

# 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 Healthcare Programs preferred drug and the preferred drug was ineffective. An adequate trial is one year.
  - The list of Montana Healthcare Programs preferred drugs is on the Pharmacy webpage of the Provider Information website <https://medicaidprovider.mt.gov/enduserproviders>.
- 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