

Targeted Immunomodulators
Entyvio (vedolizumab)
Effective 06/01/2025

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|------------------------------|---|---------------------|---|
| Plan | <input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| Benefit | <input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit | | |
| Specialty Limitations | N/A | | |
| Contact Information | Medical and Specialty Medications | | |
| | All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 |
| | Non-Specialty Medications | | |
| | All Plans | Phone: 800-711-4555 | Fax: 844-403-1029 |
| Notes | Entyvio is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. | | |

Overview

Entyvio (vedolizumab) is an integrin receptor antagonist indicated for Adult Ulcerative Colitis (UC) and Adult Crohn's Disease (CD).

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met:

Ulcerative Colitis (UC)

1. Diagnosis of moderate to severe ulcerative colitis
2. Appropriate dosing

Crohn's Disease (CD)

1. Diagnosis of moderate to severe Crohn's disease
2. Appropriate dosing
3. **For a diagnosis of fistulizing Crohn's disease**, an inadequate response, adverse reaction or contraindication to Avsola (infliximab-axxq), Remicade (infliximab), Inflectra (infliximab-dyyb) or Renflexis (infliximab-abda) should be documented.

Requests for More Frequent or Higher Doses

Requests for more frequent or higher doses of injectable biologics may be approved if **ALL** of the following is provided:

1. Severe disease
2. Partial response to FDA-approved dosing of current biologic therapy
3. Specialist consult for the requested indication

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy and request can be recertified if dosing is appropriate.

Limitations

1. Initial approvals will be granted for 4 months.
2. Reauthorizations will be granted for 12 months.

References

1. Entyvio (vedolizumab) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America Inc; June 2024.
2. Kornbluth A, Sachar DB, and the Practice Parameters Committee of the American College of Gastroenterology. Ulcerative Colitis Practice Guidelines in Adults. Am J Gastroenterol. 2010; 105:501–523. Available at <http://s3.gi.org/physicians/guidelines/UlcerativeColitis.pdf>. Accessed September 6, 2016.
3. Lichtenstein GR, Hanauer SB, Sandborn WJ, and the Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's disease in adults. Am J Gastroenterol. 2009. Available at <http://s3.gi.org/physicians/guidelines/CrohnsDiseaseinAdults2009.pdf>. Accessed September 6, 2016.
4. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1):S2-S25.
5. Sandborn WJ, Feagan BG, Rutgeerts P, et al. Vedolizumab as induction and maintenance therapy for Crohn's disease. N Engl J Med 2013; 369:711.
6. Loftus EV Jr, Colombel JF, Feagan BG, et al. Long-term Efficacy of Vedolizumab for Ulcerative Colitis. J Crohns Colitis 2017; 11:400

Review History

02/23/15 – Reviewed

02/22/16 – Reviewed

02/27/17 – Reviewed and revised (adopted ST) in P&T Meeting

03/01/18 – Reviewed and revised (adopted MH RS) and Effective

02/20/19 – Reviewed in P&T Meeting

01/11/2023 – Reviewed and updated for Jan P&T. Matched MH UPPL. Appropriate diagnosis was replaced with a specific indication throughout. Clarified reauth criteria and initial approval duration from 4 to 6 months. Removed trial requirements from UC and CD criteria. Added Avsola as a trial requirement for fistulizing CD. Effective 3/1/23.

09/13/2023 – Reviewed and updated for P&T. Updated initial approval to 4 months. Added criteria regarding higher/more frequent dose for CoT. Effective 10/02/2023.

05/15/25 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. Updated formatting and references. Moved “Requests for More Frequent or Higher Doses” criteria into coverage guidelines section. Effective 6/1/25

