COMMUNICATION

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PLEASE REVIEW

# Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

## Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and disease prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252, ext. 219.

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

## New Black Box Warning for Prolia™

The Food and Drug Administration (FDA) has added a boxed warning to the osteoporosis therapy Prolia (denosumab). This new warning states that there is an increased risk of severe hypocalcemia in patients with advanced chronic kidney disease (CKD), particularly patients on dialysis.

### Background:

Prolia was approved in June 2010 to treat postmenopausal women with osteoporosis at high risk for bone fracture. Eventually, Prolia gained approval to treat men with osteoporosis, glucocorticoid induced osteoporosis, bone loss in men receiving androgen deprivation therapy for prostate cancer and in women receiving aromatase inhibitor therapy for breast cancer. The drug works by blocking a protein called RANK (receptor activator of nuclear factor kappa beta) and helps prevent osteoclasts from breaking down bone in the body.

### Hypocalcemia Warning:

Severe hypocalcemia appears to be more common in patients with CKD who also have mineral and bone disorder (CKD-MBD). In patients with advanced CKD taking Prolia, severe hypocalcemia caused serious harm, including hospitalization, life-threatening events, and even death.

Patients typically developed severe hypocalcemia 2 to 10 weeks following each Prolia injection, with the greatest risk occurring during Weeks 2 to 5.

To minimize the risk of hypocalcemia in advanced chronic kidney disease, patients should be assessed for the presence of chronic kidney disease mineral and bone disorder with intact parathyroid hormone (iPTH), serum calcium, 25(OH) vitamin D, and 1,25(OH)2 vitamin D prior to decisions regarding Prolia treatment.

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REFERENCES:

1. Formulary Watch. (2024, January 19). FDA adds boxed warning to Prolia in patients with kidney disease. https://www.formularywatch.com/view/fda-adds-boxed-warning-to-prolia-in-patients-with-kidney-disease
2. Center for Drug Evaluation and Research. (n.d.). Osteoporosis drug Prolia increases the risk of severe hypocalcemia. U.S. Food and Drug Administration. https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-increased-risk-severe-hypocalcemia-patients-advanced-chronic-kidney disease#:~:text=FDA%20is%20adding%20a%20Boxed,of%20chronic%20kidney%20disease%2Dmineral

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