

Entyvio® Intravenous (vedolizumab)

When requesting Entyvio® Intravenous (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 Intravenous is indicated in adults for the treatment of:

- moderately to severely active ulcerative colitis.
- moderately to severely active Crohn's disease.

Coverage Guidelines

Crohn's Disease

The individual must meet all of the following criteria for initial authorization:

- Is 18 years of age or older;
- Entyvio Intravenous is prescribed by or in consultation with a gastroenterologist;
- Meets one of the following:
 - o Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
 - o Had ileocolonic resection; OR
 - o Has tried a biologic agent (e.g., adalimumab, certolizumab pegol, infliximab, ustekinumab, risankizumab); OR
 - o Has tried one conventional systemic therapy (e.g., 6-mercaptopurine, azathioprine, methotrexate); OR

Note: Mesalamine products do not count as systemic therapy.

 - o Has tried, is currently taking, or has a contraindication to systemic corticosteroids.

Ulcerative Colitis

The individual must meet all of the following criteria for initial authorization:

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

Note: Mesalamine products do not count as systemic therapy.

 - o Has pouchitis and has tried one of the following: an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema (e.g., hydrocortisone enema), or mesalamine enema.

The individual must meet all of the following criteria for re-authorization (applies to both Crohn's disease and Ulcerative Colitis):

- Has been established on Entyvio therapy for at least 6 months (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Entyvio should be considered under initial criteria*);
- Meets one of the following:
 - o Has experienced a beneficial clinical response in at least one objective measure compared to baseline (e.g., fecal markers, serum markers, imaging studies, endoscopic assessment, and/or reduced dose of corticosteroids); OR
 - o Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, fatigue, stool frequency, and/or blood in stool)

Approval duration (initial and renewal): 12 months

Dosing Recommendations

Crohn's Disease and Ulcerative Colitis:

Administer 300 mg as an intravenous infusion at Week 0, Week 2, Week 6, then every 8 weeks thereafter.

References

1. Entyvio intravenous infusion [prescribing information]. Deerfield, IL: Takeda; September 2023.
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 Apr158(5):1450-1461.