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Romosozumab

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Related Coverage Resources

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Overview

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

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

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** of 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.

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

Evenity (romosozumab-aqqg) is considered experimental, investigational or unproven for **ANY** other use including the following (this list may not be all inclusive):

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.

Background

OVERVIEW

Evenity, a sclerostin inhibitor, is indicated for the treatment of **osteoporosis** in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.[1] It is recommended to adequately supplement with calcium and vitamin D during treatment with Evenity. According to the Evenity prescribing information, the anabolic effect of Evenity wanes after 12 monthly doses of therapy. Therefore, limit the duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive therapy (e.g., alendronate) should be considered.

Guidelines

Evenity is cited guidelines that discusses the management of postmenopausal osteoporosis.[2,3]

- **Postmenopausal Osteoporosis:** The Endocrine Society (2020) issued a guideline update regarding the pharmacological management of osteoporosis in postmenopausal women which addressed Evenity.[2] In postmenopausal women with osteoporosis at very high risk of fractures such as patients with severe osteoporosis (i.e., low T-score < -2.5 and fractures) or multiple fractures, Evenity therapy is recommended for up to 1 year for the reduction of vertebral, hip, and nonvertebral fractures. The recommended dose is 210 mg monthly by subcutaneous injection for 12 months. In postmenopausal women with osteoporosis who have completed a course of Evenity, antiresorptive osteoporosis therapy is recommended to maintain bone density gains and reduce fracture risk.
- **Treatment and Prevention of Osteoporosis:** In 2022, the Bone Health and Osteoporosis Foundation updated a guideline for the prevention and treatment of osteoporosis (2022).[3] In the 12-month FRAME trial involving women with postmenopausal osteoporosis, Evenity, compared with placebo, reduced the risk of new vertebral fracture by 73% and clinical fractures by 36%. In the ARCH trial, high-risk postmenopausal women experienced significantly fewer fractures when given Evenity compared with alendronate for 12 months (48% fewer new vertebral fractures, 19% fewer non-vertebral fractures, and 38% fewer hip fractures). However, the Boxed Warning that Evenity has regarding an increased risk for myocardial infarction, stroke, and cardiovascular death was concerning.

References

1. Evenity® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; April 2020.
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.