

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; September 2, 2020; April 22, 2022; January 24, 2024

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:

- Prescribed by or in consultation with a specialist (endocrinologist, rheumatologist, or obstetrician/gynecologist) **-AND-**
- The patient is taking calcium and vitamin D (Must be confirmed in medical records or pharmacy claims) **-AND-**
- Documented diagnosis of osteoporosis with a DXA hip (femoral neck), spine T-score, ≤ -2.5 (dated within the past **2 years**). *(Must be confirmed in medical records.)*
 - **No Reclast trial required**

-OR-
- Documented diagnosis of osteoporosis of the 1/3 radius (distal radius) if the patient has primary hyperparathyroidism, or if the femoral neck or spine are not evaluable. *(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 $\geq 20\%$ 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:

- The patient is taking calcium and vitamin D (Must be confirmed in medical records or pharmacy claims)
- AND-**
- 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 AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as a 60mg/ml prefilled syringe.