

GCHP Medi-Cal Clinical Guidelines Romosozumab (Evenity™)

PA Criteria	Criteria Details						
Covered Uses (FDA Approved Indication)	Postmenopausal osteoporosis with high risk for fracture or in patients in whom other available osteoporosis therapy has failed or cannot be taken.						
Exclusion Criteria	<ul style="list-style-type: none">• In combination with denosumab, bisphosphonates, calcitonin, raloxifene, zoledronic acid, teriparatide or abaloparatide.• High risk of cardiovascular disease and stroke (e.g., prior history of MI or stroke).• Hypocalcemia.						
Required Medical Information	<p>Must meet ALL of the following:</p> <ul style="list-style-type: none">• Treatment of osteoporosis in postmenopausal women at high risk of fracture• Bone mineral density (BMD) T-score of less than or equal to -2.5 or FRAX Score indicating major fracture risk greater than 20 percent or HIP Fracture greater than 3%, or non-traumatic fracture.• Tried and failed, or is intolerant, or has a contraindication to bisphosphonate therapy.• Tried and failed, or is intolerant, or has a contraindication to injectable. osteoporosis treatment drugs such as teriparatide, denosumab and abaloparatide.• Confirmation of no prior myocardial infarction or stroke within one year of starting Evenity.• Confirmation of taking a minimum 500 mg calcium and 600 IU vitamin D daily or contraindication. <p>Renewal request will not be approved per FDA indication.</p>						
Age Restriction	18 years of age and older						
Prescriber Restrictions	None						
Coverage Duration	12 months (duration of therapy is up to 12 months) – 1 time approval per lifetime						
Other Criteria / Information	<p>Criteria adapted from DHCS April 2024</p> <table><tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr><tr><td>J3111</td><td>Injection, romosozumab-aqqg, 1mg (Evenity™)</td><td>210mg subcutaneously monthly; each monthly dose given as two separate 105-mg injections administered immediately one after the other. Up to 12 months of duration of therapy.</td></tr></table>	HCPCS	Description	Dosing, Units	J3111	Injection, romosozumab-aqqg, 1mg (Evenity™)	210mg subcutaneously monthly; each monthly dose given as two separate 105-mg injections administered immediately one after the other. Up to 12 months of duration of therapy.
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STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Lily Yip, Director of Pharmacy Services; Yoonhee Kim, Clinical Programs Pharmacist	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