Clinical Policy: Vedolizumab (Entyvio)
Reference Number: ERX.SPMN.153
Effective Date: 10/2016
Last Review Date: 12/2016

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that vedolizumab (Entyvio®) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Ulcerative Colitis (must meet all):
      1. Prescribed by or in consultation with a gastroenterologist;
      2. Age ≥ 18 years;
      3. Diagnosis of moderately to severely active ulcerative colitis (UC);
      4. Member has failed one of the following therapies unless intolerant or contraindicated:
         a. A biologic for UC other than Entyvio;
         b. An immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) for ≥ 3 consecutive months;
      5. Member has failed Humira AND one other TNF-α inhibitor (i.e., Cimzia, Remicade), each trialed for ≥ 3 consecutive months, unless intolerant or contraindicated;
      6. After initial dosage regimen, prescribed maintenance dose does not exceed the 300 mg every 8 weeks.

   Approval duration: 6 months

   B. Crohn’s Disease (must meet all):
      1. Prescribed by or in consultation with a gastroenterologist;
      2. Age ≥ 18 years;
      3. Diagnosis of moderately to severely active Crohn’s disease (CD) and (a or b):
         a. Has one of the following poor prognostic indicators for CD:
            i. Age < 18 years;
            ii. Perianal disease;
            iii. Upper gastrointestinal tract involvement;
            iv. Multiple extra-intestinal manifestations;
            v. Active tobacco use;
            vi. Perforating (i.e., fistulizing) disease;
         b. Member has failed one of the following therapies unless intolerant or contraindicated:
            i. A biologic for CD other than Entyvio;
            ii. An immunomodulator (e.g., azathioprine, 6-MP, MTX) for ≥ 3 consecutive months;
      4. Member has failed Humira AND one other TNF-α inhibitor (i.e., Cimzia, Remicade), each trialed for ≥ 3 consecutive months, unless intolerant or contraindicated;
5. After initial dosage regimen, prescribed maintenance dose does not exceed the 300 mg every 8 weeks.

**Approval duration: 6 months**

C. **Other diagnoses/indications:** Refer to ERX.SPMN.16 - Global Biopharm Policy.

II. **Continued Approval**
A. **Crohn’s Disease and Ulcerative Colitis** (must meet all):
   1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
   2. Member is responding positively to therapy;
   3. Prescribed regimen does not exceed 300 mg every 8 weeks.

**Approval duration: 12 months**

B. **Other diagnoses/indications** (must meet 1 or 2):
   1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
   2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

**Background**

**Description/Mechanism of Action:**
Vedolizumab, an integrin receptor antagonist, is a humanized IgG1 monoclonal antibody produced in Chinese hamster ovary cells that binds to the human α4β7 integrin and blocks the interaction of α4β7 integrin with mucosal addressin cell adhesion molecule-1 (MAdCAM-1) and inhibits the migration of memory T-lymphocytes across the endothelium into inflamed gastrointestinal parenchymal tissue. The interaction of the α4β7 integrin with MAdCAM-1 has been implicated as an important contributor to the chronic inflammation that is a hallmark of ulcerative colitis and Crohn’s disease.

**Formulations:**
Entyvio is available for injection as a 300 mg of lyophilized vedolizumab in a single-use 20 mL vial.

**FDA Approved Indications:**
Entyvio is an integrin receptor antagonist/intravenous injectable formulation indicated for:
- Adult ulcerative colitis
  Adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a 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 the endoscopic appearance of the mucosa, and
    - Achieving corticosteroid-free remission.
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- Adult Crohn’s disease
  Adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.
  - Achieving clinical response,
  - Achieving clinical remission, and
  - Achieving corticosteroid-free remission.

Appendices
Appendix A: Abbreviation Key
6-MP: 6-mercaptopurine
CD: Crohn’s disease
MAdCAM-1: mucosal addressin cell adhesion molecule-1
TNF: tumor necrosis factor
UC: ulcerative colitis

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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Reviews, Revisions, and Approvals

<table>
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Policy split from USS.SPMN.24 Irritable Bowel Disease (IBD) Treatments and converted to new template. Removed safety criteria. Added dosing per PI. Modified approval duration to 6 months for initial and 12 months for re-auth.
CD/UC: Removed criteria related to concomitant use with other biologics. Added requirement for trial and failure of PDL Humira as one of the two required TNF inhibitors, unless contraindicated.
CD: Modified criteria requiring failure of immunomodulator, corticosteroids or aminosalicylate to failure of “corticosteroid, with or without immunomodulator” per 2014 AGA Clinical decision tool.
For all trial/failure requirements, indicated that member can also meet criteria if intolerant (as opposed to just contraindicated) to therapy in question. Modified the following initial criteria sets:
-UC: removed option for trial/failure of corticosteroid and aminosalicylate.
-CD: added poor prognostic indicators as alternative to trial/failure requirement. Modified trial/failure requirement to indicate an
immunomodulator (as opposed to a corticosteroid with or without an immunomodulator) must be trialed.

References
1. Entyvio Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America Inc.; May 2014. Available at www.entyviohcp.com

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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