PHARMACY POLICY STATEMENT **Indiana Medicaid**	
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 products includes Humira 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 moderate to severe active CD with demonstrated corticosteroid dependence; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a gastroenterologist; AND
4. Member has documented trial and failure of or contraindication to Humira. Treatment failure requires at least 12 weeks of therapy without an adequate response; AND
5. Member has had a documented inadequate response to 6-mercaptopurine, azathioprine or methotrexate; OR
6. Member has severe esophageal or gastroduodenal disease; OR
7. Member has extensive small-bowel disease involving more than 100 cm; OR
8. Member has a history of colonic resection; OR
9. Member has a history of two or more small bowel resections; OR
10. Member has perianal or rectal disease.
11. **Dosage allowed:** 300 mg intravenously at 0, 2, and 6 weeks, then 300 mg intravenously every 8 weeks thereafter.

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

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease; AND
4. Therapy should be discontinued in patients who show no evidence of therapeutic benefit by week 14.

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 moderate to severe active UC with demonstrated corticosteroid dependence; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a gastroenterologist; AND
4. Member has documented trial and failure of or contraindication to Humira. Treatment failure requires at least 12 weeks of therapy without an adequate response; AND
5. Member was hospitalized with fulminant ulcerative colitis (i.e. severe UC with distension, and acute, severe toxic symptoms including fever and anoxia); OR
6. Member was hospitalized and after three days of IV steroids still has a C-reactive protein (CRP) greater than 45 or more than 8 bloody bowel movements; OR
7. Member has moderate to severe active UC and meets ALL of the 3 following criteria:
   a) Member is refractory to or requires continuous immunosuppression with corticosteroids (i.e. methylprednisolone, prednisone) at a dose of 40-60 mg/day of prednisone (or equivalent); AND
   b) Member is refractory to or has a contraindication to 5-aminosalicylic acid agents (i.e. balsalazide (Colazal), mesalamine (Asacol), sulfasalazine); AND
   c) Member is refractory to or has a contraindication to immunosuppresssants (azathioprine and 6-mercaptopurine).
8. **Dosage allowed:** 300 mg intravenously at 0, 2, and 6 weeks, then 300 mg intravenously every 8 weeks thereafter.

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

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease; AND
4. Therapy should be discontinued in patients who show no evidence of therapeutic benefit by week 14.

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 following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Ankylosing Spondylitis
- Asthma
- Cellulitis
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e. Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Guttate psoriasis
- Infectious uveitis
- Lupus perino
- Osteoarthritis

- Plaque Psoriasis
- Psoriatic Arthritis
- Relapsing polychondritis
- Rheumatoid Arthritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu's arteritis
- Vogt-Koyanagi

DATE	ACTION/DESCRIPTION
05/12/2017	New policy for Entyvio created. For both diagnosis CD and UC: TNF inhibitor Humira is listed as required trial. List of diagnoses considered not medically necessary added.

References:

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2014.
2. Feagan, BG, Rutgeerts, P, Sands, BE, et al. Vedolizumab as induction and maintenance therapy for ulcerative colitis. The New England journal of medicine. 2013 Aug 22;369(8):699-710. PMID: 23964932.
3. 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. PMID: 24859203.
4. Sandborn, WJ, Feagan, BG, Rutgeerts, P, et al. Vedolizumab as induction and maintenance therapy for Crohn's disease. The New England journal of medicine. 2013 Aug 22;369(8):711-21. PMID: 23964933.
5. 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 Dec;145(6):1459-63.
6. MCG, 20th edition, 2016.
7. Sandborn, W., Binion, D., Persley, K., Atreja, A., & Kosinski, L. (2014). AGA Institute Guidelines for the Identification, Assessment and Initial Medical Treatment in Crohn's Disease: Clinical Decision Support Tool. AGA Institute. Retrieved August 14, 2015, from www.gastro.org/IBDcarepathway.

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