VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Bone Modifiers – Evenity Utilization Management Medical Policy
- Evenity® (romosozumab-aqqg subcutaneous injection – Amgen)

REVIEW DATE: 10/23/2024

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] 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. Evenity should be administered by a healthcare provider.

Guidelines

Evenity is cited in guidelines that discuss the management of postmenopausal osteoporosis.[2,3]

- **Postmenopausal Osteoporosis:** The Endocrine Society (2020) issued a guideline update regarding the pharmacological management of osteoporosis in postmenopausal women which addressed Evenity.[2] 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 subcutaneous 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.
- **Treatment and Prevention of Osteoporosis:** In 2022, the Bone Health and Osteoporosis Foundation updated a guideline for the prevention and treatment of osteoporosis (2022).[3] In the 12-month FRAME trial involving women with postmenopausal osteoporosis, Evenity, compared with placebo, reduced the risk of new vertebral fracture by 73% and clinical fractures by 36%. In the ARCH trial, high-risk postmenopausal women experienced significantly fewer fractures when given Evenity compared with alendronate for 12 months (48% fewer new vertebral fractures, 19% fewer non-vertebral fractures, and 38% fewer hip fractures). However, the Boxed Warning that Evenity has regarding an increased risk for myocardial infarction, stroke, and cardiovascular death was concerning.

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 (A, B, and C):
   - **A)** The patient meets ONE of the following (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)** According to the prescriber, 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 at least one oral bisphosphonate or oral bisphosphonate-containing product and meets ONE of the following (a or b):
       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)** According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
         Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
       - **b)** 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 (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 (a or b):
       - **a)** According to the prescriber, the patient has severe renal impairment or chronic kidney disease; OR
         Note: An example of severe renal impairment is a creatinine clearance < 35 mL/minute.
       - **b)** 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 administered subcutaneously once every month for no more than 12 monthly doses during a therapy course.

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 2024.
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.
3. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2022;33:2049-2102.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Osteoporosis – Treatment for a Postmenopausal Patient:** The exception that the patient has had an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy was removed. Instead, this exception was incorporated into a Note that lists osteoporotic fracture or a fragility fracture as an example of inadequate efficacy or significant intolerance to a trial of an oral bisphosphonate or an oral bisphosphonate-containing product.	05/24/2023
Annual Revision	No criteria changes.	06/05/2024
Early Annual Revision	**Osteoporosis Treatment for a Postmenopausal Patient:** The exception to the requirement for a trial of a bisphosphonate due to severe renal impairment or chronic kidney disease were revised. The criteria are now combined and the phrase "according to the prescriber" was added.	10/23/2024