Mountain-Pacific Quality Health

Montana Healthcare Programs
Physician Administered Drug Coverage Criteria

PROLIA® (denosumab)

I. Medication Description

Prolia® is a RANK Ligand inhibitor indicated for:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

II. Position Statement

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:

- 18 years of age or older
- Prolia® is being used for one of the following indications:
    - Treatment of postmenopausal women with osteoporosis at high risk for fracture
    - Treatment to increase bone mass in men with osteoporosis at high risk for fracture
    - Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
    - Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
    - Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer
- Is at high risk for fracture defined as meeting at least one of the following:
    - Bone mineral density (BMD) T-score $\leq$-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:
        - 10-year probability of hip fracture $\geq$3 percent (determined by FRAX) **OR**
        - 10-year probability of any major osteoporosis-related fracture $\geq$20% (determined by FRAX) **OR**
        - History of low-trauma fragility fracture (particularly at the spine, hip, wrist, humerus, rib and pelvis).
- Unless contraindicated, had an adequate trial with a Montana Healthcare Programs-preferred drug and the preferred drug was ineffective (An adequate trial is one year.)
    - List of Montana Healthcare Programs-preferred drugs can be found at: https://medicaidprovider.mt.gov/19

- Does not have pre-existing hypocalcemia
- Takes at least 1000mg/day of calcium and at least 400IU/day of vitamin D (unless contraindicated) and any deficiencies have been corrected
- Is not pregnant
- Is not taking Xgeva®

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Has been adherent to Prolia®
- Continues to take calcium and vitamin D (unless contraindicated)
- Has experienced a positive clinical response (e.g., T-score has increased or has not continued to decrease, absence of fracture, etc.).

V. Quantity Limitations

Max of 60mg SQ every 6 months

VI. Coverage Duration

- Initial approval duration: 1 year
- Renewal approval duration: 1 year