

## 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:

- Ulcerative colitis
- Crohn's disease

### Coverage Guidelines

#### Crohn's Disease

The individual must meet the following criteria for 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
- Has a contraindication to systemic corticosteroids; 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.

#### 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, 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™ for intravenous injection [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; March 2020.
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. Vedolizumab (Entyvio®). In: DRUGDEX® System Micromedex. Greenwood Village, CO: Thompson Reuters (Healthcare) Inc. [Updated; April 03, 2020; Accessed May 28, 2020].