

GCHP Medi-Cal Clinical Guidelines Bezlotoxumab (Zinplava™)

PA Criteria	Criteria Details						
Covered Uses (FDA Approved Indication)	Clostridioides difficile infection (CDI), secondary prevention. To reduce recurrence of Clostridioides difficile infection (CDI) who are receiving antibacterial drug treatment of CDI and are at high risk for CDI recurrence.						
Exclusion Criteria	Treatment of CDI. Bezlotoxumab is not an antibacterial drug and should only be used in conjunction with antibacterial treatment of CDI.						
Required Medical Information	<ul style="list-style-type: none">Confirmed diagnosis of CDI and for secondary prevention ANDHigh risk of CDI recurrence defined as<ul style="list-style-type: none">≥ 65 years of ageImmunocompromisedClinically severe CDI – WBC ≥ 15,000 cells/mL or serum creatinine ≥ 1.5mg/dLConfirmation will be using in conjunction with standard care antibiotic for CDI.						
Age Restriction	1 year of age and older						
Prescriber Restrictions	Infectious disease specialist, or gastroenterologist.						
Coverage Duration	One time for single dose per lifetime (repeat doses have not been studied).						
Other Criteria / Information	Criteria adapted from DHCS March 2024. <table><tr><th>HCP</th><th>Description</th><th>Dosing, Units</th></tr><tr><td>J0565</td><td>Injection, bezlotoxumab, 10mg (Zinplava™)</td><td>10mg/kg as a single dose</td></tr></table>	HCP	Description	Dosing, Units	J0565	Injection, bezlotoxumab, 10mg (Zinplava™)	10mg/kg as a single dose
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STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Yoonhee Kim, Clinical Programs Pharmacist Lily Yip, Director of Pharmacy Services	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