PROLIA® REMS

FDA Required REMS Safety Information / Important Safety Update

Dear Healthcare Provider:

The FDA has required this safety update as part of the Prolia® REMS (**R**isk **E**valuation and **M**itigation **S**trategy) to inform healthcare providers about the following **serious risk of Prolia®**:

Severe Hypocalcemia in Patients with Advanced Kidney Disease

Patients with advanced chronic kidney disease (eGFR < 30 mL/min/1.73 m^2), including dialysis-dependent patients, are at greater risk of severe hypocalcemia following Prolia® administration.

- Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported.
- To minimize the risk of hypocalcemia in patients with advanced chronic kidney disease (CKD):
  - Evaluate for the presence of chronic kidney disease-mineral bone disorder (CKD-MBD) with intact parathyroid hormone (iPTH), serum calcium, 25(OH) vitamin D, and 1,25 $(OH)_2$ vitamin D prior to decisions regarding Prolia® treatment.
  - Consider assessing bone turnover status (serum markers of bone turnover or bone biopsy) to evaluate the underlying bone disease that may be present.
  - Monitor serum calcium weekly for the first month after Prolia® administration and monthly thereafter.
  - Coordinate care with healthcare providers with expertise in CKD-MBD for patients with advanced chronic kidney disease.

Role of the Healthcare Provider

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

This letter does not contain the complete safety profile for Prolia®. Please review the Prescribing Information enclosed.

All Prolia® REMS materials are also available at www.proliahcp.com.

Reporting Adverse Events

To report Adverse Reactions with Prolia®, please call Amgen Inc. at 1-800-772-6436, or report the event at FDA MedWatch.

Sincerely,

Amgen Inc.