

## romosozumab (Evenity)

### Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

### 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 request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

### 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.

### 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  $\geq 3\%$  or a 10-year major osteoporosis-related fracture probability  $\geq 20\%$  based on USA-adapted WHO absolute fracture risk model (FRAX risk assessment)]*]

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A56538MADD\_1024

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Effective: 12/01/2024

Y0118\_24\_675A1\_C 10162024

H2819\_24\_675A1\_C Accepted 10212024

2. One of the following:
  - a. Intolerable side effect to bisphosphonate (oral and IV) therapy or Prolia, or contraindication to bisphosphonate (oral and IV) therapy and Prolia
  - b. Inadequate response, as evidenced by documented worsening BMD, following at least two years of therapy with a bisphosphonate or Prolia
  - c. Patient is at very high risk of fracture by meeting at least One of the following:
    - i. Fracture while on bisphosphonate therapy or Prolia
    - 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, Prolia)

**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

**Additional Information**

**Summary of Evidence**

The contents of this policy were created after examining the following resources:

1. The prescribing information for Evenity
2. ACOG Committee on Clinical Practice Guidelines–Gynecology. Management of Postmenopausal Osteoporosis: ACOG Clinical Practice Guideline No. 2 (2022)
3. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis - 2020 UPDATE
4. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update (2020)

**Explanation of Rationale:**

- Support for FDA-approved indications can be found in the manufacturer’s prescribing information
- Support for using bisphosphonates or Prolia for osteoporosis in postmenopausal women at high risk for bone fracture is found in several treatment guidelines:

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- The 2022 ACOG Clinical Practice Guideline on the Management of Postmenopausal Osteoporosis supports the use of antiresorptive agents (i.e., bisphosphonates and denosumab), which have broad-spectrum antifracture efficacy, as first-line therapy for most patients with osteoporosis and elevated fracture risk.
- The 2020 AACE/ACE Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis states that alendronate, denosumab, risedronate, and zoledronate are appropriate as initial therapy for most osteoporotic patients with high fracture risk.
- The 2020 Endocrine Society Guideline Update on the Pharmacological Management of Osteoporosis in Postmenopausal Women recommends bisphosphonates as initial treatment and denosumab as an alternative initial treatment in postmenopausal women at high risk for fractures.

## References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at <https://www.cms.gov/Medicare-Coverage-Database/search.aspx>
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS. Available by subscription at <http://www.lexi.com>
5. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
6. Evenity (romosozumab-aqqg) Prescribing Information. Thousand Oaks, CA: Amgen Inc.; 4/2024.
7. Camacho PM, Petak SM, Binkley 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.
8. 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
9. Qaseem A, Forcica 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.
10. 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.
11. 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: 4Q2024

Changes from previous policy version:

- New Part B policy

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Effective: 12/01/2024

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*

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