Entyvio® (vedolizumab)
Effective 02/20/19

Plan	☒ MassHealth ☐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.		
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	N/A		

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

Coverage Guidelines
Ulcerative Colitis (UC)
Authorization may be granted for members a diagnosis of UC when the following criteria are met:
1. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction, or contraindication to at least ALL the following:
        i. Aminosalicylate
        ii. Corticosteroid
        iii. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate) *
            1. Note: * If a request documents severe disease, a trial of an oral immunomodulator may be bypassed.
    b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication
2. Dosing is appropriate (see appendix A).
3. Prescriber provides clinical rationale for use of the requested agent instead of Humira (i.e. member has had an inadequate response, adverse reaction, or contraindication to Humira).

Crohn's Disease (CD)
Authorization may be granted for members with a diagnosis of CD when the following criteria are met:
1. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction, or contraindication to at least ALL the following:
        i. Aminosalicylate

ii. Antibiotic
iii. Corticosteroid
iv. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate) *
1. Note: * If a request documents severe disease, a trial of an oral immunomodulator may be bypassed.

b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication

2. Dosing is appropriate (see appendix A).
3. Prescriber provides clinical rationale for use of the requested agent instead of Humira (i.e. member has had an inadequate response, adverse reaction, or contraindication to Humira).
4. **For a diagnosis of fistulizing Crohn's disease,** an inadequate response, adverse reaction or contraindication to Remicade®(infliximab), Inflectra® (infliximab-dyyb) or Renflexis® (infliximab- abda) should be documented.

Continuation of Therapy
Reauthorization requires physician documentation indicating a positive response to therapy.

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

Appendices
Appendix A: Dosing

	Dosing
Entyvio® (vedolizumab)	**Crohn's disease, ulcerative colitis:** Initial: 300 mg IV at weeks 0, 2 and 6 Maintenance: 300 mg IV every 8 weeks.

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

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