MEDICAL MUTUAL®

# Drug Policy

**Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.**

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| **Policy:** | **201423** | **Initial Effective Date: 09/05/2014**<br>**Annual Review Date: 11/21/2024**<br>**Last Revised Date: 11/21/2024** |
| **Code(s):** | **HCPCS J3380** | |
| **SUBJECT:** | **Entyvio™ (vedolizumab injection for intravenous [IV] use)** | |

☒Subject to Site of Care

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

## POLICY STATEMENT

This policy involves the use of Entyvio. Prior authorization is recommended for medical benefit coverage of Entyvio. Coverage is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy, and Labs/Diagnostics** for the diagnosis provided. The requirement that the patient meet the Criteria and **Waste Management** applies for all covered conditions. **Conditions Not Recommended for Approval** are listed following the Recommended Authorization Criteria and Waste Management section.

Because of the of the specialized skills required for evaluation and diagnosis of patients treated with Entyvio as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Entyvio to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is required, a response to therapy is required for continuation of therapy.

## RECOMMENDED AUTHORIZATION CRITERIA

### Food and Drug Administration (FDA)-Approved Indications

**1. Crohn's Disease (CD).**

**Criteria.** *The patient must meet the following criteria (a, b, c AND d):*

**a)** The patient is 18 years of age or older; AND

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**b)** The patient has tried at least one TNF blocker (e.g., Humira, Cimzia, or Remicade) or one immunomodulator for Crohn's disease for at least 2 months, unless intolerant or has had an inadequate response with, was intolerant to, or demonstrated dependence on corticosteroids;[2-3] AND
**c)** Entyvio is prescribed by or in consultation with a gastroenterologist; AND
**d)** Site of care medical necessity is met*

**Dosing in CD.** *Dosing must meet the following*: 300 mg as an IV infusion at Weeks 0, 2, and 6, then Q8W thereafter.[1]

**Initial Approval/Extended Approval.**
**a)** *Initial Approval*: Initial approval for patients starting Entyvio is for 14 weeks
**b)** *Extended Approval*: Approve for an additional 12 months of therapy if the patient has responded, as determined by the prescribing physician. The patient may not have a full response by Week 14, but there should be some response.

The recommended dose is 300 mg as a 30-minute IV infusion at Week 0, 2, and 6, and Q8W thereafter; therapy should be discontinued in patients who show no benefit by Week 14.[1]

**Duration of Therapy in CD.** Indefinite if the patient is responding.

**Labs/Diagnostics:** None required.

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**2. Ulcerative Colitis (UC).**

**Criteria.** *The patient must meet the following criteria (a, b, c AND d):*
**a)** The patient is 18 years of age or older; AND
**b)** The patient has tried at least one TNF blocker (e.g., Humira, Remicade, or Simponi [subcutaneous]) or one immunomodulator for UC, unless intolerant or has had an inadequate response with, was intolerant to, or demonstrated dependence on corticosteroids; AND
**c)** Entyvio is prescribed by or in consultation with a gastroenterologist; AND
**d)** Site of care medical necessity is met*.

**Dosing in UC.** *Dosing must meet the following*: 300 mg as an IV infusion at Weeks 0, 2, and 6, then Q8W thereafter.[1]

**Initial Approval/Extended Approval.**
**a)** *Initial Approval*: Initial approval for patients starting Entyvio is for 14 weeks
**b)** *Extended Approval*: Approve for an additional 12 months of therapy if the patient has responded (e.g., decreased stool frequency or rectal bleeding), as determined by the prescribing physician. The patient may not have a full response by Week 14, but there should be some response.

The recommended dose is 300 mg as a 30-minute IV infusion at Week 0, 2, and 6, and Q8W thereafter; therapy should be discontinued in patients who show no benefit by Week 14.[1]

**Duration of therapy in UC:** Indefinite if the patient is responding.

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**Labs/Diagnostics:** None required.

**Other Uses with Supportive Evidence**

**3. Management of Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**

**Criteria.** *The patient must meet the following criteria (a, b, AND c):*
- **a)** The patient is 18 years of age or older; AND
- **b)** Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, tremelimumab, dostarlimab, retifanlimab, nivolumab/relatlimab, tislelizumab, toripalimab, etc.); AND
  - i. Patient has mild (G1) diarrhea or colitis related to their immunotherapy with persistent or progressive symptoms and a positive lactoferrin/calprotectin; OR
  - ii. Patient has moderate (G2) to severe (G3-4) diarrhea or colitis related to their immunotherapy
- **c)** Site of care medical necessity is met*.

**4. Dosing in Management of Immune Checkpoint Inhibitor-Related Diarrhea/Colitis.** *Dosing must meet the following*: 300 mg intravenously at weeks 0, 2, & 6

**Initial Approval/Extended Approval.**
- **c)** *Initial Approval*: Initial approval for patients starting Entyvio is for 3 total doses on weeks 0, 2, & 6.
- **d)** *Extended Approval*: Not recommended

**Duration of therapy in Management of Immune Checkpoint Inhibitor-Related Diarrhea/Colitis:** Only recommended for 3 total doses.

**5. Acute Graft Versus Host Disease (aGVHD)**

**Criteria.** *The patient must meet the following criteria (a, b, c AND d):*
- **a)** The patient is 18 years of age or older; AND
- **b)** Patient has received an allogeneic hematopoietic stem cell transplant; AND
- **c)** Used for steroid-refractory acute GVHD; AND
- **d)** Used in combination with systemic corticosteroids as additional therapy following no response to first-line therapies
- **e)** Site of care medical necessity is met*.

**Dosing in aGVHD.** *Dosing must meet the following*: 300 mg intravenously at weeks 0, 2, & 6, then 300 mg intravenously every 8 weeks

**Initial Approval/Extended Approval.**
- **e)** *Initial Approval*: Initial approval for patients starting Entyvio is for 14 weeks

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**f)** *Extended Approval*: Approve for an additional 6 months of therapy if the patient has responded [e.g. Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score, etc.) or Patient-reported symptoms (e.g., Lee Symptom Scale, etc.)]as determined by the prescribing physician.

**Duration of therapy in aGVHD:** Indefinite if the patient is responding.

6. **Patient has been Established on Entyvio.** Approve if the patient has been taking Entyvio AND meets the conditions for coverage required for **Dosing, Extended Approval, Duration of Therapy, and Labs/Diagnostics** for an approved use in this *Entyvio Utilization Review* policy. Site of care medical necessity must be met*.

**Waste Management.** Entyvio is supplied in a single-dose glass vial that contains 300 mg of vedolizumab as a white to off-white lyophilized cake. Only one vial should be needed per dose.

**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Entyvio has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. **Concurrent Use with a Biologic used for an Inflammatory Condition** (e.g., Cimzia [certolizumab pegol subcutaneous {SC} injection], Humira [adalimumab SC injection], Remicade, Renflexis, Inflectra [infliximab IV infusion], Simponi [golimumab SC injection], Tysabri® [natalizumab IV infusion]). The combination of Entyvio used simultaneously with another biologic has not been evaluated for efficacy or safety. Entyvio binds specifically to α4β7 integrin and blocks the interaction of α4β7 integrin with MAdCAM-1, thus inhibiting migration of memory T-lymphocytes; there is a Warning concerning infection in patients treated with Entyvio.[1] Therefore, co-administration of Entyvio with other biologics has the risk of added immunosuppression.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

1. Entyvio™ for intravenous injection [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; June 2022.

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3. Sands BE, Feagan BG, Rutgeerts P, et al. Effects of vedolizumab induction therapy for patients with Crohn's disease in whom tumor necrosis factor antagonist treatment had failed. *Gastroenterology.* 2014;147(3):618-627
4. Feagan BG, Rutgeerts P, Sands BE, et al. Vedolizumab as induction and maintenance therapy for ulcerative colitis. *N Engl J Med*. 2013;369(8):699-710.
5. Bressler B, Marshall JK, Bernstein CN, et al. Clinical practice guidelines for the medical management of nonhospitalized ulcerative colitis: the Toronto consensus. *Gastroenterology*. 2015;148(5):1035-1058.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) vedolizumab. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2024.
7. Bergqvist, V, Hertervig E, Gedeon P, et al. Vedolizumab treatment for immune checkpoint inhibitor-induced enterocolitis. Cancer Immunology Immunotherapy 66: 581-592, No. 5, May 2017.
8. Chen YB, Shah NN, Renteria AS, et al. Vedolizumab for prevention of graft-versus-host disease after allogeneic hematopoietic stem cell transplantation. Blood Adv. 2019 Dec 10;3(23):4136-4146. doi: 10.1182/bloodadvances.2019000893. PMID: 31821456; PMCID: PMC6963235.

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**FOR MEDICAL BENEFIT COVERAGE REQUESTS:**

**Prior approval is required for HCPCS Code J3380**

**Edits and Denials:**

**Prior approval:** Prior approval is required for Entyvio **(HCPCS Code J3380)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician consultant for review if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

| **HCPCS Code(s):** | |
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| J3380 | Injection, vedolizumab, 1 mg |

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