

Evenity® (romosozumab-aqqg) (Subcutaneous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 210 billable units every month for 12 doses

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria ^{1,17}

- Member is receiving calcium and Vitamin D supplementation if dietary intake is inadequate; **AND**
- Member does NOT have any FDA labeled contraindications to the requested agent (e.g., hypocalcemia, known hypersensitivity to Evenity); **AND**
- Member has not had a myocardial infarction or stroke within the preceding year (*Note: in members with other cardiovascular disease and/or risk factors, consider whether benefits of therapy outweigh the risks*); **AND**
- Will not be used in combination with bisphosphonates, denosumab, or parathyroid hormone analogs/related peptides; **AND**

Treatment of Postmenopausal Women with Osteoporosis † ^{1,9,10,14,16,17}

- Member must be at a high risk for fracture^{**}; **AND**
- Member has a documented diagnosis of osteoporosis indicated by one or more of the following:
 - T-score by DXA of ≤ -2.5 in the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; **OR**
 - History of fragility fracture to the hip or spine, regardless of T-score; **OR**
 - T-score by DXA between -1.0 and -2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; **AND**

- History of fracture of proximal humerus, pelvis, or distal forearm; **OR**
- FRAX 10-year probability for major fracture $\geq 20\%$ or hip fracture $\geq 3\%$; **AND**
- Member has one of the following §:
 - Documented treatment failure or ineffective response[‡] to a minimum (12) month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; **OR**
 - Member has a documented contraindication* or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid; **AND**
- Member has one of the following §:
 - Documented treatment failure or ineffective response[‡] to a minimum (12) month trial on previous therapy with *RANKL*-blocking agents such as denosumab, etc.; **OR**
 - Member has a documented contraindication* or intolerance to *RANKL*-blocking agents such as denosumab, etc.

§ Members with very high risk for fracture defined as a recent fracture (within the last 12 months), fractures while on osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm, T-score < -3.0, very high fracture probability by FRAX (major osteoporotic fracture > 30%, hip fracture > 4.5%), or high fall risk or history of injurious falls are not subject to prior trial and failure requirements with bisphosphonates and/or denosumab ^{9-11,14}

‡Ineffective response is defined as one or more of the following: ^{14,16,17}
– Decrease in T-score in comparison with baseline T-score from DXA scan – Member has a new fracture while on bisphosphonate or <i>RANKL</i>-blocking therapy
**High risk for fractures include, but are not limited to, one or more of the following: ^{16,17}
– History of an osteoporotic fracture as an adult – Parental history of hip fracture – Low BMI – Rheumatoid arthritis – Alcohol intake (3 or more drinks per day) – Current smoking – History of oral glucocorticoids ≥ 5 mg/d of prednisone (or equivalent) for >3 months (ever)
*Examples of contraindications to oral bisphosphonate therapy include the following: ¹⁵
– Documented inability to sit or stand upright for at least 30 minutes – Documented pre-existing esophageal disorders such as achalasia, esophageal stricture, esophageal varices, or Barrett's esophagus – Surgical anastomoses are present in the GI tract after certain types of bariatric surgery (e.g., Roux-en-Y gastric bypass) – Documented pre-existing hypocalcemia – Documented pre-existing renal insufficiency defined as creatinine clearance < 30-35 mL/min
*Examples of contraindications to injectable bisphosphonate therapy include the following: ¹⁵
– Documented pre-existing hypocalcemia – Documented pre-existing renal insufficiency defined as creatinine clearance < 30-35 mL/min
*Examples of contraindications to <i>RANKL</i>-blocking therapy include the following: ¹⁹

- Documented pre-existing hypocalcemia
- Documented hypersensitivity to the active ingredient or its excipients

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Duration of authorization has not been exceeded (*refer to Section I*)

V. Dosage/Administration ¹

Indication	Dose
Osteoporosis	210 mg administered subcutaneously (as two separate subcutaneous injections of 105 mg each) by a health care provider every month for a total of 12* monthly doses.
*Note: The anabolic effect of Evenity wanes after 12 monthly doses of therapy. Therefore, the duration of Evenity use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.	

VI. Billing Code/Availability Information

HCPCS Code:

- J3111 – Injection, romosozumab-aqqg, 1 mg; 1 billable unit = 1 mg

NDC:

- Evenity 105 mg/1.17 mL single-use plastic prefilled syringe (carton of two): 55513-0880-xx
- Evenity 105 mg/1.17 mL single-use glass prefilled syringe (carton of two): 55513-0998-xx
- Evenity 105 mg/1.17 mL single-use glass prefilled syringe with automatic needle guard (carton of two): 55513-0509-xx

VII. References

1. Evenity [package insert]. Thousand Oaks, CA; Amgen Inc.; January 2026. Accessed June 2026.
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Appendix A – Non-Quantitative Treatment Limitations (NQL) Factor Checklist

Non-quantitative treatment limitations (NQLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
M80.00XA- M80.08XS	Age-related osteoporosis with current pathological fracture
M81.0	Age-related osteoporosis without current pathological fracture

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC