GCHP Medi-Cal Clinical Guidelines
Vedolizumab (Entyvio™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	• Crohn's disease (CD) • Ulcerative colitis (UC) *Non-FDA approved indication or off-label use will be reviewed if there is sufficient documentation of efficacy and safety in published literature.*
Exclusion Criteria	• Active, serious infection, latent (untreated) tuberculosis. • Combination with another monoclonal antibody / biologic therapy.

Required Medical Information	Crohn's disease
	• Clinic notes confirming the diagnosis of moderately to severely active CD AND
	• Inadequate response, intolerance or contraindication to at least one of the following therapies:
	  ○ Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
	  ○ Azathioprine
	  ○ Mercaptopurine
	  ○ Methotrexate
	  ○ TNF blocker
	
	Ulcerative colitis
	• Clinic notes confirming the diagnosis of moderately to severely active UC AND
	• Inadequate response, intolerance or contraindication to at least one of the following therapies:
	  ○ Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
	  ○ Azathioprine
	  ○ Mercaptopurine
	  ○ TNF blocker
	
	Renewal requires favorable response or positive benefit from vedolizumab.
	
	Off-label indications: 1) The requested unlabeled use must represent reasonable and current prescribing practices based on current medical literature, provider organizations, or academic & professional specialists. 2) In addition, one of the following is required: a. Documentation of trial & failure (or contraindication) to on-label treatments, or b. There are no FDA-approved drug treatments for the diagnosis.

Age Restriction	18 years of age and older
Prescriber Restrictions	Gastroenterologist.

Coverage Duration	Initial: Six months; Renewal: 12 months
Other Criteria / Information	Criteria adapted from DHCS March 2024 Entyvio™ Prefilled Pen, and Prefilled Syringe are FDA approved as a self-administered injection and should be provided to the member by a pharmacy through pharmacy benefit. Entyvio™ Vial: FDA approved for administration by health care provider.

HCPCS	Description	Dosing, Units
J3380	Injection, vendolizumab, 1mg (Entyvio™)	300mg at week zero, two, six then every eight weeks.

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Lily Yip, Director of Pharmacy Services; Yoonhee Kim, Clinical Programs Pharmacist	N/A
Approved	N/A	5/15/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025
Approved	N/A	7/18/2024	Medical Advisory Committee (MAC)	3/1/2025