. American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450-1461.
6. 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.
7. 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.
8. Conrad MA, Stein RE, Maxwell EC, et al. Vedolizumab therapy in severe pediatric inflammatory bowel disease. Inflamm Bowel Dis. 2016; 22(10):2425-2431.
9. 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.