

Romosozumab-aqqg (Evenity®)

Place of Service

Office Administration

Infusion Center Administration

Home Infusion Administration

Outpatient Facility Administration*

[*Prior authorization required – see section (1)]

HCPCS: J3111 per 1 mg

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

- [Osteoporosis in postmenopausal women at high risk for bone fracture](#)

AHFS therapeutic class: bone anabolic agents

Mechanism of action: sclerostin inhibitor

(1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for romosozumab-aqqg (Evenity®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Osteoporosis in postmenopausal women at high risk for bone fracture

1. One of the following:

- a. Patient has one or more non-traumatic fractures as evident by chart notes, OR
- b. T-score less than or equal to -2.5 SD, OR
- 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 absolute fracture risk model (FRAX® risk assessment)]

AND

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, or
- b. Inadequate response, as evidenced by documented worsening BMD, following at least two years therapy with a bisphosphonate or Prolia, or
- 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, or
 - II. Patient has experienced a recent fracture (within the past 12 months) or history of multiple fractures, or
 - III. Patient experienced a fracture while on long-term glucocorticoid therapy, or
 - IV. T-score less than -3.0, or
 - V. Patient is at high risk for falls, or
 - VI. 10-year hip fracture probability of > 4.5% based on FRAX® score, or

- VII. 10-year major osteoporosis-related fracture probability > 30% based on FRAX® score

AND

3. **Effective 1/28/2024 and after:** Not being used in combination with other drug therapy for osteoporosis (e.g., Forteo, teriparatide, Tymlos, Prolia)

Covered Dose

Up to 210 mg SC once monthly for 12 doses

Coverage period

One year

ICD-10:

M80.0-M81.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for romosozumab-aqqg (Evenity®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 105 mg/1.17 mL single-use prefilled syringes (carton of two)

Table 1. Clinical Risk Factors for Osteoporosis-Related Fractures in POSTMENOPAUSAL WOMEN

Risk Factors
Prior low-trauma fracture as an adult
Advanced age (\geq 65yrs)
Low body weight [$<$ 57.6 kg(127lb)]
Family history of osteoporosis or fractures
Use of corticosteroids
Cigarette smoking
Excessive alcohol consumption (\geq 3 drinks per day)
Secondary osteoporosis (e.g. rheumatoid arthritis)
Early menopause

<https://www.aace.com/files/postmenopausal-guidelines.pdf>

FRAX tool: FRAX is a tool developed by the World Health Organization (WHO) to predict a patient's risk of having an osteoporosis-related fracture in the next 10 years. Generally, it is used for people not already being treated for osteoporosis. The calculation tool can be found at this link:

<http://www.shef.ac.uk/FRAX/>

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Evenity® (romosozumab-aqqg) [Prescribing information]. Thousand Oaks, CA: Amgen Inc.; 4/2020.
- 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.
- 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.
- 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.
- 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.

(7) Policy Update

Date of last review: 4Q2023

Date of next review: 4Q2024

Changes from previous policy version:

- Section (2): Osteoporosis in postmenopausal women at high risk for bone fracture –
 - **Effective 1/28/2024 and after**, will manage combination use with other drug therapies for osteoporosis
 - Removed management for cardiovascular events

Rationale: Evenity prescribing information

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*