

GCHP Medi-Cal Clinical Guidelines Enfortumab (Padcev™)

PA Criteria	Criteria Details		
Covered Uses (FDA approved indication)	<ul style="list-style-type: none">In combination with pembrolizumab for the treatment of adult patients with locally advanced or metastatic urothelial cancer.As a single agent for the treatment of adult patients with locally advanced or metastatic urothelial cancer who:<ul style="list-style-type: none">have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum containing chemotherapy, orare ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.		
Exclusions	Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). Grade 4 or recurrent Grade 3 skin reactions. Grade 3 or 4 Pneumonitis/Interstitial Lung Disease (ILD).		
Required Medical Information	<u>Initial therapy - Must meet ALL of the following:</u> <ul style="list-style-type: none">FDA – approved indication and dosing regimenLocally advanced or metastatic urothelial cancerFailure of both of the following in the neoadjuvant/adjuvant, locally advanced or metastatic setting:<ul style="list-style-type: none">A programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. Examples of these are avelumab, atezolizumab, durvalumab, nivolumab, and pembrolizumab; ANDA platinum-containing chemotherapy (cisplatin or carboplatin based)		
Age Restriction	18 years of age and older. < 21 years of age check – for CCS eligibility.		
Prescriber Restrictions	Hematologist, oncologist		
Coverage Duration	Initial: Six months Renewal: Six months		
Other Criteria / Information	Adapted from DHCS Pharmacy Manual Chemo Drug e-h May 2024.		
	HCPCS	Description	Dosing, Units
	J9177	Enfortumab vedotin-ejfv 0.25mg injection (Padcev)	1.25mg/kg [up to maximum dose of 125mg (or 500 units)] on days one, and eight of 21-day cycle; or days one, eight and 15 of 28-day cycle.



STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	1/15/2025	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