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 Endocrine Society (2019) and The American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) (2016) osteoporosis treatment guidelines recommend bisphosphonate agents (alendronate, risedronate, and zoledronic acid) initial therapy for most individuals at high risk of fracture given their efficacy to reduce hip, nonvertebral, and spine fractures. The Endocrine Society and AACE/ACE also recommend Prolia (denosumab) as initial (or alternative initial) treatment for those at high risk for fracture. For those at especially high fracture risk, the Endocrine Society recommends anabolic agents Forteo (teriparatide) or Tymlos (abaloparatide); AACE/ACE recommends Forteo (teriparatide), Prolia (denosumab), or zoledronic acid be considered in this population. Both guidelines precede FDA approval of Evenity.

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).
Higher risk for fracture may be defined as:
1. History of osteoporotic fracture; or
2. Multiple risk factors for fractures, including but not limited to: Prior low-trauma fracture as an adult, advanced age, gender, ethnicity, low bone mineral density, low body weight, family history of osteoporosis, use of glucocorticoids (daily dosage equivalent to 5 mg or greater prednisone for at least 3 months), cigarette smoking, excessive alcohol consumption (3 or more drinks per day), secondary osteoporosis (such as, rheumatoid arthritis), early menopause, height loss or kyphosis, fall risk and low calcium intake; or
3. 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. Has been refractory to a prior trial of a~~n oral~~ bisphosphonate; **OR**
   B. Is intolerant to or has a contraindication to a~~n oral~~ bisphosphonate as defined by:
      1. Hypersensitivity to TWO ~~oral~~ 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. Uncorrected hypocalcemia; **OR**
      5. 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 (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 (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.

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] (Effective 10/1/19)
J3490	Unspecified drugs when specified as [Evenity] (Delete 10/1/19)
J3590	Unspecified drugs when specified as [Evenity (Delete 10/1/19)

ICD-10 Diagnosis

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

Document History

Revised: 08/16/2019
Document History:

- 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.