

Pharmacy Prior Authorization
Clinical Guidelines - Injectable Osteoporosis Medications

Evenity® (romosozumab-aqqg)

Treatment of Osteoporosis in Postmenopausal Women only

Authorization Guidelines:

- Member will be supplemented with adequate calcium and vitamin D
- Member does not have contraindication to requested drug
 - Evenity: Member does not have hypocalcemia, or myocardial infarction or stroke within preceding year

Treatment of Osteoporosis in Postmenopausal Women:

- Diagnosis of osteoporosis with T-score less than -2.5, or fragility fracture at hip, spine, wrist, arm, rib, or pelvis; OR
- T-score between -1.0 and -2.5 and high risk for osteoporosis fracture
 - Fracture Risk Assessment Tool (FRAX) risk of greater than or equal to 3.0% for hip fracture, or greater than or equal to 20% for any major osteoporosis related fracture, or multiple risk factors for fracture
 - *See Additional information for detail
- Member has one of the following:
 - Therapeutic failure of preferred oral or intravenous bisphosphonate despite compliance
 - Including new fracture or reduction in bone mineral density per recent dual energy X-ray absorptiometry (DEXA) scan, after 2 years of oral bisphosphonate
 - Contraindication or severe intolerance to oral bisphosphonate
 - For example, current upper gastrointestinal symptoms, inability to swallow, or inability to remain in upright position after oral bisphosphonate administration for required length of time

APPROVAL DURATION: One year

Note: Cumulative use of Evenity (romosozumab-aqqg) is limited to 12 monthly doses

QUANTITY LIMITS: Evenity: two 105 mg/1.17 mL pens per 30 days

ADDITIONAL INFORMATION:

- It is recommended by American Association of Clinical Endocrinologists (AACE) and the Endocrine Society that the member's serum 25-hydroxyvitamin D level be ≥ 30 ng/mL and patients should receive calcium and vitamin D from diet and/or supplements to improve effectiveness of the medications and to prevent hypocalcemia.
- Fracture Risk Assessment Tool (FRAX) Calculator:
<http://www.shef.ac.uk/FRAX/tool.jsp?locationValue=9>
- Severe Hypercalcemia = albumin-corrected calcium (cCa) greater than 12 mg/dL [3.0 mmol/L]
 - Formula: albumin-corrected calcium (cCa) in mg/dL = Ca in mg/dL + 0.8 (4.0 g/dL - member albumin [g/dL]).

Major Risk factors for Osteoporotic Fractures:

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- a. low body mass index
- b. previous fragility fracture
- c. parental history of hip fracture
- d. glucocorticoid treatment (refer to specific criteria above for this indication)
- e. current smoking
- f. alcohol intake of 3 or more units per day
- g. rheumatoid arthritis
- h. secondary causes of osteoporosis

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