

Entyvio® (vedolizumab)

When requesting Entyvio® (vedolizumab), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indications

Entyvio is an integrin receptor antagonist indicated for the treatment of Crohn's Disease and Ulcerative colitis in adults with moderately to severely active disease.

Coverage Guidelines

Crohn's Disease

The individual must meet the following criteria for initial authorization:

- Is 18 years of age or older; AND
- Entyvio is prescribed by or in consultation with a gastroenterologist; AND
- Meets one of the following:
 - Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
 - Had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); OR
 - Has tried a biologic agent (e.g., adalimumab, certolizumab pegol, infliximab, ustekinumab); OR
 - Has tried one conventional systemic therapy (e.g., 6-mercaptopurine, azathioprine, cyclosporine, methotrexate); OR
 - Has tried or is currently taking systemic corticosteroids; OR
 - Has a contraindication to systemic corticosteroids.

For reauthorization, the individual must show therapeutic response to Entyvio.

Ulcerative Colitis

The individual must meet the following criteria for initial authorization:

- Has had a trial of one systemic or biologic agent (e.g., adalimumab, infliximab, golimumab, 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or corticosteroid); AND
- Is 18 years of age or older; AND
- Entyvio is prescribed by or in consultation with a gastroenterologist.

For reauthorization, the individual must show therapeutic response to Entyvio.

Approval duration (initial): 14 weeks

Approval duration (renewal): 12 months

Dosing Recommendation

The recommended dose (ulcerative colitis and Crohn's disease) is 300 mg administered as an intravenous infusion over 30 minutes at 0, 2, and 6 weeks, and then once every 8 weeks thereafter.

References

1. Entyvio intravenous infusion [prescribing information]. Deerfield, IL: Takeda; August 2021.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2018;113(4):481-517.
3. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.
4. Bressler B, Marshall JK, Bernstein CN, et al. Clinical practice guidelines for the medical management of nonhospitalized ulcerative colitis: the Toronto consensus. *Gastroenterology*. 2015;148(5):1035-1058.
5. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology*. 2021;160(7):2496-2508.
6. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology*. 2020 Apr;158(5):1450-1461.