

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:

- Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids
- Adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids

Coverage Guidelines

Crohn's Disease

For an initial authorization:

- 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
- Is contraindicated to systemic corticosteroids therapy AND
- Entyvio is prescribed by or in consultation with a gastroenterologist

For a re-authorization:

- Has responded to Entyvio therapy

Ulcerative Colitis

For an initial authorization:

- Had a 2-month trial of or intolerance to at least one systemic agent including a biologic agent (e.g., adalimumab, infliximab, golimumab, 6-mercaptopurine, azathioprine, corticosteroid) AND
- Entyvio is prescribed by or in consultation with a gastroenterologist

For a re-authorization:

- Has responded to Entyvio therapy

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 every 8 weeks thereafter.

References

1. Entyvio™ for intravenous injection [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; February 2018.
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.