

## UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Bone Modifiers – Evenity Utilization Management Medical Policy

- Evenity® (romosozumab-aqqg subcutaneous injection – Amgen)

**REVIEW DATE:** 05/18/2022

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### 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.<sup>1</sup> 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 in a guideline that discusses the management of postmenopausal osteoporosis.<sup>2</sup>

- **Postmenopausal Osteoporosis:** The Endocrine Society (2020) issued a guideline update regarding the pharmacological management of osteoporosis in postmenopausal women which addressed Evenity.<sup>2</sup> 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 SC 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.

### POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Evenity. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Coverage is limited to 12 monthly doses during the therapy course. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Evenity is recommended in those who meet the following criteria:

#### FDA-Approved Indication

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1. **Osteoporosis Treatment of a Postmenopausal Patient.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, and C):
    - A) The patient meets ONE of the following conditions (i, ii, or iii):

- i. 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. Patient has had an osteoporotic fracture or a fragility fracture; OR
  - iii. Patient meets both of the following (a and b):
    - a) Patient has low bone mass; AND  
Note: Examples of a low bone mass include 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 patient is at high risk for fracture; AND
- B) The patient meets ONE of the following (i, ii, iii, or iv):
- i. Patient has tried ibandronate injection (Boniva IV) or zoledronic acid injection (Reclast); OR
  - ii. Patient has tried one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a, b, or c):  
Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), and Boniva (ibandronate tablets).
    - a) Patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber; OR  
Note: An example of inadequate efficacy is ongoing and significant loss of bone mineral density (BMD) or a lack of a BMD increase.
    - b) Patient has had an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy; OR
    - c) Patient has experienced significant intolerance to an oral bisphosphonate; OR  
Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, or a femoral fracture.
  - iii. Patient cannot take an oral bisphosphonate due to one of the following circumstances (a, b, or c):
    - a) Patient cannot swallow or has difficulty swallowing; OR
    - b) Patient cannot remain in an upright position post oral bisphosphonate administration; OR
    - c) Patient has a pre-existing gastrointestinal medical condition; OR  
Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).
  - iv. Patient meets one of the following conditions (a, b, or c):
    - a) Severe renal impairment; OR  
Note: An example of severe renal impairment is a creatinine clearance < 35 mL/min.
    - b) Chronic kidney disease; OR
    - c) Patient has had an osteoporotic fracture or a fragility fracture; AND
- C) Patient has received no more than 12 monthly doses during this therapy course.

**Dosing.** Approve 210 mg of Evenity subcutaneously once every month for no more than 12 monthly doses during a therapy course.

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#### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Evenity is not recommended in the following situations:

1. **Osteoporosis Prevention.** Evenity is not indicated for the prevention of osteoporosis.
2. **Concurrent Use of Other Medications for Osteoporosis.**

Note: 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.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### 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.

### HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<b>Osteoporosis – Treatment for a Postmenopausal Patient:</b> The definition of low bone mass was moved from the criteria to a Note. Also, the wording that the “prescribing physician” had to make this determination was changed to state “prescriber”. Regarding the criterion that requires a trial of one oral bisphosphonate, the examples of oral bisphosphonates are now provided in a Note. The wording for the criterion regarding inadequate response to an oral bisphosphonate was changed to “experienced inadequate efficacy”. For this criterion, “prescribing physician” was changed to “prescriber”. The examples of inadequate efficacy to an oral bisphosphonate were moved from the criteria to a Note. The wording regarding intolerability to an oral bisphosphonate was changed to “experienced significant intolerance”. The examples of significant intolerance were moved from the criteria to a Note. The examples of pre-existing gastrointestinal medical conditions were moved from the criteria to a Note. The example of severe renal impairment (creatinine clearance < 35 mL/min) was moved from the criteria to a Note.	04/28/2021
Annual Revision	<b>Conditions Not Recommended for Approval:</b> To the Note which lists the medications that should not be used with Evenity, it was clarified that this does NOT exclude use of calcium and/or vitamin D supplements in combination with Evenity.	05/18/2022