

POLICY: Bone Modifiers – Evenity™ (romosozumab-aqqg injection for subcutaneous use – Amgen)

DATE REVIEWED: 04/22/2020

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.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).

In 2020 the Endocrine Society issued a guideline update regarding the pharmacological management of osteoporosis in postmenopausal women which addressed Evenity.⁶ 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. Coverage is limited to 12 monthly doses during the therapy course. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. 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.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

- 1. Osteoporosis Treatment of 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 is at high risk for fracture; AND
 - B)** The patient meets ONE of the following (i, ii, iii, or iv):
 - i.** The patient has tried 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.

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Evenity has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Osteoporosis Prevention.** Evenity is not indicated for the prevention of osteoporosis.
2. **Concurrent Use of Other Medications for Osteoporosis.**
Note: Examples include oral bisphosphonates (e.g., alendronate, risedronate, ibandronate), intravenous bisphosphonates (zoledronic acid injection [Reclast], intravenous ibandronate), Prolia® (denosumab injection for subcutaneous use), teriparatide injection for subcutaneous use (Forteo®/Bonsity®), Tymlos® (abaloparatide injection for subcutaneous use), and calcitonin nasal spray (Miacalcin®/Fortical®).
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™ injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; December 2019.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis. *Endocrin Pract.* 2016;22(Suppl 4):1-42. Available at: <http://journals.aace.com/doi/pdf/10.4158/EP161435.GL>. Accessed on April 16, 2020.
3. Cosman F, de Beur SJ, LeBoff MS, et al. Clinician’s guide to prevention and treatment of osteoporosis. *Osteoporos Int.* 2014;25:2359-2381. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4176573/pdf/198_2014_Article_2794.pdf. Accessed on April 16, 2020.
4. Qaseem A, Forciae MA, McLean RM, et al, Clinical Guidelines Committee of the American College of Physicians. Treatment of low bone density or osteoporosis to prevent fractures in men and women: a clinical practice guideline update from the American College of Physicians. *Ann Intern Med.* 2017;166(11):818-839.
5. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2019;104:1595-1622.
6. 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*	Date Reviewed
New Policy	---	04/17/2019
Selected revision	Osteoporosis Treatment for a Postmenopausal Patient: The criterion that requires that the patient has received no more than 12 monthly doses during their lifetime was modified to remove “their lifetime” and replaced with the phrasing “this therapy course.” There is no lifetime therapy limit listed in product labeling.	05/08/2019
Annual revision	The following changes were made: 1. Conditions Not Recommended for Approval: For the criteria regarding Concurrent Use of Other Medications for Osteoporosis, the examples of other medications used for osteoporosis were moved from the criteria to a note. Reference to calcium and vitamin D was deleted.	04/22/2020