Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 5, 2023 May 8, 2024

EVENITY® (romosozumab-aqqg)

LENGTH OF AUTHORIZATION: Up to 1 year; Lifetime maximum of 12 monthly doses.

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Prescribed by or in consultation with a specialist (endocrinologist, rheumatologist, or obstetrician/gynecologist)
- Patient must be post-menopausal AND have a diagnosis of osteoporosis indicated by at least one of the following:
    - DXA hip (femoral neck) or spine T-score ≤ -2.5 (dated within the past year); **OR**
    - History of a fracture of the spine or hip (must be confirmed in medical records); **OR**
    - History of T-score between -1.0 and -2.5 if FRAX (WHO Fracture Risk Assessment Tool) major osteoporotic fracture probability is ≥ 20% or hip fracture probability is 3% (must be confirmed in medical records).
- Patient has not had a heart attack or stroke within the past 12 months.
- Patient must be receiving daily calcium and vitamin D supplementation.
- Patient must not have hypocalcemia. (Pre-existing hypocalcemia must be corrected prior to initiating therapy).
- Patient must have documented treatment failure or an inadequate response to ≥ 12 month trial of the following unless intolerant or contraindicated:
    - Injectable bone resorption inhibitors (i.e., pamidronate or zoledronic Acid); AND
    - Oral bisphosphonate (i.e., alendronate)

      NOTE: Treatment failure is defined by progression of bone loss as documented by bone density measurements (BMD) after at least 12 months of therapy OR occurrence of an osteoporotic fracture after having been compliant on at least 12 months of therapy.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as a 105 mg/1.17 mL solution in a single-use prefilled syringe for injection.