

GCHP Medi-Cal Clinical Guidelines Unclassified Drugs (J3490) and Unclassified Biologics (J3590)

PA Criteria	Criteria Details									
Covered Uses (FDA Approved Indication)	Drug / biologic specific									
Exclusion Criteria	Drug / biologic specific									
Required Medical Information	<ul style="list-style-type: none">The requested drug or biologic is prescribed for an FDA-approved indication and dosing regimen.The patient does not have any clinically relevant contraindications.If DHCS has a clinical criteria available, then DHCS clinical criteria shall be followed to determine medical necessity.<ul style="list-style-type: none">Refer to https://mcweb.apps.prd.cammis.medi-cal.ca.gov/publications/manual?community=pharmacy for DHCS clinical criteria.If DHCS does not have clinical criteria available, but MCG clinical criteria is available then MCG should be followed to determine medical necessity.									
Age Restriction	Drug/biologic specific. For < 21 years of age – check for CCS eligibility									
Prescriber Restrictions	Prescribed by relevant specialist within normal scope of practice.									
Coverage Duration	Initial: Three months; Renewal: Six months									
Other Criteria / Information	<table><tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr><tr><td>J3490</td><td>Unclassified Drug</td><td>Drug specific</td></tr><tr><td>J3590</td><td>Unclassified Biologics</td><td>Biologic specific</td></tr></table>	HCPCS	Description	Dosing, Units	J3490	Unclassified Drug	Drug specific	J3590	Unclassified Biologics	Biologic specific
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STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	1/27/2025	N/A	Lily Yip, Director of Pharmacy Services; Yoonhee Kim, Clinical Programs Pharmacist	N/A
Approved	N/A	2/13/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025