Pharmacy Drug Policy Checklist

POLICY NAME	Entyvio (vedolizumab)	POLICY #	2262P

Criteria

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

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