Clinical Policy: Vedolizumab (Entyvio)

Reference Number: CP.PHAR.265
Effective Date: 07/16
Last Review Date: 07/17

Coding Implications
Revision Log

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

Description

Vedolizumab (Entyvio®), 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.

FDA approved indication

Entyvio is indicated for the treatment of:

- 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.
- 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.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Entyvio is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ulcerative Colitis (must meet all)**:**

1. Diagnosis of ulcerative colitis (UC);
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;

4. Failure of a thiopurine (e.g., azathioprine, 6MP), used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of adalimumab *(Humira is preferred)* AND one other TNF α inhibitor indicated for UC (i.e., infliximab), each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for adalimumab and all TNFα inhibitors*
6. Dose does not exceed the following:
   a. Initial: 300 mg at weeks 0, 2, and 6
   b. Maintenance: 300 mg every 8 weeks.

Approval duration: 6 months

B. Crohn's Disease (must meet all)**:**

1. Diagnosis of Crohn's disease (CD) and (a or b):
   a. Member is identified as moderate/high risk based on one of the following:
      i. Age at initial diagnosis < 30 years;
      ii. Extensive anatomic involvement (e.g., ileocecal disease, continuous ileocolonic disease, small bowel disease);
      iii. Perianal and/or severe rectal disease;
      iv. Deep ulcers;
      v. Prior surgical resection;
      vi. Stricturing and/or penetrating behavior;
   b. Failure of an immunomodulator (e.g., azathioprine, 6MP, MTX), used for ≥ 3 months unless contraindicated or clinically significant adverse effects are experienced;
2. Failure of adalimumab (*Humira is preferred)* AND one other TNF α inhibitor (i.e.,infliximab, Cimzia) each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for adalimumab and all TNFα inhibitors*
3. Prescribed by or in consultation with a gastroenterologist;
4. Age ≥ 18 years;
5. Dose does not exceed the following:
   a. Initial: 300 mg at weeks 0, 2, and 6
   b. Maintenance: 300 mg every 8 weeks.

Approval duration: 6 months

C. Other diagnoses/indications: Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose 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 Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PHAR.57 - Global Biopharm Policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 - Global Biopharm Policy or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

6-MP: 6-mercaptopurine
CD: Crohn's disease
MAdCAM-1: mucosal addressin cell adhesion molecule-1
TNF: tumor necrosis factor
UC: ulcerative colitis

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CD/UC	Initial: 300 mg IV at weeks 0, 2, and 6. Maintenance: 300 mg IV every 8 weeks.	Maintenance: 300 mg every 8 weeks

VI. Product Availability

Drug	Availability
Vedolizumab (Entyvio)	Single-use vial: 300 mg/20mL

VII. References

1. Entyvio Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America Inc.; May 2014. Available at www.entyviohcp.com
2. Lichtenstein GR, Hanauer SB, Sandborn WJ, and the Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's disease in adults. Am J Gastroenterol. 2009;104(2):465-483.
3. Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2010;105;501-523.
4. Sandborn WJ. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. Gastroenterology 2014; 147: 702-705.
5. Dassopoulos T, Cohen R, Scherl E, et al. Ulcerative Colitis Clinical Care Pathway. American Gastroenterological Association. 2015. Available at http://campaigns.gastro.org/algorithms/UlcerativeColitis/
6. Ordas I, Feagan BG, Sandborn WJ. Early use of immunosuppressives or TNF antagonists for the treatment of Crohn's disease: time for a change. Gut. 2011 Dec; 60(12):1754-63.

7. Bernell O, Lapidus A, Hellers G. Risk Factors for Surgery and Postoperative Recurrence in Crohn's Disease. Annals of Surgery. 2000; 231(1): 38-45.

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.

HCPCS Codes	Description
J3380	Injection, vedolizumab, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Policy split from CP.PHAR.87.IBD Treatment_4_. CD/UC: removed criteria related to concomitant use with other biologics, and concurrent administration of live; added dosing; added requirement for trial and failure of PDL Humira as one of the two required TNF inhibitors, unless contraindicated. CD: added poor prognostic indicators; modified criteria requiring failure of immunomodulator, corticosteroids or aminosalicylate to failure of "corticosteroid, with or without immunomodulator" per 2014 AGA Clinical decision tool. Re-auth: added criteria related to dosing per PI and reasons to discontinue. Modified approval duration to 6 months initial and 12 months for renewal.	06/16	07/16
Removed trial and failure of corticosteroid as an option for moderate to severe CD, per 2014 AGA Clinical decision tool- corticosteroids are appropriate for low-risk patients. UC: removed option of trial of aminosalicylates per 2015 AGA Clinical Care Pathway.	11/16	
Converted to new template. UC: removed Cimzia as example of second TNF for redirection as Cimzia is not indicated for UC; change required trials from immunomodulator to specifically thiopurines based on AGA and ACG guidelines and removed MTX as example of acceptable trial. Clarified immunomodulator redirection for maintenance requests for all indications. CD: modified poor prognostic indicator list to match AGA guidelines. Safety criteria revised according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs.	07/17	07/17
CD: Reclassified "failure of an immunomodulator…" as one of the options to meet criteria point 1 (along with other poor prognostic indicators), instead of as an alternative to failing Humira and another TNF inhibitor in criteria point 2.	08/17	

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.