CareSource Rxinnovations

# PHARMACY POLICY STATEMENT
## Arkansas PASSE

| DRUG NAME | Entyvio (vedolizumab) |
|---|---|
| BILLING CODE | J3380 |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Office/Outpatient |
| STATUS | Prior Authorization Required |

Entyvio is an integrin receptor antagonist indicated in adults for the treatment of moderately to severely active ulcerative colitis (UC) or moderately to severely active Crohn's disease (CD). It targets the immune system of the gut and has a favorable safety profile, without the risk for PML that can occur with the more broadly acting anti-integrin drug, Tysabri, which is also used for Crohn's disease.
CD and UC are inflammatory bowel diseases. CD can affect any part of the GI tract whereas UC only affects the large intestine (colon and rectum). CD can affect the entire thickness of the bowel wall whereas UC only affects the inner-most lining.

Entyvio (vedolizumab) will be considered for coverage when the following criteria are met:

## Crohn's Disease (CD)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a documented diagnosis of moderately to severely active CD; AND
4. Member has tried and failed at least 12 weeks of an anti-TNF agent (e.g., Cimzia, Humira, or Remicade), unless not tolerated or contraindicated.
5. **Dosage allowed/Quantity limit:** 300 mg IV infusion at 0, 2, and 6 weeks, and every 8 weeks thereafter. (1 vial per 56 days following induction)
   *Note*: Therapy should be discontinued if no evidence of therapeutic benefit by week 14.

***If all the above requirements are met, the medication will be approved for 4 months.***

For **reauthorization**:
1. Chart notes have been provided showing improvement in signs and symptoms of CD such as mucosal healing, fewer flare-ups, or ability to taper off steroids.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## Ulcerative Colitis (UC)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a documented diagnosis of moderately to severely active UC; AND

4. Member must have a documented trial and inadequate response with **one** of the following:
   a) 3 months of 6-mercaptopurine or azathioprine
   b) 30 days of a corticosteroid (e.g., budesonide, prednisone, methylprednisolone)
   c) 3 months of 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.).
5. **Dosage allowed/Quantity limit:** 300 mg IV infusion at 0, 2, and 6 weeks, and every 8 weeks thereafter. (1 vial per 56 days following induction)
   *Note:* Therapy should be discontinued if no evidence of therapeutic benefit by week 14.

***If all the above requirements are met, the medication will be approved for 4 months.***

For **reauthorization**:
1. Chart notes have been provided showing improvement in signs and symptoms of UC such as clinical remission, decrease in rectal bleeding, decreased corticosteroid use, or improved endoscopic appearance of the mucosa.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## CareSource considers Entyvio (vedolizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|---|---|
| **05/08/2017** | New policy for Entyvio created. Policy SRx-0041 archived. For both diagnoses CD and UC: TNF inhibitor Humira was listed as required trial. List of diagnoses considered not medically necessary was added. |
| **02/26/2019** | Humira removed from required trials. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Initial authorization length increased to 12 months. Inadequate response to trial agents combined under member's history; CDAI and Mayo scoring requirement added; severity factors for CD removed from requirements. |
| **11/23/2020** | Replaced list of excluded diagnoses with the generic statement. Updated references. Removed TB requirements (not necessary for this drug).<br>CD: Removed CDAI score requirement. Specified length of trials for conventional therapies, previously not specified. Added a trial of TNF inhibitor in accordance with guidelines. Reduced initial auth approval to 4 months (must discontinue if no benefit observed after 14 weeks).<br>UC: Removed Mayo score and endoscopy subscore requirements. Specified length of trials for conventional therapies. Reduced initial auth approval to 4 months (must discontinue if no benefit observed after 14 weeks). |
| **08/09/2022** | Transferred policy to new template. Added QL.<br>Crohn's: Added reference. Removed requirement for trial of conventional therapy. Added ability to taper off steroids as an option to meet renewal criteria.<br>UC: Added improved endoscopic appearance as option for renewal criteria. |

References:


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13. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology*. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022

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