



## PROLIA<sup>®</sup> REMS

# FDA Required REMS Safety Information

### Serious Risks Associated with Prolia<sup>®</sup> (denosumab)

- Hypocalcemia
- Osteonecrosis of the Jaw
- Atypical Femoral Fractures
- Serious Infections
- Dermatologic Reactions

Month YYYY

## Important Safety Update

Dear [Professional Society]:

The FDA has required Amgen to distribute this safety update to your organization as part of our PROLIA<sup>®</sup> REMS (**R**isk **E**valuation and **M**itigation **S**trategy) program. We request that you inform your members about the following **serious risks of Prolia<sup>®</sup>**:

### Hypocalcemia

- Hypocalcemia may be exacerbated by the use of Prolia<sup>®</sup>.

### Osteonecrosis of the Jaw

- Osteonecrosis of the jaw (ONJ) has been reported in patients receiving Prolia<sup>®</sup>.

### 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<sup>®</sup>. 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<sup>®</sup> presented with serious infections, such as serious skin infection and endocarditis, leading to hospitalization more frequently than the placebo group.

### Dermatologic Reactions

- In a clinical trial, women with postmenopausal osteoporosis treated with Prolia<sup>®</sup> presented with generalized epidermal and dermal adverse events at a significantly higher rate compared to the placebo group. These included dermatitis, eczema, and rashes.

## Role of the Healthcare Provider

- ✓ **Make note** of these risks and discuss them with your patients using the non-promotional **Patient Counseling Toolkit**, which includes:
  - [Patient Counseling Chart for Healthcare Providers](#)
  - [Patient Brochure](#)
  - [Prescribing Information](#)
  - [Medication Guide](#)

**Note:** These materials are available to order through 1-800-77-AMGEN (1-800-772-6436) or by downloading the information from [www.proliahcp.com/risk-evaluation-mitigation-strategy](http://www.proliahcp.com/risk-evaluation-mitigation-strategy).

- ✓ **Review** information in the **Medication Guide and Patient Counseling Chart** with each patient, including the serious risks of Prolia<sup>®</sup> 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**.
- ✓ **Visit** [www.proliahcp.com/risk-evaluation-mitigation-strategy](http://www.proliahcp.com/risk-evaluation-mitigation-strategy) for more information about the Prolia<sup>®</sup> REMS.

## Indication

Prolia<sup>®</sup> is a RANK ligand (RANKL) inhibitor indicated for the:

- 1) treatment of postmenopausal women with osteoporosis at high risk for fracture,
- 2) treatment to increase bone mass in men with osteoporosis at high risk for fracture,
- 3) treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, and
- 4) treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

**This letter does not contain the complete safety profile for Prolia<sup>®</sup>. Please visit [www.proliahcp.com/risk-evaluation-mitigation-strategy](http://www.proliahcp.com/risk-evaluation-mitigation-strategy) for more information about Prolia<sup>®</sup> and the Prolia<sup>®</sup> REMS Program. A link to the full Prescribing Information is provided where risks associated with Prolia<sup>®</sup> are clearly outlined.**

## Reporting Adverse Events

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. Healthcare providers should report all suspected adverse events associated with Prolia<sup>®</sup> to the FDA or to Amgen at 1-800-772-6436.

Sincerely,

Isma Benattia, MD  
Vice President, Global Patient Safety  
Amgen