Physician Administered Drug Prior Authorization Criteria for Prolia®

Version 1, 9-13-2017

Prolia® Denosumab

Prolia is a RANK Ligand inhibitor.

Indications[1]**,** Prolia® is used for**:**

- Treatment of postmenopausal women with osteoporosis at high risk for fracture, history of osteoporotic fracture; or
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture, history of osteoporotic fracture; or
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer; or
- Treatment to increase bone mass in women at high risk for fracture receiving aromatase inhibitor therapy for breast cancer.

Criteria for Approval[1,2]**:**

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

- Member has experienced osteoporotic fracture or
- Member BMD T-scores are -2.5 or less at the lumbar spine or femoral neck; and
- 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[12]; 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.; 5/2017, Accessed September 8, 2017.
2. Clinician's Guide to Prevention and Treatment of Osteoporosis as corrected Osteoporosis Int. 2015, 26(7) 2045; as accessed September 8 - 11, 2017

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