

GCHP Medi-Cal Clinical Guidelines Inotuzumab Ozogamicin (Besponsa™)

PA Criteria	Criteria Details		
Covered Uses (FDA approved indication)	Treatment of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients 1 year of age and older.		
Exclusion Criteria	Hepatic Veno-occlusive disease.		
Required Medical Information	<ul style="list-style-type: none">• Diagnosis of relapsed or refractory CD22-positive B-cell precursor ALL and• Alternative treatment(s) have been tried or considered, have failed, or are contraindicated.		
Age Restriction	1 year of age and older. < 21 years of age – check for CCS eligibility.		
Prescriber Restrictions	Hematologist, Oncologist		
Coverage Duration	Initial: Three months Renewal: Four months		
Other Criteria / Information	Adapted from DHCS Pharmacy Manual Chemo Drug i-l January 2025.		
	HCPCS	Description	Dosing, Units
	J9229	Inotuzumab ozogamicin 0.1mg injection (Besponsa)	<u>Induction</u> : 0.8 mg/m2 IV infusion day one followed by 0.5 mg/m2 on days eight and 15 of 21-day cycle. <u>Consolidation (dosing regimen depends on response to treatment)</u> : 0.5 mg/m2 day one, eight and 15 of 28-day cycle OR 0.8 mg/m2 day one then 0.5 mg/m2 day eight and 15 of 28-day cycle. Maximum of six cycles.

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	1/24/2025	N/A	Yoonhee Kim, Clinical Programs Pharmacist Lily Yip, Director of Pharmacy Services	N/A
Approved	N/A	2/13/2025	Pharmacy & Therapeutics (P&T) Committee	6/1/2025



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