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Partnering within our communities to provide solutions to better health

Montana Healthcare Programs
Drug Prior Authorization (PA) Criteria

Entyvio® (vedolizumab) Pen or Syringe 108mg/0.68ml

I. Medication Description

Entyvio® Pen and Syringe are subcutaneously delivered integrin receptor antagonists indicated in adults for the treatment of moderately to severely active ulcerative colitis in the maintenance phase of treatment after two intravenous infusions. Entyvio® Pen and Syringe are products that can be injected by a healthcare provider or a patient who has been trained in self-injection.

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderately to severely active ulcerative colitis.
- Has shown clinical benefit from IV Entyvio after at least 6 weeks.

Prescriber requirements:

- Must be prescribed by, or in consult with, a gastroenterology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
    - Member has shown a clinical response to treatment at week 6 and has been evaluated for transition from intravenous to subcutaneous treatment.
    - Member or caregiver has been trained in subcutaneous injection technique.
    - Members who have not shown a response by week 6 may continue to week 14 on intravenous Entyvio® at which time they will need to demonstrate clinical response for authorization to either transition to subcutaneous or continue intravenous treatment.
- Attests that member **will not** use Entyvio® concomitantly with other biologics.

Limitations:

Dosed per package labeling after intravenous infusions at week 0 and 2, then subcutaneously every 2 weeks starting at week 6.

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IV. Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations). After initial approval to switch to subcutaneous injection at week 6, patient must continue to demonstrate improvement over baseline at week 14.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Entyvio® concomitantly with other biologics.

V. Quantity Limits

Maximum Dose = 108mg every 2 weeks subcutaneous starting at week 6.

VI. Coverage Duration

Initial approval for subcutaneously dosing: After meeting criteria to switch at week 6, approval will be granted for 5 total subcutaneous injections (to week 14) at which time an update will be required.

Renewal approval duration: 12 months

References:

ENTYVIO (vedolizumab) prescribing information. Takeda Pharmaceuticals. https://content.takeda.com/?contenttype=PI&product=ENTY&language=ENG&country=USA&documentnumber=1

Sandborn WJ, Baert F, Danese S, et al. Efficacy and safety of vedolizumab subcutaneous formulation in a randomized trial of patients with ulcerative colitis. *Gastroenterology*. 2020;158(3):562-572.e12. https://pubmed.ncbi.nlm.nih.gov/31470005/