Drug Coverage Policy

Effective Date.....2/1/2026
Coverage Policy Number.....IP0179
Policy Title.....Evenity

Bone Modifiers – Evenity

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

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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. The American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) [2020] clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis list Evenity as an option for patients unable to use oral therapy and as initial therapy for patients at very high fracture risk.[4] AACE/ACE advise limiting treatment with Evenity to 1 year and following with a drug intended for long-term use, such as a bisphosphonate or denosumab.
- **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.

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POLICY STATEMENT

Prior Authorization is required 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.

Evenity is considered medically necessary when the following are met:

FDA-Approved Indication

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), Binosto (alendronate effervescent tablets for oral solution), 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 Covered

Evenity for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as newly published data are available):

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, calcium and/or vitamin D supplements may be used in combination with this medication.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Coding Information

Note:
1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J3111	Injection, romosozumab-aqqg, 1 mg

References

1. Evenity® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; October 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.
4. 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-2020 update. *Endocrin Pract*. 2020;26(Suppl 1):1-46.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	No criteria changes.	12/15/2024
Annual Revision	No criteria changes. **Added** HCPCS coding table **Added** HCPCS: J3111	1/15/2025
Annual Revision	**Osteoporosis Treatment for a Postmenopausal Patient:** • Binosto (alendronate effervescent tablets for oral solution) added as an example of a bisphosphonate.	2/1/2026

	• Added criterion for approval of Evenity where patient cannot take an oral bisphosphonate. • Added criterion for approval of Evenity where patient has severe renal impairment. • Added examples for inadequate efficacy and intolerance. **Conditions Not Recommended for Approval:** For Concurrent Use with Other Medications for Osteoporosis, the Note was modified from "this does NOT exclude use of calcium and/or vitamin D supplements in combination with Evenity" to "calcium and/or vitamin D supplements may be used in combination with this medication." **Updated Coverage Policy Title:** Changed from "*Romosozumab*" to "*Bone Modifiers – Evenity*." **Other Updates:** • Updated policy template and criteria format.	

The policy effective date is in force until updated or retired.