Mass General Brigham
Health Plan

Entyvio (vedolizumab)
Effective 10/02/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
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	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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.