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| PHARMACY POLICY STATEMENT<br>**Kentucky 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)<br>Alternative preferred product for Crohn's Disease includes Cimzia; for Ulcerative Colitis - Xeljanz<br>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., Remicade, Cimzia, 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.***

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## 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., Remicade, Cimzia, etc.);
   b) Immunomodulator (e.g., 6-mercaptopurine, azathioprine);
   c) Corticosteroids (or demonstrated dependence on corticosteroids);
   d) Salicylates (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, 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 |
|---|---|
| **05/15/2017** | New policy for Entyvio created. Policy SRx-0041 archived. For both diagnoses CD and UC: TNF inhibitor Humira was listed as required trial. Trials length changed to 30 days for each drug trial due to KY MCD regulations 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. |

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: 04/01/2019
Revised date: 02/26/2019