

POLICY NAME

Entyvio (vedolizumab)

POLICY #

2262P

Criteria

Exclusion Criteria – Any of the following prevents coverage

- ☐ **5.1** 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

Coverage Criteria for Ulcerative Colitis

- ☐ **1.1** See Ulcerative Colitis Immunomodulator Therapies policy

Coverage Criteria for Ulcerative Proctitis

- ☐ **2.1** Ordered by or in consultation with a gastroenterologist (stomach doctor)
- ☐ **2.2** Documented failure, intolerance, or contraindication to topical 5-ASA rectal suppositories and enemas
- ☐ **2.3** Documented failure, intolerance, or contraindication to systemic conventional therapy (mesalamine, sulfasalazine, prednisone, cyclosporine),
- ☐ **2.4** 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

- ☐ 3.1 See Crohn's Disease Immunomodulator Therapies policy