

Entyvio (vedolizumab)
Effective 10/02/2023

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
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
Exceptions			

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)

ALL of the following:

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

Crohn's Disease (CD)

ALL of the following:

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.

Continuation of Therapy

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

If dosing more frequent or higher than FDA-approved dosing and **ALL** of the following is documented:

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

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; February 2018.
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.

