### PHARMACY POLICY STATEMENT

**Ohio Medicaid**

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Entyvio (vedolizumab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>J3380 (1 unit = 1 mg)</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Office/Outpatient Hospital</td>
</tr>
<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Product)</td>
</tr>
<tr>
<td>QUANTITY LIMIT</td>
<td>300 units/mg per infusion</td>
</tr>
<tr>
<td>LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY</td>
<td><a href="#">Click Here</a></td>
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**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

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>05/08/2017</td>
<td>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.</td>
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References:

Effective date: 05/08/2017
Revised date: 05/08/2017