Mass General Brigham
Health Plan

Entyvio SC (vedolizumab)
Effective 12/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
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) subcutaneous (SC) 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 and documentation has been submitted:
Moderately to Severely active Ulcerative Colitis (UC)

1. The member has a diagnosis of moderately to severely active ulcerative colitis (UC)
2. ONE of the following:
    a. Greater than 6 stools per day
    b. Frequent blood in stools
    c. Frequent urgency
    d. Presence of ulcers
    e. Abnormal lab values (e.g., hemoglobin, ESR, CRP)
    f. Dependent on, or refractory to, corticosteroids
3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
    a. 6-mercaptopurine
    b. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
    c. Azathioprine
    d. Corticosteroids (e.g., prednisone)

4. ONE of the following:
    a. Entyvio subcutaneous formulation will be used as maintenance following at least two doses of Entyvio IV induction
    b. Member started therapy with at least two doses of Entyvio IV and is continuing treatment with the subcutaneous formulation
    c. Trial and failure, contraindication, or intolerance to TWO of the following:
        i. Humira, Hadlima, adalimumab-adaz, adalimumab-fjkp
        ii. Rinvoq
        iii. Simponi
        iv. Skyrizi
        v. Stelara
        vi. Xeljanz/XR

Crohn's Disease (CD)

1. The member has a diagnosis of moderately to severely active Crohn's Disease (CD)
2. ONE of the following:
    a. Frequent diarrhea and abdominal pain
    b. At least 10% weight loss
    c. Complications such as obstruction, fever, abdominal mass
    d. Abnormal lab values (e.g., C-reactive protein [CRP])
    e. CD Activity Index (CDAI) great than 220
    f. Fistulizing Crohn's disease
3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
    a. 6-mercaptopurine
    b. Azathioprine
    c. Corticosteroids (e.g., prednisone)
    d. Methotrexate
4. Member meets ONE of the following:
    a. Entyvio subcutaneous formulation will be used as maintenance following at least two doses of Entyvio IV induction
    b. Member started therapy with at least two doses of Entyvio IV and is continuing treatment with the subcutaneous formulation
    c. Trial and failure, contraindication, or intolerance to TWO of the following:
        i. Cimzia
        ii. Humira, Hadlima, adalimumab-adaz, adalimumab-fjkp
        iii. Rinvoq
        iv. Skyrizi
        v. Stelara

Continuation of Therapy

Reauthorization may be granted for members who achieve or maintain positive clinical response 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.

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. Added Skyrizi as a step through option for the treatment of ulcerative colitis. Applied Crohn's disease criteria to subcutaneous formulation. Updated verbiage for Crohn's disease to specify the condition is moderately to severely active. Added language regarding previous treatment with IV formulation. Effective 12/1/2024.