Bone Density Regulators – Sclerostin Inhibitors

WA.PHAR.145 Effective Date: 6/1/2025

Related medical policies:

Policy Name	Indications
Bone Density Regulators – Calcitonins	Hypercalcemia Paget's Disease Postmenopausal Osteoporosis Osteoporosis/Bone loss
Bone Density Regulators – Parathyroid Hormone Derivatives	Glucocorticoid Induced Osteoporosis Male Osteoporosis Postmenopausal Osteoporosis
Bone Density Regulators- RANKL Inhibitors	Giant cell tumor of bone Glucocorticoid-induced Osteoporosis Hypercalcemia of malignancy Multiple Myeloma and bone metastasis from solid tumors Postmenopausal Osteoporosis Treatment of bone loss in men prostate cancer Treatment of bone loss in women with breast cancer

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit:
https://www.coordinatedcarehealth.com/content/dam/centene/centene-pharmacy/pdl/FORMULARY-CoordinatedCare_Washington.pdf

Medical necessity

Drug	Medical Necessity
romosozumab-aqqg (Evenity)	**Romosozumab-aqqg (Evenity)** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Postmenopausal osteoporosis romosozumab-aqqg (Evenity)	Romosozumab-aqqg (Evenity) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND**

	2. Diagnosis of osteoporosis; **AND** 3. Patient is a postmenopausal female; **AND** 4. At least **ONE** of the following fracture risk categories is met: a. Presence of fragility fractures of the hip or spine regardless of bone mineral density; **OR** b. T-score ≤ -2.5 in the lumbar spine, femoral neck, total hip; **OR** c. T-score between -1 and -2.5 with a history of recent fragility fracture of proximal humerus, pelvis, or distal forearm; **OR** d. T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; **AND** 5. Medication will not be used in combination with other bone density regulators (e.g., bisphosphonates, raloxifene, RANKL inhibitors); **AND** 6. Romosozumab-aqqg may be considered medically necessary for first line therapy for severe osteoporosis if PTH analogs are contraindicated or not tolerated. Severe osteoporosis is defined as either of the following: i. T-score ≤ -2.5 with a fragility fracture; **OR** ii. History of multiple fragility fractures; **OR** iii. T-score ≤ -3 regardless of previous therapy; **OR** 7. Treatment with **ALL** the following has been ineffective unless all are contraindicated or not tolerated: a. One Preferred Apple Health Preferred Drug List (PDL) oral or intravenous bisphosphonate [minimum trial of 12 months]; **AND** b. One Preferred Apple Health Preferred Drug List (PDL) selective estrogen receptor modulator (SERM) [minimum trial of 24 months]; **AND** c. Prolia [minimum trial of 12 months] If ALL criteria are met, the request will be authorized for up to a total of 12 months of treatment per lifetime. **Criteria (Reauthorization)** romosozumab-aqqg (Evenity) cannot be renewed and may only be authorized for up to a total of 12 months of treatment per lifetime.

Dosage and quantity limits

Drug	Indication	FDA Approved Dosing	Dosage Form and Quantity Limit
romosozumab-aqqg (Evenity)	Postmenopausal osteoporosis	210 mg subcutaneously (divided into two separate 105 mg doses) once every month for a total of 12 months	• 105 mg/1.17 mL prefilled syringe: 2.34 mL/28 days

			*May only be authorized for up to a total of 12 months of treatment per lifetime.

Coding:

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

Background:

Osteoporosis is characterized by decreased bone mass and increased fracture risk, most commonly at the spine, hip, and wrist. The definition of osteoporosis with high risk of fracture is defined for men and women as BMD T-score of spine, femoral neck, and/or total hip <-2.5 without fracture, having history of hip or vertebral fracture regardless of BMD, T-score ≤ -1 and a history of recent fracture of proximal humerus, pelvis, or distal forearm, T-score between -1.0 and -2.5 in the spine, femoral neck, or total hip with a -20% 10-year FRAX risk of any fracture or -3% risk of hip fracture, and receiving long-term glucocorticoid doses greater than or equal to prednisone 7.5mg per day. The treatment of osteoporosis consists of lifestyle management (e.g., adequate calcium and vitamin D, exercise, smoking cessation, fall prevention measures, and avoidance of heavy alcohol use) and pharmacologic therapy. Patients with the highest risk of fracture are expected to derive the greatest benefit from medication therapy. The 2020 AACE/ACE treatment guideline recommendations are as follows:

1. Initial treatment for high fracture risk: alendronate, denosumab, risedronate, or zoledronic acid
2. Treatment for very-high fracture risk or patients who cannot tolerate or adhere to oral bisphosphonates: zoledronic acid, abaloparatide, denosumab, romosozumab, teriparatide

Additionally, the 2020 Endocrine Society guidelines recommend bisphosphonates as initial treatment for high-risk patients, while denosumab may be considered as an alternative initial treatment. For patients with a very high risk of fracture, teriparatide and abaloparatide are recommended. It is recommended that antiresorptive therapies follow treatment with parathyroid hormones

References

1. Evenity [package insert]. Thousand Oaks, CA; Amgen, Inc.; April 2020.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis-2020 update. Endocr Pract. 2020;26(Suppl 1):1-46.
3. Shoback D, Rosen CJ, Black DM, Cheung AM, Murad MH, Eastell R. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society guideline update. J Clin Endocrinol Metab. 2020;105(3):dgaa048.

History

Approved Date	Effective Date	Version	Action and Summary of Changes
10/16/2024	06/01/2025	30.04.48-2	Approved by DUR Board -New policy
	10/01/2019	30.04.00-1	• 07.31.2019 Updated abaloparatide, teriparatide criteria • 05.31.2019 Updated abaloparatide, teriparatide, and densoumab reauthorization criteria

			• 04.01.2019 Added Brands with Generic Equivalents policy; updated abaloparatide and teriparatide clinical policies • 04.18.2018 New Policy