CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Entyvio (vedolizumab)
BILLING CODE	J3380 (1 unit = 1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product for Crohn's Disease includes Cimzia; for Ulcerative Colitis - Xeljanz QUANTITY LIMIT— 300 units/mg per infusion
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Entyvio (vedolizumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CROHN'S DISEASE (CD)

For **initial** authorization:

1. Member is 18 years of age or older with moderately to severely active CD; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has had a documented trial and inadequate response, or intolerance to at least **one** of the following conventional therapies: a 4-week trial of a corticosteroid OR a 12-week trial of 6-mercaptopurine, azathioprine, or methotrexate. Note: Trial is not required if member is switching from another biologic agent; AND
4. Member has tried and failed at least 12 weeks of an anti-TNF agent (e.g., Cimzia, Humira, or Remicade), unless not tolerated or contraindicated.
5. **Dosage allowed:** 300 mg IV infusion at 0, 2, and 6 weeks, and every 8 weeks thereafter.

Note: Therapy should be discontinued in members who show no evidence of therapeutic benefit by week 14.

If member meets all the requirements listed above, the medication will be approved for 4 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms of CD (defined as mucosal healing, fewer flare-ups of symptoms, improved quality of life, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

ULCERATIVE COLITIS (UC)

For **initial** authorization:

1. Member is 18 years of age or older with moderately to severely active UC; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member must have a documented trial and inadequate response with **one** of the following:
   a) 3 months of 6-mercaptopurine or azathioprine;
   b) 30 days of Corticosteroid (e.g., budesonide, prednisone, methylprednisolone, etc.);
   c) 3 months of 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.).
4. **Dosage allowed:** 300 mg intravenously at 0, 2, and 6 weeks, then 300 mg intravenously every 8 weeks thereafter.

Note: Therapy should be discontinued in patients who show no evidence of therapeutic benefit by week 14.

If member meets all the requirements listed above, the medication will be approved for 4 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms of UC (defined as clinical remission, decrease in rectal bleeding, decreased corticosteroid use, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Entyvio (vedolizumab) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/08/2017	New policy for Entyvio created. Policy SRx-0041 archived. For both diagnoses CD and UC: TNF inhibitor Humira was listed as required trial. List of diagnoses considered not medically necessary was added.
02/26/2019	Humira removed from required trials. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Initial authorization length increased to 12 months. Inadequate response to trial agents combined under member's history; CDAI and Mayo scoring requirement added; severity factors for CD removed from requirements.
11/23/2020	Replaced list of excluded diagnoses with the generic statement. Updated references. Removed TB requirements (not necessary for this drug). CD: Removed CDAI score requirement. Specified length of trials for conventional therapies, previously not specified. Added a trial of TNF inhibitor in accordance with guidelines. Reduced initial auth approval to 4 months (must discontinue if no benefit observed after 14 weeks). UC: Removed Mayo score and endoscopy subscore requirements. Specified length of trials for conventional therapies. Reduced initial auth approval to 4 months (must discontinue if no benefit observed after 14 weeks).

References:

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; March 2020.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2019;114(3):384-413.
3. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology*. 2020;158(5):1450-1461.

4. Feagan, BG, Rutgeerts, P, Sands, BE, et al. Vedolizumab as induction and maintenance therapy for ulcerative colitis. *N Engl J Med* 2013; 369:699-710.
5. Sands, BE, Feagan, BG, Rutgeerts, P, et al. Effects of Vedolizumab Induction Therapy for Patients With Crohn's Disease in Whom Tumor Necrosis Factor Antagonist Treatment Had Failed. *Gastroenterology*. 2014 May 21.
6. 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.
7. Sulz MC, Burri E, Michetti P, et al. Treatment Algorithms for Crohn's Disease. *Digestion*. 2020;101 Suppl 1:43-57.
8. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2018;113(4):481-517.
9. Torres J, Bonovas S, Doherty G, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. *J Crohns Colitis*. 2020;14(1):4-22.
10. Pimentel AM, Rocha R, Santana GO. Crohn's disease of esophagus, stomach and duodenum. *World J Gastrointest Pharmacol Ther*. 2019;10(2):35-49.
11. Terdiman JP, Gruss CB, Heidelbaugh JJ, Sultan S, Falck-Ytter YT; AGA Institute Clinical Practice and Quality Management Committee. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. *Gastroenterology*. 2013;145(6):1459-1463.
12. Regueiro M, Velayos F, Greer JB, et al. American Gastroenterological Association Institute Technical Review on the Management of Crohn's Disease After Surgical Resection. *Gastroenterology*. 2017;152(1):277-295.e3.

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