**Effective Date ..... 1/15/2025**
**Coverage Policy Number.....IP0179**

# Romosozumab

## Table of Contents



## Related Coverage Resources

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## Overview

This policy supports medical necessity review for romosozumab-aqqg injection for subcutaneous use (**Evenity®**).

## Medical Necessity Criteria

**Romosozumab-aqqg (Evenity) is considered medically necessary when the following are met:**

1. **Osteoporosis Treatment for a Postmenopausal Woman.** Individual meets **ALL** the following criteria (A, B, and C):
    A. Individual meets **ONE** of the following conditions (i, ii, or iii):
        i. Individual has had a bone mineral density (BMD) T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist)

ii. Individual has had an osteoporotic fracture or a fragility fracture
iii. Individual meets **BOTH** of the following (a and b):
    a. Individual has low bone mass (for example, a T-score [current or at any time in the past] between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% [one third] radius [wrist])
    b. Prescriber determines that the individual is at high risk for fracture (for example, the FRAX® [fracture risk assessment tool] 10-year probability for major osteoporotic fracture is at least 20% or the 10-year probability of hip fracture is at least 3%)

B. Documentation of **ONE** of the following (i, ii, or iii):
    i. Individual has had failure or inadequate response to at least **ONE** of the following oral **OR** intravenous bisphosphonate products (a, b, c, or d):
    Examples of failure/inadequate response include, osteoporotic or fragility fracture while receiving bisphosphonate therapy, ongoing and significant loss of BMD, or lack of a BMD increase.

        a. alendronate tablets or oral solution (Fosamax)
        b. ibandronate intravenous injection or tablets (Boniva)
        c. risedronate tablets/delayed release tablets (Actonel/Atelvia)
        d. zoledronic acid intravenous infusion (Reclast)

    ii. Individual has a contraindication or significant intolerance to oral **AND** intravenous bisphosphonate therapy
    iii. Individual is at very high risk for fracture
    Examples include, recent fracture within past 12 months, fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than − 3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (e.g., major osteoporosis fracture > 30%, hip fracture > 4.5%)

C. Individual will not exceed a maximum of 12 monthly doses of treatment

**Dosing.** 210 mg of Evenity subcutaneously once every month for no more than 12 monthly doses during a therapy course.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

## Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: Not applicable for continuation beyond initial approval duration.

## Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Osteoporosis Prevention.** Evenity is not indicated for the prevention of osteoporosis.

2. **Concurrent Use with Other Medications for Osteoporosis.** Examples of medications for osteoporosis that Evenity should not be given with include oral bisphosphonates (e.g., alendronate, risedronate, ibandronate), intravenous bisphosphonates (zoledronic acid injection [Reclast], intravenous ibandronate), Prolia (denosumab subcutaneous injection), Forteo (teriparatide subcutaneous injection, generic), Tymlos (abaloparatide subcutaneous injection), and calcitonin nasal spray (Miacalcin/Fortical). However, this does NOT exclude use of calcium and/or vitamin D supplements in combination with Evenity.

## Coding Information

**Note:** 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

| HCPCS Codes | Description |
|---|---|
| J3111 | Injection, romosozumab-aqqg, 1 mg |

## References


1. Evenity® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; April 2024.
2. 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(3):587-594.
3. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2022; 33:2049-2102.


## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| Selected Revision | No criteria changes. | 12/15/2024 |
| Annual Revision | No criteria changes.<br><br>**Added** HCPCS coding table<br>**Added** HCPCS: J3111 | 1/15/2025 |

The policy effective date is in force until updated or retired.