

Prolia® (denosumab)

When requesting Prolia® (denosumab) for non-oncology osteoporosis, the individual requiring treatment must be diagnosed with a FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Non-Oncology Indications

- Treatment of osteoporosis in postmenopausal women
- Treatment of osteoporosis in men
- Treatment of glucocorticoid-induced osteoporosis in men and women

Approved Non-Oncology Off-Label Compendial Uses

None

Coverage Guidelines

For all indications, the individual meets the following safety criteria for approval:

- The individual has a serum calcium or corrected calcium greater than the lower limit of normal per laboratory reference.

Treatment of osteoporosis in postmenopausal women and men

- The individual is at high risk for fracture, defined as:
 - History of an osteoporotic (fragility) fracture
 - Multiple risk factors for fracture** AND a baseline bone mineral density (BMD) T-score by DXA (dual-energy x-ray absorptiometry) of less than or equal to -2.5
 - FRAX® 10-year fracture probability of greater than or equal to 20% or hip fracture probability of greater than or equal to 3% AND a baseline BMD T-score by DXA of less than or equal to -2.5
- And the individual meets one of the following conditions for approval unless history of an osteoporotic (fragility) fracture present:
 - Has failed to respond to a bisphosphonate agent (eg, alendronate, risedronate, zoledronic acid, etc.)
 - Cannot tolerate or is not a candidate for oral AND IV bisphosphonate agents due to a intolerance or contraindication such as renal impairment with a CrCl less than 35 mL/min

Treatment of glucocorticoid-induced osteoporosis in men and women

- The individual is taking greater than or equal to 7.5mg per day of prednisone (or equivalent) for at least 6 months
- The individual is at high risk for fracture, defined as:
 - o History of osteoporotic (fragility) fracture

- o Multiple risk factors for fracture AND a baseline bone mineral density (BMD) T-score by DXA (dual-energy x-ray absorptiometry) of less than or equal to -2.0
- And the individual meets one of the following conditions for approval unless history of an osteoporotic (fragility) fracture present:
 - o Has failed to respond to a bisphosphonate agent (eg, alendronate, risedronate, zoledronic acid, etc.)
 - o Cannot tolerate or is not a candidate for oral AND IV bisphosphonate agents due to a intolerance or contraindication such as renal impairment with a CrCl less than 35 mL/min

Approval duration: 12 months

*Corrected calcium (XX.X mg/dL) = measured serum calcium (XX.0 mg/dL) + 0.8 (4.0 - serum albumin [XX.X g/dL]) where 4.0 represents the average albumin level in g/dL.

** A prior fragility fracture, parental history of hip fracture, current tobacco smoking, secondary causes of osteoporosis (e.g., rheumatoid arthritis, hypogonadism, use of phenytoin, phenobarbital, long term warfarin, etc.), daily alcohol use of three or more drinks per day, advanced age (greater than 65), body habitus (weight less than 127 pounds or BMI less than or equal to 20), Caucasian or Asian race, sedentary lifestyle, diet deficient in calcium or vitamin D without adequate supplementation, long-term use of corticosteroids (defined as greater than 3 continuous months), early menopause, etc. *(Please note: this list is not all-inclusive)*

Dosing

Administer 60 mg every 6 months as a subcutaneous injection in the upper arm, upper thigh, or abdomen

References

1. Prolia prescribing information. Thousand Oaks, CA: Amgen Inc.: Revised May 2018. Accessed June 11, 2018.
2. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed February 27, 2018.
3. Camacho PM, Petak SM, et al. AACE medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract. 2016; 22 Suppl 4. Accessed February 27, 2018.
4. World Health Organization. FRAX® WHO fracture risk assessment tool. Available at: <https://www.shef.ac.uk/FRAX/>. Accessed February 27, 2018.
5. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014. Accessed February 27, 2018.
6. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2012; 97(6):1802-1822. Accessed February 27, 2018.