ALASKA MEDICAID
Prior Authorization Criteria

Entyvio® (vedolizumab)

FDA INDICATIONS AND USAGE[1]

1. Moderately to severely active ulcerative colitis (UC)

2. Moderately to severely active Crohn's disease (CD)

APPROVAL CRITERIA[1,2,3]

1. Initial Authorization Request must include:
   - Monitoring plan (*spec. for* PML, hepatic changes)
   - Previous therapies trialed and the nature of the failure.

   Ulcerative Colitis
   1. Patient is > 18 years of age; **AND**
   2. Has moderately to severely active UC; **AND**
   3. Has trialed and failed at least one conventional therapy (e.g. sulfasalazine, prednisone, azathioprine) for at least 60 days; **AND**
   4. Has trialed and failed a TNF blocker (e.g. Humira™) for at least 60 days

   Crohn's Disease
   1. Patient is > 18 years of age; **AND**
   2. Has moderately to severely active CD; **AND**
   3. Has trialed and failed at least one conventional therapy (e.g. sulfasalazine, prednisone, azathioprine) for at least 60 days; **AND**
   4. Has trialed and failed a TNF blocker (e.g. Humira™) for at least 60 days; **AND**
   5. Has a Crohn's Disease Activity Index (CDAI) > 220.

2. Reauthorization Request for use beyond 14 weeks must include:
   - A letter of medical necessity with chart notes demonstrating therapeutic benefit by week 14.
   - Documentation of tolerance and absence of adverse events.
   - For patients receiving corticosteroids at baseline, documentation of an initial attempt to taper (or a plan to attempt to taper) the corticosteroids.

DENIAL CRITERIA[1]

1. Known hypersensitivity to vedolizumab or any of its excipients.
2. Age < 18 years.
3. Current active severe infection.
4. Concurrent therapy with another integrin receptor antagonist (e.g. natalizumab) or TNF blocker (e.g. adalimumab, infliximab, certolizumab, etanercept, etc).
5. For patients initiating on therapy, CDAI score ≤ 150.
6. Renewal authorizations will not be approved if the patient has had AST/ALT > 20 times the upper limit of normal (ULN), Bilirubin > 10 times the ULN, or life-threatening diarrhea.

CAUTIONS[1]

- Patients must be monitored for new or worsening neurological issues as the risk of progressive multifocal leukoencephalopathy (PML) cannot be ruled out.
- Live vaccines should not be administered while patients are receiving vedolizumab unless determined that the benefit outweighs the risk.

DURATION OF APPROVAL

- Initial Approval: 14 weeks (IV infusions at 0, 2, 6, and 14 weeks)
    a. Entyvio subcutaneous injection (108mg every 2 weeks beginning at week 6 following IV infusions at 0 and 2 weeks)
- Reauthorization Approval: up to 12 months (IV infusions at week 22 and beyond at eight week intervals)
    a. Entyvio subcutaneous injection (108mg every 2 weeks beginning at week 6 following IV infusions at 0 and 2 weeks)

QUANTITY LIMIT

- 300mg (1 vial) per dose
- 216mg (2 syringes or pens) per 28 days

HCPCS CODE

J3380 max of 300 units (IV formulation)

NOTES

Vedolizumab is a humanized monoclonal antibody which acts as an integrin receptor antagonist. It binds to human $\alpha 4\beta 7$ integrin on the surface of a subset of memory T-lymphocytes to minimize the migration of these T-cells to inflamed tissue in the intestinal lining with the goal of interrupting the chronic inflammation contributing to the diseases' pathogenicity.

REFERENCES / FOOTNOTES:

1. Entyvio® [package insert]. Deerfield, IL; Takeda Pharmaceuticals America, Inc., 09/2023.
2. Feagan BG, Rutgeerts P, Sands BE, et al; for the GEMINI 1 Study Group. *N Engl J Med*. 2013;369(8):699-710
3. Sands BE, Peyrin-Biroulet L, et al; Vedolizumab versus Adalimumab for Moderate-to-Severe Ulerative Colitis. N Engl J Med 2019; 381:1215-1226