Pharmacy Medical Necessity Guidelines: Entyvio® (vedolizumab)

Effective: January 1, 2018

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MB/ RX	Department to Review	MM

This Pharmacy Medical Necessity Guideline applies to the following: **Tufts Health Plan Commercial Plans** ☐ Tufts Health Plan Commercial Plans – large group plans ☐ Tufts Health Plan Commercial Plans – small group and individual plans **Tufts Health Public Plans** ☐ Tufts Health Direct – Health Connector ☒ Tufts Health Together – A MassHealth Plan ☐ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan **Tufts Health Freedom Plan products** ☐ Tufts Health Freedom Plan - large group plans ☐ Tufts Health Freedom Plan - small group plans	**Fax Numbers:** MM: 888.415.9055

OVERVIEW

FDA-APPROVED INDICATIONS

Adult Crohn's Disease

Entyvio (vedolizumab) is indicated for achieving clinical response, achieving clinical remission, and achieving corticosteroid-free remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

Adult Ulcerative Colitis

Entyvio (vedolizumab) is indicated for inducing and maintaining clinical response, inducing and maintaining clinical remission, improving the endoscopic appearance of the mucosa, and achieving corticosteroid-free remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

COVERAGE GUIDELINES

The plan may authorize coverage of Entyvio (vedolizumab) for Members when the following criteria are met:

Crohn's Disease

1. The Member has a documented diagnosis of moderately to severely active Crohn's disease by a gastroenterologist

AND

2. The Member is 18 years of age or older

AND

3. The Member has demonstrated an inadequate response, loss of response or inability to tolerate an appropriate trial with two or more of the following agents:
   a) Corticosteroids (e.g., prednisone, prednisolone, methylprednisolone).
   b) 5-Aminosalicylates (e.g., balsalazide disodium, sulfasalazine, Azulfidine, Apriso, Delzicol, Pentasa, Rowasa, Dipentum, Colazal).
   c) 6-mercaptopurine (6-MP, Purinethol) and/or azathioprine (Imuran).
   d) Methotrexate (MTX)

AND

4. The Member has a documented inadequate response, loss of response or inability to tolerate Humira

Ulcerative Colitis

1. The Member has a documented diagnosis of moderately to severely active ulcerative colitis by a gastroenterologist

AND

2. The Member is 18 years of age or older

AND

3. The Member has demonstrated an inadequate response, loss of response or inability to tolerate an appropriate trial with two or more of the following agents:
   a) Corticosteroids (e.g., prednisone, prednisolone, methylprednisolone)
   b) 5-Aminosalicylates (e.g., balsalazide disodium, sulfasalazine, Azulfidine, Apriso, Delzicol, Pentasa, Rowasa, Dipentum, Colazal)
   c) 6-mercaptopurine (6-MP, Purinethol) and/or azathioprine (Imuran)
   d) Methotrexate (MTX)

AND

4. The Member has a documented inadequate response, loss of response or inability to tolerate Humira

Note: Coverage decisions for conditions other than those outlined above will be made on a case-by-case basis.

LIMITATIONS

1. Samples, free goods or similar offerings of Entyvio (vedolizumab) do not qualify for an established clinical response and will not be considered for prior authorization.
2. Entyvio (vedolizumab) will not be approved if administered concomitantly with a tumor necrosis factor antagonist or Tysabri (natalizumab).
3. Members new to the plan and stable on Entyvio (vedolizumab) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., balsalazide, methotrexate, prednisone).
4. Initial authorization will be limited to 6 months. Subsequent authorization may be given in 12-month intervals based on submission of current progress notes from the physician documenting clinical efficacy of Entyvio (vedolizumab) indicating disease stability or improvement.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J3380	Injection, vedolizumab, 1 mg

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. Crohn's & Colitis Foundation of America. What are Crohn's & Colitis? URL: ccfa.org/what-are-crohns-and-colitis. Available from Internet. Accessed 2014 September 12.
6. Cummings RJF, Keshav S, Travis SPL. Medical management of Crohn's disease. *BMJ*. 2008; 336:1063-6.
7. Entyvio prescribing information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; 2014 May.
8. 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.
9. Food and Drug Administration. Drugs@FDA. URL: accessdata.fda.gov/scripts/cder/drugsatfda. Available from Internet. Accessed 2014 September 12.
10. 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.
11. Hanauer SB. Inflammatory bowel disease: epidemiology, pathogenesis, and therapeutic opportunities. *Inflamm Bowel Dis*. 2006; 12(Suppl 1):S3-S9.
12. Humira prescribing information. North Chicago, IL: AbbVie Inc.; 2016 June.

13. 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.
14. Langan RC, Gotsch PB, Krafczyk MA et al. Ulcerative colitis: diagnosis and treatment. *Am Fam Physician*. 2007; 76:1323-30.
15. Lichtenstein GR, Hanauer SB, Sandborn WJ et al. Management of Crohn's disease in adults. *Am J Gastroenterol*. 2009; 10.1038/ajg.2008.168.
16. 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.

APPROVAL HISTORY

October 7, 2007: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- October 6, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: Added exception language for Members new to the plan and stable on Entyvio prior to enrollment.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- July 11, 2017: Administrative update to add the following Limitation: Samples, free goods or similar offerings of Entyvio (vedolizumab) do not qualify for an established clinical response and will not be considered for prior authorization.
- December 12, 2017: Effective January 1, 2018, removed criteria allowing members new to the plan stable on Entyvio (vedolizumab) to be authorized due to new state requirements. Added the following limitation: Members new to the plan and stable on Entyvio (vedolizumab) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., balsalazide, methotrexate, prednisone).

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.