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 prefilled pen/syringe Subcutaneous Injection	2 pens/syringes per 28 days

*Initiation of therapy: 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: 1 year

^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 intravenous Entyvio (vedolizumab) 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. Documentation is provided that individual has had a trial and inadequate response or intolerance to ONE (1) preferred agent [Current preferred agents include –preferred adalimumab (Reference product Humira), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab)*] unless the following is met. A trial of multiple products with the same active ingredient counts as a trial of ONE preferred agent. 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

   C. Documentation is provided that individual is currently on Entyvio (vedolizumab). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

      OR
   D. Documentation is provided for why the individual is unable to use ALL preferred agents (or all remaining preferred agents if individual has tried any preferred agent) due to one of the following:
      1. The individual is subject to a warning or contraindication that appears in the labeling of ALL preferred products and is not included in the labeling of Entyvio (vedolizumab); **OR**
      2. None of the preferred products have activity against the individual's concomitant clinical condition which is covered by Entyvio (vedolizumab);
         OR
      3. Remaining preferred agent(s) include only adalimumab (i.e. individual is unable to use all preferred agents other than adalimumab due to one of the reasons above) (Sands 2019);

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. Documentation is provided that individual has had a trial and inadequate response or intolerance to ONE (1) preferred agent [Current preferred agents include –preferred adalimumab (Reference product Humira), or Simponi (golibumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab)*] unless the following is met. A trial of multiple products with the same active ingredient counts as a trial of ONE preferred agent. 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

   C. Documentation is provided that individual is currently on Entyvio (vedolizumab). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

   OR

   D. Documentation is provided for why the individual is unable to use ALL preferred agents (or all remaining preferred agents if individual has tried any preferred agent) due to one of the following:
      1. The individual is subject to a warning or contraindication that appears in the labeling of ALL preferred products and is not included in the labeling of Entyvio (vedolizumab); **OR**
      2. None of the preferred products have activity against the individual's concomitant clinical condition which is covered by Entyvio (vedolizumab);

         OR

      3. Remaining preferred agent(s) include only adalimumab (i.e. individual is unable to use all preferred agents other than adalimumab due to one of the reasons above) (Sands 2019);

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;

   OR

   D. Individual is experiencing moderate to severe esophagitis, gastritis, or duodenitis as a result of immune checkpoint inhibitor treatment; **AND**
   E. Symptoms have not improved on corticosteroids or budesonide;

OR

IV. Acute Graft-versus-host disease (GVHD) when each of the following criteria are met (NCCN 2A):

A. Individual has a diagnosis of steroid-refractory acute GVHD; **AND**
B. Individual is initiating vedolizumab in combination with systemic corticosteroids.

Continuation requests for intravenous Entyvio (vedolizumab) 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 intravenous Entyvio (vedolizumab). 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.

Initial requests for subcutaneous Entyvio (vedolizumab) 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**
   C. Individual has been stabilized on intravenous Entyvio maintenance therapy and is switching to maintenance therapy with subcutaneous Entyvio;
   OR
   D. Documentation is provided that individual was able to complete the intravenous (IV) Entyvio (vedolizumab) induction regimen; AND
   E. Documentation is provided that individual has achieved clinical response or clinical remission from IV vedolizumab therapy; AND
   F. Documentation is provided that individual is unable to continue IV Entyvio (vedolizumab) due to no venous access;

OR

II. Crohn's disease (CD) when the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe CD;
   AND
   B. Individual has completed intravenous induction doses with Entyvio and is using subcutaneous Entyvio for maintenance therapy; **OR**
   C. Individual has been stabilized on intravenous Entyvio maintenance therapy and is switching to maintenance therapy with subcutaneous Entyvio;.
   OR
   D. Documentation is provided that individual was able to complete the intravenous (IV) Entyvio (vedolizumab) induction regimen; AND
   E. Documentation is provided that individual has achieved clinical response or clinical remission from IV vedolizumab therapy; AND
   F. Documentation is provided that individual is unable to continue IV Entyvio (vedolizumab) due to no venous access;

*Note – Trial of preferred products does not apply in states where not on formulary. Tremfya (guselkumab) non-formulary (NY).

Continuation requests for subcutaneous Entyvio (vedolizumab) 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 subcutaneous Entyvio (vedolizumab). 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 and subcutaneous 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: October 15, 2025.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; 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. Singh S, Loftus EV, Limketkai BN et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Sever Ulcerative Colitis. Gastroenterology 2024; 167:130-1343.
6. Lichtenstein GR, Loftus EV, Afzali, A et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. The American Journal of Gastroenterology 120(6):p 1225-1264, June 2025.
7. Rubin DT, Ananthakrishnan AN, Siegel CA et al. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. The American Journal of Gastroenterology 120(6):p 1187-1224, June 2025.
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. Sands BE, Peyrin-Biroulet L, Loftus EV, et al. Vedolizumab versus adalimumab for moderate to severe ulcerative colitis. New Engl J Med. 2019; 381: 1215-26.
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.
11. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 15, 2025.
    a. Management of Immunotherapy-related Toxicities. V1.2025. Revised December 20, 2024.
    b. Hematopoietic Cell Transplantation (HCT). V3.2025. Revised September 24, 2025.