Kansas City

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Evenity (romosozumab-aqqg)

Policy Number: 5.02.564
Origination: 10/2019
Last Review: 10/2023
Next Review: 10/2024

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for **Evenity (romosozumab-aqqg)** when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Evenity (romosozumab-aqqg) may be considered **medically necessary** when all the following criteria are met:

FDA-Approved Indications

1. **Osteoporosis Treatment for a Postmenopausal Patient**. Approve for 1 year if the patient meets the following criteria (**A, B and C**):
   - A) The patient meets ONE of the following conditions (**i, ii, or iii**):
     - i. The patient has had a 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), **OR**
     - ii. The patient has had an osteoporotic fracture or a fragility fracture, **OR**
     - iii. The patient has low bone mass (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]) and the physician determines that the patient it at high risk for fracture; **AND**
   - B) The patient meets ONE of the following (**i, ii, iii, or iv**):
     - i. The patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (**a, b, or c**):
       - a) The patient has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing, and significant loss of bone mineral density (BMD), lack of BMD increase); **OR**
       - b) The patient has had an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy, **OR**

c) The patient has experienced intolerability to an oral bisphosphonate (e.g., severe gastrointestinal [GI]-related adverse events, severe musculoskeletal-related adverse events, a femoral fracture), **OR**

ii. The patient cannot take an oral bisphosphonate due to one of the following circumstances (**a, b, or c**):
   a) The patient cannot swallow or has difficulty swallowing, **OR**
   b) The patient cannot remain in an upright position post oral bisphosphonate administration, **OR**
   c) The patient has a pre-existing gastrointestinal (GI) medical condition (e.g., patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), **OR**

iii. The patient has tried ibandronate injection (Boniva IV) or zoledronic acid injection (Reclast), **OR**

iv. The patient meets one of the following conditions (a, b, or c):
   a) Severe renal impairment (creatinine clearance < 35 mL/min); **OR**
   b) Chronic kidney disease; **OR**
   c) The patient has had an osteoporotic fracture or a fragility fracture.

C) The patient has received no more than 12 monthly doses during this therapy course.

Limitations of use

The anabolic effect of Evenity wanes after 12 monthly doses of therapy. Therefore, the duration of use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an antiresorptive agent should be considered.

Drug must be sourced from an approved specialty pharmacy provider or infusion provider.

When Policy Topic is not covered

Evenity (romosozumab-aqqg) is considered **not medically necessary** when the above criteria are not met and **investigational** for all other uses.

Considerations

Evenity (romosozumab-aqqg) requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, local medical policies of other health plans, Medicare (CMS), local providers.

NCDs
https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=&keywordType=starts&areaId=s29&docType=NCD&contractOption=all

LCDs
https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=&keywordType=starts&areaId=s29&docType=F,P&contractOption=all

Description of Procedure or Service

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] 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 not addressed in current medical guidelines for the management of postmenopausal osteoporosis. Many guidelines are available regarding the management of postmenopausal osteoporosis.[2-5] In general, the guidelines recommend bisphosphonate therapy as initially for women in whom pharmacologic therapy is warranted (e.g., women at high risk of fractures) to reduce the risk of fractures. For patients who are extremely high risk of fracture (e.g., previously experienced an osteoporotic or fragility fracture) other osteoporosis therapies are recommended. Other agents are also recommended for women who cannot take bisphosphonate therapy (e.g., patients with severe renal impairment [creatinine clearance < 35 mL/min], chronic kidney disease) or who have an underlying gastrointestinal condition (e.g., esophageal lesions). In general, osteoporosis is defined by the presence of fragility fractures or among women with a T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius.[2] Therapy is also recommended among women who have a T-score between -1.0 and -2.5 if a substantial risk for major osteoporotic fracture is present (e.g., Fracture Risk Assessment Tool [FRAX®] score suggests high risk).

Rationale

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Evenity (romosozumab-aqqg) while maintaining optimal therapeutic outcomes.

Warnings and Precautions

- Bone Fractures: Atypical femur fractures have been reported in patients receiving romosozumab. The fractures may occur anywhere along the femoral shaft (may be bilateral) and commonly occur with minimal to no trauma to the area. Some patients experience prodromal pain weeks or

months before the fracture occurs. New or unusual thigh, hip, or groin pain should be reported to health care provider; any patient with thigh or groin pain should be suspected of having an atypical femur fracture and should be evaluated to rule out an incomplete femur fracture. If an atypical fracture is present, assess for signs/symptoms of fracture in contralateral limb. Consider interruption of therapy based on benefits/risks.

- Cardiovascular Risks:**[Black Boxed Warning]: Romosozumab may increase the risk of MI, stroke, and cardiovascular death and should not be initiated in patients who have had an MI or stroke within the previous year. Consider benefits/risks of therapy in patients with other cardiovascular risk factors. Discontinue use if MI or stroke occurs during therapy.**
- Hypocalcemia: Hypocalcemia may occur. Correct hypocalcemia prior to initiation of therapy (contraindicated in patients with uncorrected hypocalcemia). Ensure adequate supplementation with calcium and vitamin D during therapy and monitor calcium levels closely, particularly in patients predisposed to hypocalcemia (eg, severe renal impairment and/or receiving dialysis).
- Hypersensitivity: Hypersensitivity reactions (eg, angioedema, erythema multiforme, urticaria, rash, dermatitis) have occurred; discontinue use for serious reactions (eg, anaphylaxis) and treat appropriately.
- Osteonecrosis of the jaw: Osteonecrosis of the jaw (ONJ), also referred to as medication-related osteonecrosis of the jaw (MRONJ), has been reported in patients receiving romosozumab. Known risk factors for MRONJ include tooth extraction or other invasive dental procedures, cancer diagnosis, radiotherapy, concomitant therapy (eg, angiogenesis inhibitors, bisphosphonates, chemotherapy, corticosteroids, denosumab), poor oral hygiene, and comorbid disorders (anemia, coagulopathy, infection, preexisting dental or periodontal disease). Routine oral exam is recommended prior to initiation of therapy; patients should maintain good oral hygiene during treatment. Consider risk/benefits of therapy in patients requiring invasive dental procedures. Patients developing ONJ during therapy should receive care by an oral surgeon or dentist; consider discontinuation of therapy based on risk/benefit assessment.

Billing Coding/Physician Documentation Information

J3111	Injection, romosozumab-aqqg, 1 mg

Additional Policy Key Words

N/A

Policy Implementation/Update Information

10/2019	New policy titled Evenity (romosozumab-aqqg)
10/2020	Annual review – no changes made
10/2021	Annual review – no changes made

10/2022	Annual review – added Warning and Precautions
02/2023	Added 12 month limitation to approval
10/2023	Annual review – no changes made
