Evenity (romosozumab-aqqg)

**Background**
Evenity inhibits the action of sclerostin, a regulatory factor in bone metabolism. Evenity increases bone formation and, to a lesser extent, decreases bone resorption. Animal studies showed that Evenity stimulates new bone formation on trabecular and cortical bone surfaces by stimulating osteoblastic activity resulting in increases in trabecular and cortical bone mass and improvements in bone structure and length (1).

**Regulatory Status**
FDA-approved indications: Evenity is a sclerostin inhibitor 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).

Limitations of use:
Limit duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered (1).

Evenity has a boxed warning regarding the potential to increase risk of myocardial infarction, stroke, and cardiovascular death. It should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. If a patient experiences a myocardial infarction or stroke during therapy, Evenity should be discontinued (1).
Pre-existing hypocalcemia must be corrected prior to initiating therapy with Evenity and patients must adequately supplement with calcium and vitamin D (1).

Evenity may increase risks for osteonecrosis of the jaw, hypocalcemia, and atypical femoral fracture (1).

The safety and effectiveness of Evenity in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Evenity may be considered medically necessary in postmenopausal women 18 years of age and older for osteoporosis and if the conditions indicated below are met.

Evenity may be considered investigational for patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age

18 years of age or older

Diagnosis

Patient must have the following:

Postmenopausal women with osteoporosis

AND ALL of the following:

a. Inadequate treatment response, intolerance, or contraindication to bisphosphonate therapy OR Prolia (denosumab)

b. Pre-existing hypocalcemia must be corrected prior to initiating therapy

c. Patient has T-score below -2.5 OR patient is at high risk for bone fracture(s) (prior osteoporotic fracture or multiple risk factors for fracture)

d. NO myocardial infarction or stroke within the preceding year
Prior – Approval Renewal Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 6 prefilled syringes per 90 days

Duration 12 months

Prior – Approval Renewal Limits

None

Rationale

Summary

Evenity inhibits the action of sclerostin, a regulatory factor in bone metabolism. Evenity increases bone formation and, to a lesser extent, decreases bone resorption. Animal studies showed that Evenity stimulates new bone formation on trabecular and cortical bone surfaces by stimulating osteoblastic activity resulting in increases in trabecular and cortical bone mass and improvements in bone structure and length. The safety and effectiveness of Evenity in pediatric patients less than 18 years of age have not been established (1).

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

References

**Section:** Prescription Drugs  **Effective Date:** October 1, 2019

**Subsection:** Endocrine and Metabolic Drugs  **Original Policy Date:** April 26, 2019

**Subject:** Evenity  **Page:** 4 of 5

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2019</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review</td>
</tr>
<tr>
<td>September 2019</td>
<td>Annual review. Changed requirement to trial and failure of bisphosphonate or Prolia and changed requirement to T-score below -2.5 or high risk for fracture per SME</td>
</tr>
</tbody>
</table>

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.
### Appendix 1 - List of PA Osteoporosis Medications

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>abaloparatide</td>
<td>Tymlos</td>
</tr>
<tr>
<td>denosumab</td>
<td>Prolia</td>
</tr>
<tr>
<td>romosuzumab-aqqg</td>
<td>Evenity</td>
</tr>
<tr>
<td>Teriparatide</td>
<td>Forteo</td>
</tr>
</tbody>
</table>