Entyvio (vedolizumab)
Effective January 1, 2021

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

Moderately to severely active Ulcerative Colitis (UC)
Authorization may be granted for members new to AllWays Health Partners who are currently receiving treatment with Entyvio, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for treatment of moderately to severely active UC when the following criteria are met:

1. The member has an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix A).

Moderately to severely active Crohn's Disease (CD)
Authorization may be granted for members who are currently receiving treatment Entyvio, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for treatment of moderately to severely active CD when the following criteria are met:

1. The member has an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix B).

Continuation of Therapy

Reauthorization may be granted for members, including those who are new to AllWays Health Partners, who meet ALL initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Entyvio as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

Initial approvals and reauthorizations will be granted for 12 months.

Appendices

Appendix A: Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:
    a. mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa)
    b. Rectal mesalamine (e.g., Canasa, Rowasa)
    c. Alternatives: azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
    a. Oral mesalamine, rectal mesalamine
    b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
    a. Sulfasalazine
    b. Severe disease – maintenance of remission:
4. Azathioprine, mercaptopurine
    a. Alternative: sulfasalazine
5. Pouchitis: rectal mesalamine

Appendix B: Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
    a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa)
2. Mild to moderate disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternatives: methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:
    a. Methotrexate IM
4. Moderate to severe disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – maintenance of remission
    a. Azathioprine, mercaptopurine
    b. Alternative: methotrexate IM

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 in P&T Meeting
02/27/17 – Reviewed and revised (adopted ST)
02/26/18 – Reviewed and revised
02/20/19 – Reviewed and revised in P&T Meeting
10/31/2020 – Reviewed; Updated criteria to have preferred agent for Comm/Exch strategy

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