Mass General Brigham
Health Plan

Entyvio (vedolizumab)
Effective 06/01/2024

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 indicated for Adult Ulcerative Colitis (UC) and Adult Crohn's Disease (CD).
Entyvio (vedolizumab) intravenous (IV) is indicated for Adult Ulcerative Colitis (UC).

Coverage Guidelines

<u>Moderately to severely active Ulcerative Colitis (UC)</u>
Authorization may be granted for members new to the plan who are currently receiving treatment with Entyvio IV or SC, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR

Entyvio IV
Authorization may be granted for treatment of moderately to severely active UC when the following criteria are met:

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. Paid claims or submission of medication records confirming trial and failure, contraindication, or intolerance to TWO of the following:
    a. Humira, Hadlima, adalimumab-adaz, adalimumab-fjkp
    b. Rinvoq
    c. Simponi
    d. Stelara
    e. Xeljanz/XR

Entyvio SC

1. The member has a diagnosis of moderately to severely active ulcerative colitis (UC)
2. ONE of the following:
    a. Medication will be used as maintenance dose following Entyvio IV induction
    b. Member is currently established on Entyvio IV

Moderately to severely active Crohn's Disease (CD)

Authorization may be granted for members who are currently receiving treatment Entyvio IV, 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 a diagnosis of 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. Paid claims or submission of medication records confirming trial and failure, contraindication, or intolerance to TWO of the following:
    a. Cimzia
    b. Humira, Hadlima, adalimumab-adaz, adalimumab-fjkp
    c. Rinvoq
    d. Skyrizi
    e. 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; 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.
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