Effective Date 2/8/2018

Entvyio™ (vedolizumab)

FDA approval: May 20, 2014
HCPCS:J3380
Benefit: Medical

I. Coverage Criteria:

Note: Request must be supported by submission of chart notes and patient specific documentation.

Coverage of the requested drug is provided in patient’s ≥ 18 years of age and A OR B criteria are met:

A. Diagnosis of moderately to severely active ulcerative colitis AND all the following:
   1. Medication is prescribed by, or in consultation with a gastroenterologist
   2. Conventional therapy (some examples: corticosteroids, immunomodulator) has been ineffective, contraindicated or not tolerated based on clinical documentation
   3. Inadequate response to Humira and Remicade

   OR

B. Diagnosis of moderately to severely active Crohn’s Disease AND all the following:
   1. Medication is prescribed by, or in consultation with a gastroenterologist
   2. Conventional therapy (examples: corticosteroids, immunomodulator) has been ineffective, contraindicated or not tolerated based on clinical documentation
   3. Inadequate response to Humira and Remicade

C. Quantity Limitations, Authorization Period and Renewal Criteria
   1. Quantity Limit: Limited to label dosing
   2. Initial Authorization Period: 6 months
   3. Renewal Criteria (achieves one of the following):
      • achieves clinical response to symptoms
      • achieves remission
   4. Renewal Authorization Period: 1 year

D. Entvyio is considered investigational when used for all other conditions, including but not limited to:
   1. Multiple Sclerosis
   2. Used concomitantly with TNF blockers

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***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia

Therapeutic considerations:

A. FDA approved indication/Diagnosis

1. Adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:
   - inducing and maintaining clinical response
   - inducing and maintaining clinical remission
   - improving endoscopic appearance of the mucosa
   - achieving corticosteroid-free remission

2. Adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:
   - achieving clinical response
   - achieving remission
   - achieving corticosteroid-free remission

B. Background Information

- Vedolizumab is a new molecular entity and a humanized monoclonal antibody indicated for adult patients with moderately to severely active Ulcerative Colitis (UC) or Crohn’s Disease (CD) who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.
- Inflammatory bowel disease is primarily made up of UC and CD. It is estimated to affect 396/100,000 person’s worldwide. It is estimated in the United States that 1.4 million persons may suffer from IBD.
- Vedolizumab is the second integrin receptor antagonist approved for Crohn’s disease. The first integrin inhibitor, natalizumab (Tysabri), was approved for CD in 2008.
- Other treatment options for UC may include oral and topical corticosteroids, oral and topical aminosalicylates, disease modifying anti-rheumatic drugs, anti-TNF therapies adalimumab (Humira), golimumab (Simponi) and infliximab (Remicade).
- Other treatment options for CD include oral mesalamine, disease modifying anti-rheumatic drugs, metronidazole, oral corticosteroids, anti-TNF therapies infliximab (Remicade), Adalimumab (Humira) and certolizumab pegol (Cimzia) and non-TNF therapy natalizumab (Tysabri).
- Vedolizumab may offer an advantage in convenience compared to natalizumab (Tysabri) due to it being administered less often.
- There is no data to support that vedolizumab is more efficacious compared to other therapies (example: biologics) for the treatment of CD or UC.

C. Efficacy

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D. Medication Safety Considerations

Black Box Warnings: No

*Please refer to most recent prescribing information.

E. Dosing and administration

a. Recommended dosage in UC and CD: 300 mg infused intravenously over approximately 30 minutes at zero, two and six weeks, then every eight weeks thereafter.

*Please refer to most recent prescribing information.

F. How supplied

- Sterile 20 mL single-use glass vials, containing 300 mg of vedolizumab

References:

2. © June 2014 OmedaRx Preview RX vedolizumab (Entyvio).

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*The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or [http://dailymed.nlm.nih.gov/dailymed/index.cfm](http://dailymed.nlm.nih.gov/dailymed/index.cfm)*