Mass General Brigham
Health Plan

Entyvio IV (vedolizumab)
Effective 08/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ 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		
Exceptions	N/A		

Overview
Entyvio (vedolizumab) intravenous (IV) injection is an integrin receptor antagonist indicated in adults for the treatment of:

- Moderately to severely active ulcerative colitis (UC)
- Moderately to severely active Crohn's disease (CD)

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance program
OR
Authorization may be granted if the member meets all the following diagnosis-specific criteria:

Moderately to severely active Ulcerative Colitis (UC)

1. Diagnosis of moderately to severely active ulcerative colitis (UC)
2. Member meets ONE of the following:
    a. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
        i. 6-mercaptopurine
        ii. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
        iii. Azathioprine
        iv. Corticosteroids (e.g., prednisone)
    b. Disease severity warrants a systemic biologic as first-line therapy

Moderately to severely active Crohn's Disease (CD)

1. Diagnosis of moderately to severely active Crohn's Disease (CD)
2. Member meets ONE of the following:

a. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
    i. 6-mercaptopurine
    ii. Azathioprine
    iii. Corticosteroids (e.g., prednisone)
    iv. Methotrexate
b. Disease severity warrants systemic biologic as first-line therapy

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition

Limitations

Initial approvals and reauthorizations will be granted for 24 months.

References

1. Entyvio (vedolizumab) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America Inc; April 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. Loftus EV Jr, Colombel JF, Feagan BG, et al. Long-term Efficacy of Vedolizumab for Ulcerative Colitis. J Crohns Colitis 2017; 11:400
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. 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.

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.
12/13/2023 – Reviewed and Updated for Dec P&T; Removed "must meet all initial criteria" for reauthorizations. Effective 1/1/2024
4/10/2024 – Reviewed and Updated for April P&T; Added new agent Entyvio SC to criteria. Added examples of disease progression. Removed Appendix. Added preferred agents. Effective 6/1/2024
09/11/2024 – Reviewed and updated for September P&T. Created separate policies for Entyvio IV and SC formulations. Removed biologic step through requirements for IV. Updated verbiage for Crohn's disease to

specify the condition is moderately to severely active. Updated policy to indicate that Entyvio IV is restricted to the medical benefit. Effective 10/1/2024.
10/09/2024 – Reviewed and updated at October P&T. Updated reauthorization criteria to require documentation supporting improvement in member's condition. Effective 1/1/2025.
05/14/2025 – Reviewed and updated at May P&T. Updated criteria for Crohn's disease and ulcerative colitis to remove disease characteristic requirement and allow for approval if disease severity warrants systemic biologic as first-line therapy. Effective 7/1/2025.
07/09/2025 – Reviewed and updated at July P&T. Updated approval length to 24 months. Effective 08/01/2025.