Custom Criteria for
BlueCross Blue Shield of Arizona Commercial

PROLIA® (denosumab)

Effective Date: 4/15/2015

GPI CODING:

30044530002020

DESCRIPTION:

Prolia is a human IgG2 monoclonal antibody with affinity and specificity for human receptor activator of nuclear factor kappa-B ligand (RANKL). Prolia binds to RANKL and prevents it from activating its receptor, RANK, on the surface of osteoclasts and their precursors. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone. Prolia may be used for the treatment of osteoporosis in postmenopausal women, bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer, for bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer, and osteoporosis at high risk for fracture to increase bone mass.

APPROVAL DURATION:

Approval duration: 1 year
Dosage should not be greater than 60 mg every 6 months given by subcutaneous injection

CRITERIA FOR PROLIA

Prolia is considered medically necessary with documentation of ONE of the following:

1. Postmenopausal female with osteoporosis and ALL of the following:
   - T-score of -2.5 or worse (e.g., -3.0, -3.5)
   - ONE of the following high risks for fracture
     - Osteoporotic fracture
     - Multiple risk factors for fracture (significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, e.g., seizure medicines, blood thinners, corticosteroids, high doses of vitamins A or D)
     - Failed response (as defined by prescribing provider) to previous osteoporosis therapy
     - Intolerant to previous osteoporosis therapy
   - Individual is receiving supplemental calcium and vitamin D
   - Individual is not receiving another agent with the same active ingredient denosumab

2. Female at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer and ALL of the following:
   - T-score at the lumbar spine, total hip or femoral neck of -1.0 or worse OR history of an osteoporotic fracture
   - Individual is receiving supplemental calcium and vitamin D
   - Individual is not receiving another agent with the same active ingredient denosumab

3. Male at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and ALL of the following:
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- T-score at the lumbar spine, total hip or femoral neck of -1.0 or worse OR history of an osteoporotic fracture
- Individual is receiving supplemental calcium and vitamin D
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4. Male with osteoporosis at high risk for fracture to increase bone mass and ALL of the following:
   - T-score of -2.0 or worse at the lumbar spine or femoral neck OR T-score of -1.0 or worse at the lumbar spine or femoral neck with a history of prior fragility fracture
   - ONE of the following high risks for fracture
     - Osteoporotic fracture
     - Multiple risk factors for fracture (significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, e.g., seizure medicines, blood thinners, corticosteroids, high doses of vitamins A or D)
     - Failed response (as defined by prescribing provider) to previous osteoporosis therapy
     - Intolerant to previous osteoporosis therapy
   - Individual is receiving supplemental calcium and vitamin D
   - Individual is not receiving another agent with the same active ingredient denosumab