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 < -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 ≥ 3 percent (determined by FRAX) OR
    - 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).
- 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](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