Medical Drug Clinical Criteria

Subject:	Evenity (romosozumab-aqqg)		
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Overview

This document addresses the use of Evenity (romosozumab-aqqg), a sclerostin inhibitor approved for the treatment of postmenopausal osteoporosis in a select population of women considered at high risk for fracture. Evenity is an anabolic agent, similar to Forteo (teriparatide) and Tymlos (abaloparatide), but has a unique mechanism of action.

The American College of Endocrinology (AACE/ACE) (2020) osteoporosis treatment guidelines stratify initial treatment based on risk status. For those at high risk/no prior fractures, initial therapy options include bisphosphonates (alendronate, risedronate, or zoledronic acid) or denosumab. For those at very high risk, initial therapy options are denosumab, abaloparatide, teriparatide, romosozumab, or zoledronic acid. Romosozumab may be viewed as a “rescue drug” in the near term and as an option for patients previously treated with abaloparatide or teriparatide.

The Endocrine Society osteoporosis guideline update (2020) recommends initial therapy with bisphosphonates (alendronate, risedronate, zoledronic acid, or ibandronate) or alternatively denosumab for those at high risk. Romosozumab is recommended for very high risk of fracture, such as those with severe osteoporosis (low T-score < -2.5 and fractures) or multiple vertebral fractures. Women at high risk of cardiovascular disease or stroke should not be considered for romosozumab pending further study.

Osteoporosis may be diagnosed by bone mineral density (BMD) testing indicating a T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population. It also may be clinically diagnosed based on a history of a fragility fracture (low trauma fracture). High risk for fracture is defined in the FDA label as history of osteoporotic fracture; or multiple risk factors for fractures; or a failure or intolerance to other osteoporosis therapies. A failure of other osteoporosis therapies, otherwise known as refractory disease, may be defined as a decline in BMD while on therapy (≥5%) or a fragility fracture while on therapy.

The original FDA submission of Evenity was denied based on cardiovascular safety findings in the pivotal studies. In response, the indication was narrowed to women at high risk for fracture and a black box warning was added. In addition, there is a lack of long term safety and efficacy data with Evenity; therefore, the label limits treatment duration to one year (12 monthly doses).

The black box warning for Evenity indicates the potential risk of myocardial infarction (MI), stroke, and cardiovascular death. It should not be initiated in patients who have had an MI or stroke within the preceding year and should be discontinued if a patient experiences an MI or stroke during therapy.

Clinical Criteria

When a drug is being reviewed for coverage under a member’s medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Evenity (romosozumab-aqqg)

Requests for Evenity (romosozumab-aqqg) may be approved for the following:

I. Individual is a postmenopausal female with the following:
   A. A diagnosis of osteoporosis (defined as a bone mineral density (BMD) T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture) at high risk for fracture;

AND

II. The individual meets one of the following:
   A. Individual is at very high risk for fracture as defined by one or more of the following (AACE/ACE 2020):
      1. Recent fracture (within the past 12 months)
      2. Fractures while on approved osteoporosis therapy
      3. Multiple fractures
      4. Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids)
      5. Very low T-score (less than -3.0)
      6. High risk for falls or history of injurious falls
      7. Very high fracture probability by FRAX (fracture risk assessment tool) (e.g. major osteoporosis fracture >30%, hip fracture >4.5%) or other validated fracture risk algorithm;

   OR

   B. Individual has been refractory to a prior trial of a bisphosphonate; **OR**
   C. Individual is intolerant to or has a contraindication to a bisphosphonate as defined by:
      1. Hypersensitivity to TWO bisphosphonates (one of which must be alendronate); **OR**
      2. Inability to stand or sit upright for at least 30 minutes; **OR**
      3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, atrophic gastritis, etc.); **OR**
      4. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents and zoledronic acid or creatinine clearance less than 30 mL/min for risedronate and ibandronate;

AND

III. Individual has been refractory to, is intolerant of, or has a contraindication to one of the following:
   A. Prolia (denosumab); **OR**
   B. Forteo or Bonsity (teriparatide); **OR**
   C. Tymlos (abaloparatide);

AND

IV. Individual is not using Evenity (romosozumab-aqqg) in combination with any of the following:
   A. Prolia (denosumab);
   B. Bisphosphonates;
   C. Evista (raloxifene);
   D. Miacalcin/Fortical (calcitonin nasal spray);
   E. Reclast (zoledronic acid);
   F. Forteo or Bonsity (teriparatide);
   G. Tymlos (abaloparatide);

AND

V. Individual has utilized Evenity (romosozumab-aqqg) for a total duration of less than 12 months in their lifetime.

Requests for Evenity (romosozumab-aqqg) may not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Evenity (romosozumab-aqqg) Quantity Limits

Drug	Limit
Evenity (romosozumab-aqqg) 105 mg/1.17mL prefilled syringe	2 prefilled syringes per month

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3111	Injection, romosozumab-aqqg, 1 mg Evenity]

ICD-10 Diagnosis

M80.00XA-M80.88XS	Osteoporosis with current pathological fracture
M81.0-M81.8	Osteoporosis without current pathological fracture

Document History

Reviewed: 08/18/2023
Document History:

- 08/18/2023 – Annual Review: No Changes. Coding Reviewed: No changes.
- 08/19/2022– Annual Review: No changes. Coding reviewed: No changes.
- 08/20/2021- Annual Review; No changes. Coding reviewed: No changes.
- 08/21/2020 – Annual Review: Update criteria to include factors for very high fracture risk in individuals who have not had a trial of a bisphosphonate; include Bonsity in combination criteria; remove uncorrected hypocalcemia as override for prior bisphosphonate. Administrative update to add drug specific quantity limit. Coding reviewed: No changes.
- 08/16/2019 – Annual Review: Update bisphosphonate trial requirement wording to account for intravenous options; wording and formatting updates. Coding Reviewed: Added HCPCS code J3111 for Evenity (Effective 10/1/19), Delete HCPCS codes J3490, J3590 (Effective 10/1/19).
- 05/17/2019 – Select Review: Add prior trail requirement of Prolia or Tymlos or Forteo.
- 04/10/2019 – Select Review: Add new clinical criteria document for Evenity (romosozumab-aqqg). Updated coding: added J3490, J3590 and M80.00XA-M80.88XS, M81.0-M81.8 dx codes.

References

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.