

MONTANA HEALTHCARE PROGRAMS

Prior Authorization Criteria

Version 1, 3-7-18

ENTYVIO® Vedolizumab

ENTYVIO is an integrin receptor antagonist

Indications:

1. 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 immunomodulatory, or had an inadequate response with, were intolerant to or demonstrated dependence on corticosteroids.
2. 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 TNF blocker or immunomodulatory, or had an inadequate response with, were intolerant to or demonstrated dependence on corticosteroids.

Criteria for Approval:

1. Must be prescribed by or in consult with an appropriate specialist (gastroenterologist)
2. Member has one of the two approved indications listed above.
3. Member has failed on both corticosteroids and a preferred TNF blocker (Humira).
4. Member is 18 years of age or older

Administration

ENTYVIO is administered as an IV infusion over 30 minutes.

Quantity Limit:

- 300mg at zero, two, and six weeks, then every eight weeks thereafter.
- Initial approval will be for 14 weeks (1200mg). Must show evidence of therapeutic benefit for renewal.

Criteria for Renewal Authorization Approval:

1. Yearly follow-up or consult with appropriate specialist
2. Evidence of continued therapeutic benefit
3. Compliance with treatment regimen

References:

1. Entyvio[®] [package insert] Deerfield, IL; Takeda Pharmaceuticals America, Inc.; 2/2018, Accessed March 3, 2018.
2. Lexicomp Online[®], Lexi-Drugs[®], Hudson, Ohio: Lexi-Comp, Inc.; March 6, 2018
3. Cohen, R. & Stein, A. Approach to adults with steroid-refractory and steroid-dependent ulcerative colitis. Robson, K. ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com/contents/approach-to-adults-with-steroid-refractory-and-steroid-dependent-ulcerative-colitis?search=entyvio&source=search_result&selectedTitle=5~23&usage_type=default&display_rank=5Literature (accessed on March 6, 2018)
4. Farrell, R. & Peppercorn, M. Overview of the medical management of severe or refractory Crohn disease in adults. Robson, K. ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com/contents/overview-of-the-medical-management-of-severe-or-refractory-crohn-disease-in-adults?search=refractory%20crohns%20disease&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1 (accessed on March 6, 2018)