CareSource

| PHARMACY POLICY STATEMENT<br>**Ohio 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)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 Crohn's Disease Activity Index (CDAI) of 220-450; AND
2. Member have had a documented history of an inadequate response with, lost response to, or were intolerant to **one** of the following:
   a) A tumor necrosis factor (TNF) blocker (e.g., Enbrel, Humira, etc.);
   b) Immunomodulator (e.g., 6-mercaptopurine, azathioprine);
   c) Corticosteroids (or demonstrated dependence on corticosteroids); AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Medication must be prescribed by a gastroenterologist.
5. **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 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 12 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.

***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 as defined by Mayo score of 6 or greater with an endoscopy subscore of 2 or 3; AND
2. Member have had a documented history of an inadequate response with, lost response to, or were intolerant to **one** of the following:
   a) A tumor necrosis factor (TNF) blocker (e.g., Enbrel, Humira, etc.);
   b) Immunomodulator (e.g., 6-mercaptopurine, azathioprine);
   c) Corticosteroids (or demonstrated dependence on corticosteroids);
   d) Salicylates (e.g., Apriso, balsalazide, mesalamine DR, Pentasa, sulfasalazine, etc.); AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Medication must be prescribed by a gastroenterologist.
5. **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 12 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.

***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., Humira, Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- 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 |
|---|---|
| **05/08/2017** | 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. |
| **01/19/2020** | Updated alternative preferred products and trial agents to match Ohio Department of Medicaid Unified Preferred Drug List. |

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. 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.


Effective date: 01/01/2020
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