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:

- Member is 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.
- Member is at high risk for fracture defined as meeting at least one of the following:
    - 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, member had an adequate trial with a Montana Health Care Programs preferred drug (such as alendronate, ibandronate, raloxifene, or Forteo SQ®) and the preferred drug was ineffective or caused intolerable side effects. An adequate trial is one year.
- Member does not have pre-existing hypocalcemia.

- Member takes at least 1000mg/day of calcium and at least 400IU/day of Vitamin D (unless contraindicated) and any deficiencies have been corrected.
- Member is not pregnant.
- Member is not taking Xgeva®.

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Member has been adherent to Prolia®.
- Member continues to take calcium and vitamin D (unless contraindicated).
- Member 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