

<b>POLICY NAME</b>	Entyvio (vedolizumab)	<b>POLICY #</b>	2262P
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## Criteria

### Coverage Criteria for Ulcerative Colitis

- ☐ See Ulcerative Colitis Immunomodulator Therapies policy

### Coverage Criteria for Ulcerative Proctitis

- ☐ Ordered by or in consultation with a gastroenterologist (stomach doctor)
- ☐ Documented failure, intolerance, or contraindication to topical 5-ASA rectal suppositories and enemas
- ☐ Documented failure, intolerance, or contraindication to systemic conventional therapy (mesalamine, sulfasalazine, prednisone, cyclosporine),
- ☐ Documented failure, intolerance, or contraindication to a covered adalimumab biosimilar
  - Please refer to formulary files for most accurate list of covered biosimilars

### Coverage Criteria for Crohn's Disease

- ☐ See Crohn's Disease Immunomodulator Therapies policy

## Exclusion Criteria – Any of the following prevents coverage

- ☐ Entyvio (vedolizumab) is not considered medically necessary for an individual with any of the following:
  - In combination with a TNF antagonist (etanercept, adalimumab)
  - In combination with a non-TNF antagonist immunomodulatory drug, such as natalizumab (Tysabri)
  - Active, serious infection or a history of recurrent infections
  - New or worsening neurological signs or symptoms of John Cunningham virus (JCV) infection or risk of progressive multifocal leukoencephalopathy (PML).
  - Concurrent treatment with Tacrolimus (Topical): May enhance the adverse/toxic effect of Immunosuppressants (Risk X)
  - Concurrent treatment with Pimecrolimus: May enhance the adverse/toxic effect of Immunosuppressants (Risk X)
  - Signs or symptoms of jaundice or significant liver injury Pharmacy Drug Policy & Procedure
  - Lack of therapeutic benefit after week 14 of therapy
  - Off-label (non-FDA Approved) dosing frequencies CPT Codes HCPCS Codes J3380 Injection, vedolizumab, 1mg [Entyvio] References