

Prolia® (denosumab)

When requesting Prolia® (denosumab) for non-oncology osteoporosis, the individual requiring treatment must be diagnosed with an 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

Coverage Guidelines

Osteoporosis in men and postmenopausal women

The individual must meet **all** of the following criteria for approval:

- The individual is at high risk for fracture, defined as:
 - History of an osteoporotic (fragility) fracture;
 - Current or past bone mineral density (BMD) T-score at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist); OR
 - Current or past bone mineral density (BMD) T-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist) and the patient is at high risk for fracture; AND
- The individual meets one of the following conditions for approval (not required with history of osteoporotic [fragility] fracture):
 - Has failed or had an inadequate response to a 12-month trial of an oral bisphosphonate agent (e.g., alendronate, risedronate, etc.);
 - Has tried an IV bisphosphonate agent (e.g., Boniva or Reclast); OR
 - Cannot tolerate (e.g., severe GI adverse effects) or is not a candidate for oral or IV bisphosphonate agents due to an intolerance or contraindication (e.g., renal impairment with a CrCl less than 35 mL/min, chronic kidney disease, cannot swallow oral medications).

Glucocorticoid-induced osteoporosis

The individual must meet **all** of the following criteria for approval:

- The individual is initiating or continuing systemic glucocorticoids (e.g. prednisone); AND
- The individual meets one of the following conditions for approval:
 - History of osteoporotic (fragility) fracture;
 - Has failed or had an inadequate response to a 12-month trial of an oral bisphosphonate agent (e.g., alendronate, risedronate, etc.);
 - Has tried an IV bisphosphonate agent (e.g., Reclast); OR

- o Cannot tolerate (e.g., severe GI adverse effects) or is not a candidate for oral or IV bisphosphonate agents due to an intolerance or contraindication (e.g., renal impairment with a CrCl less than 35mL/min, chronic kidney disease, or cannot swallow oral medications).

Approval duration: 12 months

Dosing Recommendations

Approve up to 60 mg, administered subcutaneously, no more frequently than once every 6 months.

References

1. Prolia® injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; May 2019.
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3. Qaseem A, Forciea MA, McLean RM, et al, for the Clinical Guidelines Committee of the American College of Physicians. Treatment of low bone density or osteoporosis to prevent fractures in men and women: a clinical practice guideline update from the American College of Physicians. *Ann Intern Med.* 2017;166(11):818-837.
4. Cosman F, de Beur SJ, LeBoff MS, et al. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporosis Int.* 2014;25:2359-2381. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4176573/pdf/198_2014_Article_2794.pdf. Accessed on June 26, 2018.
5. 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.
6. Buckley L, Guyatt G, Fink HA, et al. 2017 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. *Arthritis Rheumatol.* 2017;69(8):1521-1537. Available at: <https://www.rheumatology.org/Portals/0/Files/Guideline-for-the-Prevention-and-Treatment-of-GIOP.pdf>. Accessed on June 15, 2018.
7. Saag KG, Wagman RB, Geusens P, et al. Denosumab versus risedronate in glucocorticoid-induced osteoporosis: a multicenter, randomized, double-blind, active-controlled, double-dummy, non-inferiority study. *Lancet Diabetes Endocrinol.* 2018;6:445-454.
8. Denosumab (Prolia®). In: DRUGDEX® System Micromedex. Greenwood Village, CO: Thompson Reuters (Healthcare) Inc. [Updated; August 21, 2019; Accessed August 29, 2019].