Mass General Brigham
Health Plan

Entyvio SC (vedolizumab)
Effective 01/01/2026

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 Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 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:

<u>Moderately to Severely active Ulcerative Colitis (UC)</u>

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
3. 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 (Abbvie), Hadlima, Simlandi, Yuflyma
        ii. Omvoh

iii. Rinvoq
iv. Simponi
v. Skyrizi
vi. Selarsdi, Steqeyma, Yesintek
vii. Tremfya
viii. Xeljanz/XR
ix. Velsipity

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
3. 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 (Abbvie), Hadlima, Simlandi, Yuflyma
        iii. Omvoh
        iv. Rinvoq
        v. Skyrizi
        vi. Selarsdi, Steqeyma, Yesintek
        vii. Tremfya

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

1. Initial approvals and reauthorizations will be granted for 12 months.
2. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limit
Entyvio SC pen	2 pens per 28 days

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.
10/09/2024 – Reviewed and updated at October P&T. Added Amjevita (Nuvaila) as a preferred adalimumab formulation. Updated criteria for ulcerative colitis to include Omvoh, Tremfya, and Wezlana as biologic step options. Updated Crohn's disease criteria to include Wezlana as a biologic step option. 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. Added Omvoh and Tremfya as biologic step options for Crohn's disease. Effective 07/01/2025.
06/11/2025 – Reviewed and updated at June P&T. Added Velsipity as a previous trial option for ulcerative colitis. Added quantity limit to policy. Effective 09/01/2025.
09/10/2025 – Reviewed and updated for September P&T. Added Yesintek as an Ustekinumab trial option. Effective 10/15/2025.
10/08/2025 - Reviewed and updated at October P&T. Updated policy to reflect that Selarsdi, Steqeyma and Yesintek are the preferred Ustekinumab trial options. Updated preferred adalimumab products to Humira, Hadlima, Simlandi and Yuflyma. Effective 01/01/2026.