Clinical Criteria

Subject:	Entyvio (vedolizumab)		
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Overview

This document addresses the use of Entyvio (vedolizumab), an integrin receptor antagonist which binds specifically to the α4β7 integrin and inhibits the migration of memory T-lymphocytes across the endothelium into inflamed gastrointestinal tissue. Entyvio (vedolizumab) is approved for the treatment of Crohn's disease and ulcerative colitis.

Crohn's Disease: The American Gastrointestinal Association (AGA) clinical care pathway and American College of Gastroenterology (ACG) guidelines recommend treatment according to risk stratification and disease severity. Features of individuals at moderate to high risk include age < 30 at initial diagnosis, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and stricturing and/or penetrating behavior. Thiopurines and methotrexate are generally utilized for steroid-sparing effects and as adjunctive therapy for reducing immunogenicity with biology therapy. TNFi +/- immunomodulator (combination preferred) is recommended to induce and maintain remission in individuals with moderately to severely active disease. Non-TNFi biologics (vedolizumab and ustekinumab) +/- immunomodulator are alternate options to induce and maintain remission in moderately to severely active disease.

Ulcerative Colitis: For those with moderately to severely active disease, the American College of Gastroenterology (ACG) guidelines strongly recommend induction of remission using oral budesonide MMX, oral systemic corticosteroids, TNFi, tofacitinib or vedolizumab (moderate to high quality evidence). The American Gastroenterological Association (AGA) guidelines define moderate to severe UC as those who are dependent on or refractory to corticosteroids, have severe endoscopic disease activity, or are at high risk of colectomy. AGA strongly recommends biologics (TNFi, vedolizumab, or ustekinumab) or tofacitinib over no treatment in induction and maintenance of remission (moderate quality of evidence). For biologic-naïve individuals, Infliximab or vedolizumab are conditionally recommended over adalimumab for induction of remission (moderate quality evidence).

Pediatric Use: Two publications (Conrad 2016, Singh 2016) describe the safety and efficacy of Entyvio (vedolizumab) in pediatric individuals with Crohn's disease or ulcerative colitis who had failed prior treatment with conventional therapy or one or more TNFi. Based on the available peer-reviewed literature and views of relevant medical specialists practicing in pediatrics and pediatric gastroenterology, the use of vedolizumab to induce or maintain remission may be considered a treatment option in a subset of the pediatric population 6 years of age or older with Crohn's disease or ulcerative colitis who are refractory to treatment with conventional drug therapy or TNFi.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Entyvio (vedolizumab)

Initial ~~R~~requests for Entyvio (vedolizumab) may be approved for the following:

I. Crohn's disease (CD) when the following criteria are met:
   A. Individual is 6 years of age or older (Conrad 2016, Singh 2016) with moderate to severe CD; **AND**

B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as ~~5-Aminosalicylic acid products,~~ systemic corticosteroids~~,~~ or immunosuppressants) or a tumor necrosis factor (TNF) antagonist;

OR

II. Ulcerative colitis (UC) when the following criteria are met:
   A. Individual is 6 years of age or older (Conrad 2016, Singh 2016) with moderate to severe UC; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants) or a TNF antagonist.

Continuation requests for Entyvio (vedolizumab) may be approved if the following criterion is met:

I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

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Requests for Entyvio (vedolizumab) may not be approved for the following:

I. All other indications not included above; **OR**
II. In combination with apremilast, JAK inhibitors, other biologic drugs (such as TNF antagonists, ~~or~~ natalizumab or ustekinumab); **OR**
III. Active, serious infection or a history of recurrent infections; **OR**
IV. New or worsening neurological signs or symptoms of John Cunningham virus (JCV) infection or risk of progressive multifocal leukoencephalopathy (PML).

Quantity Limits

Entyvio (vedolizumab) Quantity Limit

Drug	Limit
Entyvio 300 mg/vial*	1 vial per 56 days (8 weeks)
Override Criteria	
*Initiation of therapy for Crohn's Disease (CD) or Ulcerative Colitis (UC): May approve up to 2 (two) additional single-use vials (300 mg/vial) in the first 6 weeks (42 days) of treatment.	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3380	Injection, vedolizumab, 1 mg [Entyvio]

ICD-10 Diagnosis

K50.00-K50.919	Crohn's disease (regional enteritis)
K51.00-K51.919	Ulcerative colitis

Document History

Revised: 11/20/2020
Document History:

- 11/20/2020 – Annual Review: Add continuation of use section; remove 5-ASA products as example of conventional therapy for Crohn's disease; add additional examples of combination use for clarity. Coding Reviewed: No changes.
- 09/23/2019 - Administrative update to add drug specific quantity limit.
- 11/16/2018 – Annual Review: Initial P&T review of Entyvio Clinical Guideline. Update clinical criteria to delete "active" disease wording. Update criteria to delete requirement agent is being used "to reduce signs and symptoms, maintain clinical response" etc. Wording and formatting changes to criteria for consistency. HCPCS and ICD-10 Coding Review: No changes.

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