Medical Policy:
EVENITY® (romosozumab)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.195	July 3, 2023	

Definitions

Romosozumab is a parenteral humanized IgG2 monoclonal antibody and sclerostin inhibitor indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, which is 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. Romosozumab has a dual effect of increasing bone formation and, to a lesser extent, decreasing bone resorption.

Length of Authorization

Coverage will be provided for 12 months and may NOT be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 210 mg every (1) month

Guideline

I. Initial Approval Criteria

Evenity *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

Osteoporosis

Evenity is medically necessary when ALL of the following criteria are met:

1. Diagnosis of postmenopausal osteoporosis; **AND**
2. Patient has **ONE** of the following: A, B, **or** C
   - A. BMD T-score ≤-2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); **OR**
   - B. History of one of the following resulting from minimal trauma:
     - a. Vertebral compression fracture
     - b. Fracture of the hip
     - c. Fracture of the distal radius
     - d. Fracture of the pelvis
     - e. Fracture of the proximal humerus; **OR**
   - C. **Both** of the following:
     - a. BMD T-score between -1 and -2.5 (BMD T-score greater than-2.5 and less than or equal to -1) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); **AND**
     - b. **ONE** of the following:
       - i. FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more
       - ii. FRAX 10-year fracture probabilities: hip fracture at 3% or more; **AND**
3. History of failure, contraindication, or intolerance to oral or intravenous bisphosphonate therapy; **AND**
4. Patient is not receiving Evenity in combination with any of the following:
   - A. Parathyroid hormone analogs (e.g., Forteo, Tymlos)
   - B. RANK ligand inhibitors (e.g., Prolia, Xgeva); **AND**
5. Evenity dosing is in accordance with the United States Food and Drug Administration approved labeling: 210mg once monthly; **AND**
6. Authorization is for no more than 12 months.

Limitations/Exclusions

Evenity is not considered medically necessary for when any of the following selection criteria is met:

1. The patient has had an MI or stroke within the previous year
2. The patient has uncorrected hypocalcemia

Dosage/Administration

Indication	Dose
Osteoporosis	Administer 210 mg subcutaneously (as two separate subcutaneous injections of 105 mg each) by a health care provider every month for a total of 12* monthly doses.

Applicable Procedure Codes

Code	Description
J3111	Effective 10/1/19, Injection, romosozumab-aqqg, 1 mg

Applicable NDCs

Code	Description
55513-0880-xx	Romosozumab-aqqg 105 mg per 1.17 mL Subcutaneous Solution Prefilled Syringe

ICD-10 Diagnoses

Code	Description
M80.00XA - M80.08XS	Age-related osteoporosis with current pathological fracture
M81.0	Age-related osteoporosis without current pathological fracture

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	7/3/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	6/14/2022	Transferred policy to new template.
EmblemHealth & ConnectiCare	8/15/2019	Removed J3590, Added New code J3111, effective 10/1/19.

References

1. Evenity™ injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; April 2019.
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3. Saag KG, Petersen J, Brandi ML, et al. Romosozumab or alendronate for fracture prevention in women with osteoporosis. *N Engl J Med*. 2017;377(15):1417-1427. [Supplementary Appendix].
4. Lewiecki EM, Danavahi RV, Lazaretti-Castro M, et al. One year of romosozumab followed by two years of denosumab maintains fracture risk reductions: result of the FRAME extension study. *J Bone Miner Res*. 2019;34(3):419-428.
5. Langdahl BL, Crittenden DB, Bolognese MA, et al. Romosozumab (sclerostin monoclonal antibody) versus teriparatide in postmenopausal women with osteoporosis transitioning from oral bisphosphonate therapy: a randomized, open-label, phase 3 trial. *Lancet*. 2017;390:1585-1594.
6. Lewiecki EM, Blicharski T, Goemaere S, et al. A Phase III randomized placebo-controlled trial to evaluate efficacy and safety of romosozumab in men with osteoporosis. *J Clin Endocrinol Metab*. 2018;103(9):3183-3193.
7. McClung MR, Grauer A, Boonen S, et al. Romosozumab in postmenopausal women with low bone mineral density. *N Engl J Med*. 2014;370(5):412-240.

8. Genant HK, Engelke K, Bolognese MA, et al. Effects of romosozumab compared with teriparatide on bone density and mass at the spine and hip in postmenopausal women with low bone mass. *J Bone Miner Res*. 2017;32(1):181-187.
9. Keaveny TM, Crittenden DB, Bolognese MA, et al. Greater gains in spine and hip strength for romosozumab compared with teriparatide in postmenopausal women with low bone mass. *J Bone Miner Res*. 2017;32(9):1956-1962.
10. Graeff C, Campbell GM, Pena J, et al. Administration of romosozumab improves vertebral trabecular and cortical bone as assessed with quantitative computed tomography and finite element analysis. *Bone*. 2015;81:364-369.
11. McClung MR, Brown JP, Diez-Perez A, et al. Effects of 24 months of treatment with romosozumab followed by 12 months of denosumab or placebo in postmenopausal women with low bone mineral density: a randomized, double-blind, phase 2, parallel group study. *J Bone Miner Res*. 2018;33(8):1397-1406.