MEDICAL MUTUAL®

Drug Policy

Policy:	**231201**	**Initial Effective Date: 12/19/2023**
Code(s):	**C9399, J3590**	**Annual Review Date: 05/22/2025**
SUBJECT:	**Entyvio ® (vedolizumab injection for subcutaneous use)**	**Last Revised Date: 05/22/2025**

Subject to: ☒Site of Care
☒Medication Sourcing

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

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.

OVERVIEW

Entyvio subcutaneous, an integrin receptor antagonist, is indicated for treatment of **ulcerative colitis**, in adults with moderate to severe active disease who have received two induction doses with Entyvio intravenous.

POLICY STATEMENT

This policy involves the use of Entyvio. Prior authorization is recommended for pharmacy benefit coverage of Entvyio. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because 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 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 allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Entyvio is recommended in those who meet the following criteria:

1. **Ulcerative Colitis (UC).**

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

a) According to the prescriber, the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months of initiating therapy with Entyvio subcutaneous; AND
b) The patient is 18 years of age or older; AND
c) 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
d) Entyvio is prescribed by or in consultation with a gastroenterologist; AND
e) Site of care medical necessity is met*.

Dosing in UC. *Dosing must meet the following*: Following the first two ENTYVIO intravenous doses administered at Week 0 and Week 2, ENTYVIO may be switched to subcutaneous injection at Week 6. Administer 108 mg as a subcutaneous injection once every 2 weeks thereafter.

Initial Approval/Extended Approval.

a) *Initial Approval*: Initial approval for Entyvio SC is for 6 months. The patient may not have a full response by Week 14, but there should be some response.
b) *Extended Approval (intravenous or subcutaneous)*: 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 and the patient has been established on Entyvio subcutaneous or intravenous for at least 6 months.

2. Crohn's Disease (CD)

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

a) According to the prescriber, the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months of initiating therapy with Entyvio subcutaneous; AND
b) The patient is 18 years of age or older; AND
c) 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; AND
d) Entyvio is prescribed by or in consultation with a gastroenterologist; AND
e) Site of care medical necessity is met*.

Dosing in CD. *Dosing must meet the following*: Following the first two ENTYVIO intravenous doses administered at Week 0 and Week 2, ENTYVIO may be switched to subcutaneous injection at Week 6. Administer 108 mg as a subcutaneous injection once every 2 weeks thereafter.

Initial Approval/Extended Approval.

a) *Initial Approval*: Initial approval for Entyvio SC is for 6 months. The patient may not have a full response by Week 14, but there should be some response.
b) *Extended Approval (intravenous or subcutaneous)*: 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 and the patient has been established on Entyvio subcutaneous or intravenous for at least 6 months.

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 intravenous infusion [prescribing information]. Deerfield, IL: Takeda; June 2022.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.
3. 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.
4. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology*. 2020;158(5):1450-1461.