

romosozumab (Evenity)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: METABOLIC BONE DISEASE AGENTS

Mechanism of Action: sclerostin inhibitor

HCPCS:

J3111:Injection, romosozumab-aqqg, 1 mg

How Supplied:

105 mg/1.17 mL solution in a single-use prefilled syringe

Condition(s) listed in policy (see coverage criteria for details)

- Osteoporosis in Postmenopausal Women at High Risk for Bone Fracture

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

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ADMINISTRATION OF EVENITY IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE
REQUIRES ONE OF THE FOLLOWING: *Supporting Documentation must be submitted to support the need for additional clinical monitoring)*

1. **Patient is receiving their first dose or is being re-initiated after at least 6 months off therapy. Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.**

Or

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on the medication based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on the medication based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Osteoporosis in Postmenopausal Women at High Risk for Bone Fracture

Meets medical necessity if all the following are met:

1. One of the following:
 - a. One or more non-traumatic fractures
 - b. T-scores less than -2.5 S.D
 - c. T-score is between -1.0 and -2.5 and patient is at high risk for fracture [*e.g. multiple risk factors or 10-year hip fracture probability >/= 3% or a 10-year major osteoporosis-related fracture probability >/= 20% based on USA-adapted WHO absolute fracture risk model (FRAX risk assessment)*]
2. One of the following:
 - a. Intolerance to prior oral and IV bisphosphonate therapy or preferred denosumab biosimilar (i.e. Jubbonti), or contraindication to bisphosphonate (oral and IV) therapy and denosumab
 - b. Inadequate response, as evidenced by documented worsening BMD, with a bisphosphonate or preferred denosumab biosimilar (i.e. Jubbonti)
 - c. Patient is at very high risk of fracture by meeting at least one of the following:
 - i. Fracture while on bisphosphonate therapy or denosumab
 - ii. Patient has experienced a recent fracture (within the past 12 months) or history of multiple fractures
 - iii. Patient experienced a fracture while on long-term glucocorticoid therapy
 - iv. T-score less than -3.0
 - v. Patient is at high risk for falls
 - vi. 10-year hip fracture probability of > 4.5% based on FRAX score
 - vii. 10-year major osteoporosis-related fracture probability > 30% based on FRAX score

3. Not being used in combination with other drug therapy for osteoporosis (e.g., Forteo, teriparatide, Tymlos, denosumab)

Covered Doses:

210 mg given subcutaneously once monthly for 12 doses

Coverage Period:

One year

ICD-10:

M80.00XA, M80.00XD, M80.00XG, M80.00XK, M80.00XP, M80.00XS, M80.011A, M80.011D, M80.011G, M80.011K, M80.011P, M80.011S, M80.012A, M80.012D, M80.012G, M80.012K, M80.012P, M80.012S, M80.019A, M80.019D, M80.019G, M80.019K, M80.019P, M80.019S, M80.021A, M81.0, M81.6, M81.8

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Evenity (romosozumab-aqqg) Prescribing Information. Thousand Oaks, CA: Amgen Inc.; 4/2024.
4. Camacho PM, Petak SM, Blinkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis - 2020 UPDATE. *Endocr Pract.* 2020;26(Suppl 1):1-46.
5. Cosman F, de Beur SJ, LeBoff MS, et al. Clinician's Guide to Prevention and Treatment of Osteoporosis. *Osteoporos Int.* 2014;25(10):2359-2381
6. Qaseem A, Forciea MA, McLean RM, Denberg TD, Clinical Guidelines Committee of the American College of Physicians. Treatment of Low Bone Density or Osteoporosis to Prevent Fractures in Men and Women: A Clinical Practice Guideline Update From the American College of Physicians. *Ann Intern Med.* 2017;166(11):818-839.
7. Shoback D, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society guideline update. *J Clin Endocrinol Metab* 2020; 105:587-594.
8. ACOG Committee on Clinical Practice Guidelines—Gynecology. Management of Postmenopausal Osteoporosis: ACOG Clinical Practice Guideline No. 2. *Obstet Gynecol.* 2022 Apr 1;139(4):698-717. doi: 10.1097/AOG.0000000000004730. Erratum in: *Obstet Gynecol.* 2022 Jul 01;140(1):138.

Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- Osteoporosis: Removed management of bisphosphonate duration of use in patients who have documented worsening of BMD (Rationale: 2020 AACE Practice Guidelines for Osteoporosis)

Blue Shield of California Medication Policy to Determine Medical Necessity

Reviewed by P&T Committee

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