

# Entyvio<sup>®</sup> (vedolizumab)



## Pharmacy Coverage Policy

**Effective Date:** November 22, 2023

**Revision Date:** November 22, 2023

**Review Date:** November 15, 2023

**Line of Business:** Medicaid - Kentucky, Medicaid - South Carolina, Medicaid - Ohio

**Policy Type:** Prior Authorization

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### Products Affected

Entyvio intravenous solution

### Listed Indications

[Ulcerative Colitis](#)

[Crohn's Disease](#)

### Ulcerative Colitis

#### Does the member meet all of the following criteria?

Criteria #1 The member has a diagnosis of moderately to severely active ulcerative colitis.

Criteria #2 The member is 18 years of age or older.

Criteria #3 The member has had prior therapy, contraindication, or intolerance with at least one form of conventional therapy including: aminosaliclates (e.g. mesalamine and sulfasalazine), immunomodulators (e.g. azathioprine) or corticosteroids (e.g. prednisone, hydrocortisone, methylprednisolone)

#### Approval Duration

Initial Entyvio (vedolizumab) will be approved in plan year durations or as determined through clinical review.

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### Crohn's Disease

#### Does the member meet all of the following criteria?

Criteria #1 The member has a diagnosis of moderately to severely active Crohn's disease

Criteria #2 The member is 18 years of age or older.

Criteria #3 The member has had prior therapy, contraindication, or intolerance with at least one form of conventional therapy including: aminosaliclates (e.g. mesalamine and sulfasalazine), immunomodulators (e.g. azathioprine) or corticosteroids (e.g. prednisone, hydrocortisone, methylprednisolone)

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### Background

This is a prior authorization policy about Entyvio (vedolizumab).

Ulcerative colitis (UC) is a disease in which the lining of the colon becomes inflamed and develops ulcers, leading to bleeding and diarrhea. The inflammation almost always affects the rectum and lower part of the colon, but it can affect the entire colon. Two main goals of treatment for UC are to achieve remission and maintain remission. The treatment of mild UC relies on initial medical management with corticosteroids and anti-inflammatory agents, such as sulfasalazine, in conjunction with symptomatic treatment with antidiarrheal agents and rehydration. For more severe disease, biologic agents, thiopurines and corticosteroids are often used.

Crohn's disease (CD) is an idiopathic, chronic inflammatory process of the gastrointestinal (GI) tract that can affect any part of the tract from the mouth to the anus. For colon and small bowel inflammation in CD, anti-inflammatory drugs (e.g. sulfasalazine) or antibiotics are helpful. Biologic

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therapy may provide benefits in patients who have moderate to severe debilitating symptoms of CD, who have documented active inflammation, or who are dependent on corticosteroids and unable to taper without return of symptoms.

### Warnings and Precautions:

- Hypersensitivity Reactions (including anaphylaxis): Discontinue Entyvio if anaphylaxis or other serious allergic reactions occur.
- Infections: Treatment with Entyvio is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding Entyvio in patients who develop a severe infection while on treatment with Entyvio.
- Progressive Multifocal Leukoencephalopathy (PML): Although no cases have been observed in Entyvio clinical trials, JCV infection resulting in PML and death has occurred in patients treated with another integrin receptor antagonist. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms.

Entyvio (vedolizumab) is an integrin receptor antagonist.

Entyvio (vedolizumab) binds to the  $\alpha 4\beta 7$  integrin and blocks the interaction of  $\alpha 4\beta 7$  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  $\alpha 4\beta 7$  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.

Entyvio (vedolizumab) is indicated in adults for the treatment of:

- moderately to severely active ulcerative colitis
- moderately to severely active Crohn's disease

Vedolizumab is supplied as Entyvio in 300 mg single-use 20 mL vials.

### Provider Claim Codes

For medically billed requests, please visit [www.humana.com/PAL](http://www.humana.com/PAL). Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

### Medical Terms

Entyvio; vedolizumab; Crohn's disease; ulcerative colitis; inflammatory bowel disease

### References

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