



## Prior Authorization Approval Criteria

### *Prolia (denosumab)*

**Generic name:** denosumab

**Brand name:** Prolia

**Medication class:** human IgG2 monoclonal antibody

**FDA-approved uses:**

- Treatment of postmenopausal osteoporosis
- 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

**Available dosage forms:** Single use prefilled syringe and a single use vial containing 1ml of 60mg/ml solution.

**Usual dose:** 60mg subcutaneously administered by a healthcare professional once every 6 months.

**Duration of therapy:** Indefinite

**Approximate yearly cost:** \$1980.00/year  
(based on AWP 2010)

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Failed/intolerant to at least 2 bisphosphonates
- Postmenopausal women who require treatment of osteoporosis and are at high risk for fracture. (According to the WHO diagnostic classification, osteoporosis is defined by BMD at the hip or spine that is less than or equal to 2.5 standard deviations below the young normal mean reference population. (1 SD= 10-15% of the BMD value in g/cm<sup>2</sup>.)

OR

- Men receiving androgen deprivation therapy for nonmetastatic prostate cancer
  - ECOG  $\leq$  2
  - One of the following:
    - T score at the lumbar spine, total hip, or femoral neck of less than -1.0
    - 70 years or older
    - History of osteoporotic fracture

OR

- Women receiving adjuvant aromatase inhibitor therapy for nonmetastatic breast cancer
  - T score at the lumbar spine, total hip, or femoral neck of less than -1.0

**Cautions:**

- Denosumab has the potential to cause the same serious side effects like the bisphosphonates, such as osteonecrosis of the jaw and atypical features.

**Contraindications:**

- Uncorrected pre-existing hypocalcemia.

**Not approved if:**

- Does not meet the above stated criteria.
- Have any contraindications to the use of Prolia.

**Special Considerations:**

- Medical Benefit. Must be administered by a healthcare professional.
- Patient should be advised to take 1000mg daily of Calcium and at least 400IU of vitamin D daily.
- Denosumab appears to prevent fractures in postmenopausal women at a similar rate to bisphosphonates but there have not been any head to head comparisons.
- Used for treatment...not prevention.
- Osteoporosis is characterized by low bone mass, deterioration of bone tissue and disruption of bone architecture, compromised bone strength and an increase in the risk of fracture.

- **Risk factors included in the WHO fracture risk assessment model**

- Current age
- Gender
- A prior osteoporotic fracture
- Femoral neck BMD
- Low body mass index
- Oral glucocorticoids  $\geq 5$  mg/d of prednisone for  $\geq 3$ mo (ever)
- Rheumatoid arthritis
- Secondary osteoporosis
- Parental history of hip fracture
- Current smoking
- Alcohol intake (3 or more drinks/d)

Other risk factors include:

- Lifestyle factors
- Genetic factors
- Hypogonadal states
- Endocrine disorders
- Gastrointestinal disorders
- Hematologic disorders
- Rheumatic and autoimmune diseases
- Medications

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 12/08/10

Revised: 12/2011