

PROLIA (denosumab)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Robert Sterling, MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Prolia is a genetically engineered human IgG monoclonal antibody which inhibits proteins necessary for osteoclast activation, thereby inhibiting bone resorption (up to 85%).

Authorization: postmenopausal women at high risk for fracture who are intolerant of or unresponsive to other therapies; treatment of bone loss in women with breast cancer who are receiving aromatase inhibitor therapy; men with osteoporosis at high risk for fracture; treatment of bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer.

Not indicated for prevention of skeletal-related events with multiple myeloma.

Unlabeled Use: treatment of bone destruction caused by rheumatoid arthritis. (See VCHCP policy on Coverage of Prescription Medication for Off-Label Use.)

Dosing: 60mg subcutaneously every six months

PRECAUTIONS: all patients should receive calcium 1000 mg and at least 400 IU vitamin D daily; correct hypocalcemia and monitor serum calcium, especially in dialysis patients; monitor serum phosphorus; osteonecrosis of the jaw (ONJ) after tooth extraction or dental abscess; back pain; arthralgias; fatigue

DRUG INTERACTIONS: may increase the risk of infections in patients taking immunosuppressants.

REFERENCES

- Smith MR, Egerdie B, Hernández Toriz N, et al, "Denosumab in Men Receiving Androgen-Deprivation Therapy for Prostate Cancer," *N Engl J Med*, 2009, 361(8):745-55.
- Smith MR, Saad F, Coleman R, et al, "Denosumab and Bone-Metastasis- Free Survival in Men With Castration-Resistant Prostate Cancer: Results of a Phase 3, Randomised, Placebo-Controlled Trial," *Lancet*, 2012, 379(9810):39-46.
- Lipton A, Steger GG, Figueroa J, et al, "Randomized Active-Controlled Phase II Study of Denosumab Efficacy and Safety in Patients With Breast Cancer-Related Bone Metastases," *J Clin Oncol*, 2007, 25(28):4431-7.
- McClung MR, Lewiecki EM, Cohen SB, et al, "Denosumab in Postmenopausal Women With Low Bone Mineral Density," *N Engl J Med*, 2006, 354(8):821-31.
- National Osteoporosis Foundation (NOF), "Clinician's Guide to Prevention and Treatment of Osteoporosis," Washington, DC, 2013. Available at <http://www.nof.org/files/nof/public/content/resource/913/files/580.pdf>
- Papapoulos S, Chapurlat R, Libanati C, et al, "Five Years of Denosumab Exposure in Women With Postmenopausal Osteoporosis: Results from the First Two Years of the FREEDOM Extension," *J Bone Miner Res*, 2012, 27(3):694-701.
- IOM (Institute of Medicine), *Dietary Reference Intakes for Calcium and Vitamin D*, Washington, DC: The National Academies Press, 2011.
- Kendler DL, Roux C, Benhamou CL, et al, "Effects of Denosumab on Bone Mineral Density and Bone Turnover in Postmenopausal Women Transitioning from Alendronate Therapy," *J Bone Miner Res*, 2010, 25(1):72-81.

Revision History:

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD

Date Approved by P&T Committee: 1/27/15

Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/26/16

Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/24/17

Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/23/18

Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – check ESI