Entyvio® (vedolizumab)

FDA INDICATIONS AND USAGE[1]

- Moderately to severely active ulcerative colitis (UC) in adults who have had:
  - an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or
  - an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.
- Moderately to severely active Crohn's disease (CD) in adults who have had:
  - an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor blocker or immunomodulator; or
  - an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

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 a TNF blocker and one other therapy.

   Crohn's Disease
   1. Patient is > 18 years of age; **AND**
   2. Has moderately to severely active CD; **AND**
   3. Has trialed and failed a TNF blocker and one other therapy; **AND**
   4. 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. 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[1,2]

- 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 (Infusions at 0, 2, 6, and 14 weeks)
- Reauthorization Approval: up to 12 months (Infusions at week 22 and beyond at eight week intervals)

QUANTITY LIMIT

- 300mg (1 vial) per dose

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., May 2014.
2. Vedolizumab (Entyvio) for inflammatory bowel disease. *Med Lett Drugs Ther*. 2014;56(1451):86-87.
3. Dretzke J, Edlin R, Round J et al. A systematic review and economic evaluation of the use of tumour necrosis factor-alpha (TNF-a) inhibitors, adalimumab and infliximab, for Crohn's disease. *Health Technol Assess* 2011;15(6). Available at http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0048961/pdf/TOC.pdf. Accessed November 17, 2014.