

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 ulcerative colitis (UC)

- Adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulators; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids

Adult Crohn's disease (CD)

- Adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulators; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids

Approved Off-Label Compendial Use(s)

None

Coverage Guidelines

For all approved indications, the individual must meet **all** of the following criteria for approval:

- Does not have active, severe infection
- Entyvio (vedolizumab) will not be used in combination with another biologic agent (e.g., IL-inhibitor, rituximab, TNF-inhibitor, T-cell costimulation modulator)
- Is at least 18 years of age
- For a re-authorization request, an individual has shown evidence of therapeutic benefit by week 14 of therapy

For Crohn's disease and Ulcerative colitis initial authorization:

- Has moderately to severely active disease AND
- Had an inadequate/lost response or intolerance to a tumor necrosis factor (TNF) blocker (e.g., infliximab, adalimumab, certolizumab) OR

- Had an inadequate/lost response or intolerance to an immunomodulators (e.g., 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) OR
- Had an inadequate response, intolerance, or dependency to corticosteroids

Approval duration (initial and renewal): 12 months

Dosing Recommendations

The recommended dose 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 prescribing information. Deerfield, IL. Takeda Pharmaceuticals America, Inc. February 2018.
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3. Lichtenstein GR, Loftus JR EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol* 2018;113:481-517.
4. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Use of Thiopurines, Methotrexate, and Anti-TNF-alpha Biologic Drugs for the Induction and Maintenance of Remission in Inflammatory Crohn's Disease. *Gastroenterology* 2013;145:1459-1463.
5. Gomollon F, Dignass A, Annese V, et al. 3rd European Evidence-based Consensus on the Diagnosis and Management of Crohn's Disease 2016: Part 1: Diagnosis and Medical Management. *Journal of Crohn's and Colitis*. 2017:3-25
6. Kornbluth A, Sachar DB, and The Practice Parameters Committee of the American College of Gastroenterology. Erratum: Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol*. 2010;105:501-523.
7. Harbord M, Eliakim R, Bettenworth D, et al. Third European Evidence-based Consensus on Diagnosis and Management of Ulcerative Colitis. Part 2: Current Management. *Journal of Crohn's and Colitis*. 2017:769-784.