Pharmacy Policy

Entyvio

Policy Number: 9.120
Version Number: 2.0
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Entyvio (vedolizumab)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Use of Entyvio in combination with a tumor necrosis factor antagonist or Tysarbi (natalizumab)
Required Medical Information	Diagnosis of one of the following: Crohn's disease (CD) that is moderately to severely active; ***AND*** 1. One of the following: a. An inadequate response or adverse reaction to at least a 3 consecutive

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	month trial of ONE of the following or an contraindication to them **ALL**: i. 6-mercaptopurine ii. azathioprine iii. methotrexate **OR** b. An inadequate response, or adverse reaction to at least a 3 month trial of one biologic DMARD that is FDA-approved for CD; ***AND*** 2. An inadequate response or adverse reaction to at least a consecutive 3 month trial of Humira or a contraindication to Humira. Ulcerative colitis (UC) that is moderately to severely active; ***AND*** 1. One of the following: a. An inadequate response, contraindication or intolerance to at least a 3 month consecutive trial of TWO of the following or a contraindication to them ALL: i. 5-aminosalicylic acid (e.g. mesalamine) ii. 6-mercaptopurine, azathioprine, and/or methotrexate iii. corticosteroids; **OR** b. An inadequate response, or adverse reaction to at least a 3 month trial of one biologic DMARD that is FDA-approved for UC; ***AND*** 2. An inadequate response or adverse reaction to at least a consecutive 3 month trial of Humira or a contraindication to Humira.
Age Restrictions	18 years of age or older
Prescriber Restriction	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Quantity Limit	300mg vial – 3 vials for the first 6 weeks, then 1 vial every 8 weeks thereafter
Other criteria	Reauthorization: 1. Member has previously met initial criteria. **AND** 2. Clinical condition has improved or stabilized

Applicable Coding:

Code	Medication
J3380	Entyvio® (vedolizumab injection)

Clinical Background Information and References

1. Baumgart DC and Sandborn WJ. Inflammatory bowel disease: clinical aspects and established and evolving therapies. Lancet. 2007; 369:1641-57.
2. Beattie RM, Croft NM, Fell JM et al. Inflammatory bowel disease. Arch Dis Child. 2006; 91:426-32.
3. Carter MJ, Lobo AJ, Travis SP et al. Guidelines for the management of inflammatory bowel disease in adults. Gut. 2004; 53(Suppl 5):V1-16.
4. Chan J. The pharmacologic management of Crohn's disease. Formulary. 2008; 43:93-104.
5. Cummings RJF, Keshav S, Travis SPL. Medical management of Crohn's disease. BMJ. 2008; 336:1063-6.
6. Entyvio prescribing information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; Accessed July 2021.
7. Feagan BG, Rutgeerts P, Sands BE et al. Vedolizumab as induction and maintenance therapy for ulcerative colitis. N Engl J Med. 2013; 369(8):699-710.
8. Ford AC, Sandborn WJ, Khan KJ et al. Efficacy of biological therapies in inflammatory bowel disease: systematic review and meta-analysis. Am J Gastroenterol. 2011; 106:644-659.
9. Hanauer SB. Inflammatory bowel disease: epidemiology, pathogenesis, and therapeutic opportunities. Inflamm Bowel Dis. 2006; 12(Suppl 1):S3-S9.
10. Humira prescribing information. North Chicago, IL: AbbVie Inc.; 2016 June. 2324444 3 Pharmacy Medical Necessity Guidelines: Entyvio® (vedolizumab)
11. Kornbluth A, Sachar DB. Erratum: ulcerative colitis practice guidelines in adults: American College of Gastroenterology, practice parameters committee. Am J Gastroenterol. 2010; 105:501-523.
12. Langan RC, Gotsch PB, Krafczyk MA et al. Ulcerative colitis: diagnosis and treatment. Am Fam Physician. 2007; 76:1323-30.
13. Lichtenstein GR, Hanauer SB, Sandborn WJ et al. Management of Crohn's disease in adults. Am J Gastroenterol. 2009; 10.1038/ajg.2008.168.
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Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
6/12/2018	Moved from Policy 9.126 Systemic Immunomodulators	11/01/2018	P&T Committee
05/09/2019	P&T annual review. Criteria for UC: changed non biologic DMARDs requirement of cyclosporine to MTX	09/02/2019	P&T Committee and NH DHHS
6/11/2020	P&T Annual Review, No changes required	10/1/2020	P&T Committee
12/1/2020	9.183 Entyvio Policy retired, new policy created. Removed adherence from policy	1/1/2021	P&T Committee
8/12/2021	P&T Annual Review: Update to CD and UC criteria to align with current guidelines; addition of time requirement for required trial drugs; addition of meeting initial criteria to reauthorization criteria.	1/1/2022	P&T Committee

Next Review Date

8/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government

agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.