Evenity (romosozumab-aqqg) Medical Drug Criteria Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
02-01-2025

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
EVENITY® (romosozumab-aggg) Subcutaneous Injection	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 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

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Postmenopausal Osteoporosis	The American Association of Clinical Endocrinologists/American College of Endocrinology joint guidelines for postmenopausal osteoporosis state that there are several pathways to diagnose osteoporosis.(3) • T-score -2.5 or below in the lumbar spine, femoral neck, total proximal femur or distal 1/3 of the radius • Low-trauma spine or hip fracture (regardless of bone mineral density) • T-score between -1.0 and -2.5 and a fragility fracture of proximal humerus, pelvis, or distal forearm • T-score between -1.0 and -2.5 and high FRAX (Fracture Risk Assessment Tool) (or if available, TBS [trabecular bone score]-adjusted FRAX) fracture based on country-specific thresholds The World Health Organization (WHO) has defined T-score criteria as follows:(3) • Normal: T-score -1.0 or above • Osteopenia: T-score between -1.0 and -2.5 • Osteoporosis: T-score at or below -2.5 • Severe or established osteoporosis: -2.5 or below with fragility fracture
Very High-Risk Postmenopausal Women	The 2020 American Association of Clinical Endocrinology (AACE) Guidelines created a 'very high-risk' category for post-menopausal women with osteoporosis. The following patients are considered to be at very high fracture risk:(3) • Patients with a recent fracture (within the past 12 months) • Patients with fractures while on approved osteoporosis therapy • Patients with multiple fractures

	• Patients with fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) • Patients with a very low T-score (less than -3.0) • Patients with a high risk for falls or history of injurious falls • Patients with very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or other validated fracture risk algorithm Patients who have been diagnosed with osteoporosis but do not meet the above definition of very high fracture risk are considered to be at high risk.(3) The AACE recommends alendronate, denosumab, risedronate, and zoledronate as appropriate initial therapy for most osteoporotic patients with high fracture risk. Abaloparatide, denosumab, romosozumab, teriparatide, and zoledronate should be considered for patients unable to use oral therapy and as initial therapy for patients at very high fracture risk.(3)
Treatment	According to the The Bone Health and Osteoporosis Foundation, postmenopausal women and men age 50 and older presenting with the following should be considered for treatment:(2) • A hip or vertebral fracture • A fracture of the pelvis, proximal humerus, or distal forearm in a person with low bone mass or osteopenia • T-score of -2.5 or lower at the femoral neck, total hip, lumbar spine, or 33% radius • T-score between -1 and -2.5 at the femoral neck or total hip and a 10-year probability of a hip fracture greater than or equal to 3% or a 10-year probability of a major osteoporosis-related fracture greater than or equal to 20% based on the US-adapted FRAX algorithm In their 2020 Postmenopausal Osteoporosis Guidelines, the AACE stated that osteoporosis can be diagnosed if there is a fragility fracture in the absence of other metabolic bone disease, independent of the T-score. Thus, patients with a T-score indicating osteopenia, but who have had a fragility fracture of the spine, hip, proximal humerus, pelvis, or distal forearm should be diagnosed with osteoporosis and considered for pharmacologic therapy.(3) The American College of Rheumatology recommends against the use of EVENITY in glucocorticoid induced osteoporosis except in patients intolerant of other agents.(4)
Safety	EVENITY carries several boxed warnings:(1) • EVENITY may increase the risk of myocardial infarction, stroke and cardiovascular death. • EVENITY should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. If a patient experiences a myocardial infarction or stroke during therapy, EVENITY should be discontinued. EVENITY carries the following contraindications:(1) • Hypocalcemia • Known hypersensitivity to EVENITY or to any component of the product formulation Pre-existing hypocalcemia must be corrected prior to initiating therapy with EVENITY.(1)

REFERENCES

Number	Reference
1	EVENITY prescribing information. Amgen Pharmaceuticals. April 2020.
2	LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporosis International*. 2022;33(10):2049-2102. doi:10.1007/s00198-021-05900-y
3	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. https://www.endocrinepractice.org/article/S1530-891X(20)42827-7/fulltext
4	Humphrey MB, Russell L, Danila MI, et al. 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis & Rheumatology*. 2023;75(12):2088-2102. doi:10.1002/art.42646
5	Reference no longer used.
6	Reference no longer used.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

HCPC Codes	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
J3111	Evenity	romosozumab-aqqg inj soln prefilled syringe	105 MG/1.17ML	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Evenity	romosozumab-aqqg inj soln prefilled syringe	105 MG/1.17 ML	2	Syringes	30	DAYS	One year cumulative maximum duration of therapy for Evenity		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Evenity	romosozumab-aqqg inj soln prefilled syringe	105 MG/1.17ML	Commercial ; HIM ; ResultsRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Evenity	romosozumab-aqqg inj soln prefilled syringe	105 MG/1.17ML	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. The patient has a diagnosis of osteoporosis and ALL of the following: A. ONE of the following: 1. The patient's sex is female and ONE of the following: A. The patient is postmenopausal **OR** B. The requested agent is medically appropriate for the patient's sex and menopause status **OR** 2. The patient's sex is male AND the requested agent is medically appropriate for the patient's sex **AND** B. The patient's diagnosis was confirmed by ONE of the following: 1. A fragility fracture in the hip or spine **OR** 2. A T-score of -2.5 or lower **OR** 3. A T-score of -1.0 to -2.5 and ONE of the following: A. A fragility fracture of the proximal humerus, pelvis, or distal forearm **OR** B. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** C. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** C. ONE of the following: 1. The patient is at a very high fracture risk as defined by ONE of the following: A. Patient had a recent fracture (within the past 12 months) **OR** B. Patient had fractures while on FDA labeled osteoporosis therapy **OR** C. Patient has had multiple fractures **OR** D. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** E. Patient has a very low T-score (less than -3.0) **OR** F. Patient is at high risk for falls or has a history of injurious falls **OR** G. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** 2. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 3. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 4. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **AND** 2. ONE of the following: A. The patient is not hypocalcemic **OR** B. If the patient is hypocalcemic, it will be corrected prior to use of the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), or parathyroid hormone analog for osteoporosis (e.g., abaloparatide, teriparatide) **AND** 4. The patient does not have any FDA labeled contraindications to the requested agent **AND** 5. The requested quantity (dose) is within FDA labeled dosing **AND** 6. The total duration of treatment with EVENITY (romosozumab-aqqg) has not exceeded 12 months in lifetime **Length of Approval:** up to a total of 12 months of treatment per lifetime