

Montana Healthcare Programs Physician Administered Drug Coverage Criteria

EVENITY® (romosozumab-aqqg)

I. Medication Description

Evenity® is a sclerostin inhibitor indicated for:

 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.

II. <u>Position Statement</u>

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all the following criteria:

- Member is 18 years of age or older.
- Member is a postmenopausal woman with osteoporosis at high risk for fracture.
- Member is at high risk for fracture defined as meeting at least one of the following:
 - o BMD T-score ≤ -2.5 at femoral neck or spine.
 - BMD T-score between -1 and -2.5 at the femoral neck or spine AND one of the following:
 - A 10-year probability of hip fracture >3 percent (determined by FRAX) OR
 - A 10-year probability of any major osteoporosis-related fracture ≥20% (determined by FRAX) OR
 - History of low-trauma fragility fracture (particularly at the spine, hip, wrist, humerus, rib and pelvis)
- Member has not had a myocardial infarction or stroke within previous year.
- Member has not previously used Evenity® for a total duration of more than 12 months.
- Member does not have pre-existing hypocalcemia.
- Member should be adequately supplemented with calcium and vitamin D while on Evenity®, unless contraindicated.
- Member must have had an inadequate response, intolerance or contraindication to **all** of the following medications (an adequate trial duration is one year for each medication):
 - A Montana Health Care Programs preferred bisphosphonate AND
 - o Forteo SQ® AND
 - o Prolia®

IV. Renewal Coverage Criteria

Authorization beyond 12 months is not indicated.

V. Quantity Limitations

Max 210mg SQ monthly for 12 total doses.

VI. <u>Coverage Duration</u>

Initial approval duration: 1 year (12 monthly doses)

Renewal approval duration: none