BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.30.063

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	April 26, 2019
Subject:	Evenity	**Page:**	1 of 5

Last Review Date: March 8, 2024

Evenity

Description

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

Parathyroid Hormone Analogs, Prolia, Xgeva

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** if the conditions indicated below are met.

Evenity may be considered **investigational** 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
e. **NO** cumulative therapy with Evenity for longer than 12 months

f. **NO** concurrent therapy with another Prior Authorization (PA) medication for osteoporosis (see Appendix 1)

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

1. Evenity [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2020.

Policy History

Date	Action

April 2019	Addition to PA
June 2019	Annual review
September 2019	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
December 2020	Annual review and reference update
March 2021	Annual review
March 2022	Annual review
December 2022	Annual review. Changed policy number to 5.30.063
March 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 - List of PA Osteoporosis Medications

Generic Name	Brand Name
abaloparatide	Tymlos
denosumab	Prolia
romosuzumab-aqqg	Evenity
teriparatide	Bonsity
teriparatide	Forteo
teriparatide	Teriparatide