Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 10, 2010 October 20, 2011; May 1, 2012, August 16, 2017, June 4, 2018

PROLIA® (denosumab) Injection

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:

INITIATION OF THERAPY:

For the treatment of men and postmenopausal women with osteoporosis at high risk for fracture:

- Documented diagnosis of osteoporosis with A DXA hip (femoral neck) or spine T-score ≤ -2.5 (dated within the past year). ***(Must be confirmed in medical records.)***
  - **No Reclast trial required**

-OR-

- History of a fracture of the spine or hip. ***(Must be confirmed in medical records.)***
  - **No Reclast trial required**

-OR-

- Trial (minimum of one year) and failure of the bisphosphonate Reclast (zoledronate).
  - **NOTE: If the patient is unable to swallow oral bisphosphonates or unable to maintain an upright position after taking an oral bisphosphonate a trial of IV Reclast is still required.**
  - Failure may be defined as intolerance (adverse reaction, contraindication . . .) to other bisphosphonates or no increase from baseline bone mineral density (BMD) (as indicated by the T-score history) or recurring fractures (in the absence of major trauma) following at least one year of therapy.
  - If patient has adverse reaction to other bisphosphonates, a one year trial is not required. –

AND

- History of T-score between -1.0 and -2.5 if FRAX (WHO fracture Risk Assessment Tool) major osteoporotic fracture probability is ≥ 20% or hip fracture probability is 3%. ***(Must be confirmed in medical records.)***

For the 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; treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture:

- Verify diagnosis through progress notes

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CONTINUATION OF THERAPY:

- Medical records must demonstrate a stable BMD (within interventional goals) or an increasing BMD after a minimum trial of one year of therapy.
    - T-score test results may date back as far as five years.
    - Depending on level of BMD progression retesting may be done from every one to five years.
    - Medical records should demonstrate improvement by providing reference to the sequential progression or stability of the BMD.

DOSING:

- Prolia should be administered by a healthcare professional.
- Administered as 60 mg every 6 months as a subcutaneous injection in the upper arm, upper thigh, or abdomen.