GCHP Medi-Cal Clinical Guidelines
Natalizumab (Tysabri™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	• Induce or maintain remission of moderate to severe Crohn's disease (CD). • Relapsing form of Multiple sclerosis (RRMS).

Exclusion Criteria	• Prior or current diagnosis of PML
	• Concurrent use with and immunosuppressants or immunomodulators such as but not limited to:
	  ○ Azithromycin, methotrexate, 6-mercaptopurine.
	  ○ TNF inhibitors [e.g., etanercept (Enbrel™), infliximab (Remicade™), adalimumab (Humira™)].
	  ○ Ustekinumab (Stelara™), vedolizumab (Entyvio™).
	• Dose requested greater than 300 mg every four weeks.

Required Medical Information	Prescriber is certified with, and the member is enrolled in Tysabri Outreach Unified Commitment to Health (TOUCH) program. **CD** – Inadequate response to, or inability to tolerate, use of tumor necrosis factor inhibitors (e.g., infliximab). **RRMS** • Baseline cranial MRI AND • Documentation confirming clinical relapse occurring during previous 12 months AND • Used as monotherapy. Renewal will require documentation showing favorable response to natalizumab.
Age Restriction	18 years of age and older
Prescriber Restrictions	CD: Gastroenterologist RRMS: Neurologist
Coverage Duration	Initial: Three months; Renewal: Six months
Other Criteria / Information	Criteria adapted from DHCS March 2024 & MCG

HCPCS	Description	Dosing, Units
J2323	Injection, natalizumab, 1mg (Tysabri™)	300mg IV infusion over one hour every four 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