IMPORTANT PRESCRIBING INFORMATION

May 21, 2020

Subject: **Temporary Prolia® (denosumab) Injection, for subcutaneous use, Administration by Patient or Caregiver During COVID-19 Public Health Emergency**

Dear Health Care Provider:

Following consultation with the U.S. Food and Drug Administration (FDA), Amgen is issuing this letter to provide you with safety information regarding temporary administration of Prolia during the COVID-19 pandemic. Prolia is intended for multiple osteoporosis indications.

The current U.S. prescribing information states that Prolia (denosumab) should be administered by a healthcare provider. At this time, self-administration of Prolia is not approved in the United States. However, administration by healthcare providers may be a challenge in the context of the current COVID-19 pandemic. FDA has informed Amgen that it does not intend to object to our dissemination of this letter or the accompanying temporary Instructions for Use and video only for the duration of the COVID-19 public health emergency declared by the Secretary of Health and Human Services on January 31, 2020.

While administration of Prolia by a healthcare provider remains the preferred mode of administration where possible, there may be cases where the healthcare provider determines that self-administration of Prolia by a patient or lay caregiver may be temporarily warranted in the context of local COVID- 19-related guidelines and restrictions, and individual patient factors.

Prescriber Action:

Amgen recommends that healthcare providers consider the following when assessing the risk-benefit of temporary self-administration with Prolia for individual patients during the COVID-19 Public Health Emergency:

- Patient/caregiver administration should ONLY be performed if approved by a healthcare provider and only after there has been appropriate instruction and supervision by that healthcare provider.
- The option for patient/caregiver administration at home is only intended for patients who are continuing Prolia therapy and have no history of hypersensitivity with Prolia and stable serum calcium levels following prior Prolia administrations (i.e., it is not intended for initiation of Prolia therapy).
- Inform patients that Prolia may cause hypersensitivity events such as anaphylaxis, facial swelling, urticaria and injection site reactions. Instruct patients to contact their HCP if such reactions occur.

For more information on administration of Prolia by a patient/caregiver, please refer to and direct your patients and their caregivers to the following two supplemental materials:

  - Temporary Self-Administration Instructions for Use (www.pi.amgen.com/united_states/prolia/prolia_pfs_temporary_self-admin_ifu.pdf)
    These may be printed by the HCP, patient or caregiver.
  - Self-Administration Demonstration Video (www.prolia.com/self-injection/video)

You should discuss the potential benefits and risks of self-administration with your patient.

About Prolia

Prolia, manufactured by Amgen, is approved for the following indications per the Highlights in the Prescribing Information:

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

Health care providers and patients should report any adverse events suspected to be associated with Prolia and product complaints to Amgen at 1-800-77-AMGEN (1-800-772-6436) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Company Contact Point

Should you have any questions about the information in this letter or the safe and effective use of Prolia, contact Amgen's medical information department at 1-800-77-AMGEN (1-800-772-6436).

This letter is not intended as a complete description of the benefits and risks related to the use of Prolia. Please see the FDA-approved Prescribing Information (www.pi.amgen.com/united_states/prolia/prolia_pi.pdf) and Medication Guide (www.pi.amgen.com/united_states/prolia/prolia_mg.pdf) for a complete discussion of the risks associated with Prolia.

Sincerely,

Darryl Sleep, MD

Senior Vice President, Global Medical and Chief Medical Officer