FDA REQUIRED REMS Safety Information for Prolia® (denosumab)

Serious Risks Associated with Prolia®:

Hypocalcemia and Mineral Metabolism
Hypocalcemia may be exacerbated by the use of Prolia®. In patients predisposed to hypocalcemia and disturbances of mineral metabolism, clinical monitoring of calcium and mineral levels is highly recommended.

Osteonecrosis of the Jaw
Osteonecrosis of the Jaw (ONJ) has been reported in patients receiving Prolia®. ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing.

Atypical Subtrochanteric and Diaphyseal Femoral Fractures
Atypical low-energy or low trauma subtrochanteric and diaphyseal femoral fractures, which may be bilateral, have been reported in patients receiving Prolia®. Atypical femoral fractures most commonly occur with minimal or no trauma to the affected area.

Serious Infections
In a clinical trial, women with postmenopausal osteoporosis treated with Prolia® presented with serious infections, such as infections of the abdomen, urinary tract, and ear, as well as endocarditis.

Dermatologic Reactions
In a clinical trial, women with postmenopausal osteoporosis treated with Prolia® presented with generalized epidermal and dermal adverse events at a significantly higher rate compared to the placebo group.

Role of the Healthcare Provider

- ✓ **Review** information in the Prolia® Medication Guide and Patient Counseling Chart with each patient, including the serious risks of Prolia® and the symptoms of each risk.
- ✓ **Advise** each patient to seek prompt medical attention if they have signs or symptoms of any of the serious risks.
- ✓ **Provide** each patient a copy of the Medication Guide and Patient Brochure.

Prolia® is Indicated for the:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture
- 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

Reporting Adverse Events
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. Healthcare providers should report all suspected adverse events associated with Prolia® to the FDA or to Amgen at 1-800-772-6436.

This journal information piece is part of the FDA-required Prolia® REMS. Visit www.proliahcp.com/risk-evaluation-mitigation-strategy *for more information.*

For complete safety information, see the Prescribing Information available at www.proliahcp.com/risk-evaluation-mitigation-strategy.

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