Pharmacy Policy

Entyvio

Policy Number: 9.120
Revision Number: R0
Version Effective Date: 1/1/2021

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: 1. A diagnosis of Crohn's disease (CD) that is moderately to severely active; ***AND*** a. An inadequate response, contraindication or intolerance to use of **two** of the following: i. 5-aminosalicylic acid (e.g. mesalamine) ii. 6-mercaptopurine or azathioprine iii. methotrexate

[+] *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.

	iv. corticosteroids; ***AND*** b. An inadequate response, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira 2. A diagnosis ulcerative colitis (UC) that is moderately to severely active; ***AND*** a. An inadequate response, contraindication or intolerance to use of **two** of the following: i. 5-aminosalicylic acid (e.g. mesalamine) ii. 6-mercaptopurine, azathioprine, and/or methotrexate iii. corticosteroids; ***AND*** b. An inadequate response, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of 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
Other criteria	Reauthorization: 1. 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.; 2014 May.
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.
14. Sandborn WJ, Feagan BG, Rutgeerts P et al. Vedolizumab as induction and maintenance therapy for Crohn's disease. N Engl J Med. 2013; 369(8):711-21.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.183 Entyvio Policy retired, new policy created. Removed adherence from policy, updated to reflect NH PDL	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

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.