Gold Coast Health Plan (GCHP) Medi-Cal Clinical Guidelines
Inebilizumab-cdon (Uplizna ™)

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	• Immunoglobulin G4-related disease (IgG4-RD) in adults • Neuromyelitis optica spectrum disorder (NMOSD) in adults who are anti-aquaporin-4 (AQP4) antibody positive
Exclusion Criteria	Active hepatitis B infection, active tuberculosis disease, or untreated TB infection (latent TB)

Required Medical Information	**Initial**: Must meet ALL of the following:
	• All vaccines must be administered at least four weeks prior to treatment initiation
	• Screened for hepatitis B virus (HBsAg and anti-HBc measurements) and active tuberculosis prior to treatment initiation
	• Anti-aquaporin-4 (AQP4) antibody positive
	• History of one or more relapses that required rescue therapy during the previous 12 months or two or more relapses requiring rescue therapy during the previous 24 months
	• Not receiving inebilizumab concurrently with other biologics used to treat NMOSD (e.g., eculizumab (Soliris), or satralizumab (Enspryng)
	
	Renewal:
	• Demonstrating clinical benefit evidenced by any one of the following:
	  ○ Reduction in frequency and number of attacks
	  ○ Disease stabilization while on inebilizumab treatment
	  ○ Reduction in number of NMOSD-related hospitalizations
	• Absence of unacceptable toxicity from the drug such as serious or life-threatening
	infusion related reactions, serious infections including Progressive Multifocal Leukoencephalopathy (PML), hypogammaglobulinemia necessitating intravenous
	Immunoglobulin (IVIG) or leading to recurrent infections

Age Restriction	18 years and older 18 to 21 years of age – check for CCS
Prescriber Restrictions	Immunologist, hematologist, or other physicians specialized in the treatment of NMOSD or IgG4-RD
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Criteria/Information	Criteria adapted from DHCS July 2025 **HCPCS** | **Description** | **Dosing, Units**

	J1823	Injection, inebilizumab-cdon, 1 mg (UpliznaTM)	300mg IV on day 1, followed by 300mg IV two weeks later. Then 300mg IV Q6months (beginning 6 months after the first 300mg dose)	

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	Oct. 14, 2025		Yoonhee Kim, Clinical Pharmacist	