MONTANA HEALTHCARE PROGRAMS

November 22, 2017

Physician Administered Drug Prior Authorization Criteria for Prolia®

Version 2, 11-27-18

Prolia® Denosumab Prolia is a RANK Ligand inhibitor.

Indications[1]:

- 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 non-metastatic prostate cancer
- Treatment to increase bone mass in women at high risk for fracture receiving aromatase inhibitor therapy for breast cancer.

Criteria for Approval[1,2]:

1. Member has one of the indications above **and** is at high risk for fracture defined as either
   a. A recent history of osteoporotic fracture
   b. BMD T-scores of -2.5 or less at the lumbar spine or femoral neck
   c. FRAX score shows 10-year hip fracture risk of 3% or higher or 10-year risk of major osteoporotic fracture of 20% or higher.[3]

AND

2. Member had an adequate trial with a Montana Health Care Programs preferred drug such as Alendronate, Forteo® SQ, or Raloxifene and the preferred drug was ineffective or caused intolerable side effects. An adequate trial is 180 days.

AND

3. **All** of the following:
   - Member is over 18 years old[1]; and
   - Member does not have pre-existing hypocalcemia[1]; and
   - Member has discontinued use of tobacco products[2]; and
   - Member completes weight bearing exercise daily[2]; and
   - Member takes calcium at least 1000 mg/day and Vitamin D at least 400 IU daily[1,2] and any deficiencies have been corrected; and
   - Member is not taking Xgeva®[1]; and
   - Member is not pregnant[1]; and
   - The side effects have been discussed with the patient and the patient agrees to submit to treatment.

Quantity Limit:

Member receives one injection (60 mg) SC every 6 months as provided by healthcare professional.

Criteria for Renewal Authorization Approval:

- Member has been compliant and adherent to this regimen and continued to take calcium and vitamin D.
- The member's T-score has increased or has not continued to decrease.
- The member has quit tobacco use.

Criteria for Denial:

- The member has not completed an adequate trial with the preferred drugs.
- The member has discontinued use of calcium and Vitamin D.
- The member has not discontinued use of tobacco products.
- The member has not started and continued a regular weight bearing exercise program.

Clinical Monitoring:

Within 14 days after starting Prolia® clinical monitoring of calcium, phosphorus and magnesium is required[1].

References:

1. Prolia® [package insert] Thousand Oaks, CA; Amgen Inc.; 5/2018, Accessed November 27, 2018.
2. Clinician's Guide to Prevention and Treatment of Osteoporosis as corrected Osteoporosis Int. 2015, 26(7) 2045; as accessed September 8 - 11, 2017
3. Clinical Resource, *Managing Osteoporosis: Screening, Treatment, and More*. Pharmacist's Letter/Prescriber's Letter. July 2017.