Mass General Brigham
Health Plan

Entyvio SC (vedolizumab)
Effective 01/01/2027

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	Entyvio IV is restricted to the medical benefit		

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
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted if the member meets all of 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. 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. Adalimumab-aaty, adalimumab-adaz, or Hadlima
        ii. Omvoh
        iii. Rinvoq
        iv. Simponi
        v. Skyrizi
        vi. Selarsdi, Steqeyma, or Yesintek
        vii. Tremfya
        viii. Velsipity

Crohn's Disease (CD)

1. Diagnosis of moderately to severely active Crohn's Disease (CD)
2. 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. Adalimumab-aaty, adalimumab-adaz, or Hadlima
        iii. Omvoh
        iv. Rinvoq
        v. Skyrizi
        vi. Selarsdi, Steqeyma, or Yesintek
        vii. Tremfya

Continuation of Therapy

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

1. Submission of medical records (e.g. chart notes) documenting an improvement in the 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 24 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.
02/11/2026 – Reviewed and updated at February P&T. Updated approval length. Effective 05/01/2026.
03/11/2026 – Reviewed and updated for March P&T. Administrative update - changing verbiage in reauthorization criteria from “documentation is submitted” to “submission of medical records (e.g., chart notes…” and updating language for members who are new to the Plan. Effective 05/01/2026.
04/15/2026 – Reviewed and updated at April P&T. Updating previous trial language for ulcerative colitis and Crohn's disease to allow for bypassing conventional therapy if member has severe disease that warrants a biologic or targeted synthetic therapy as first-line therapy. Effective 08/16/2026.
07/15/2025 – Reviewed and updated at July P&T. Removed conventional therapy step requirements from initial criteria for ulcerative colitis and Crohn’s disease. Effective 08/16/2026.
09/09/2026 – Reviewed and updated at September P&T. Updating preferred adalimumab products throughout policy. Effective 01/01/2027.
10/14/2026 – Reviewed and updated at October P&T. Removing Xeljanz/tofacitinib as a previous trial option. Effective 01/01/2027.