You are invited to learn about:

Prolia® (denosumab) for the Treatment of Postmenopausal Osteoporosis in Women at High Risk for Fracture

Prolia® is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia® reduces the incidence of vertebral, nonvertebral, and hip fractures.

Please join us for an informative discussion on postmenopausal osteoporosis in women at high risk for fracture, and learn about Prolia®, the first RANKL inhibitor approved by the FDA.

Specific topics will include:
- Mechanism of Action of Prolia®
- Clinical efficacy and safety of Prolia®
- Identification of appropriate patients for Prolia®

Please RSVP to:
Sarah Doup
Tel: 515-480-0234
E-mail: sdoup@amgen.com

Wednesday, November 09, 2016
6:00 PM CT  Presentation and Discussion

Sam & Gabe’s Italian Bistro
8631 Hickman Rd
Urbandale, IA 50322
Speaker
Dudley Phipps, PA-c
PA-C, CCD, FLS
Iowa Ortho

Important Safety Information

Contraindications: Prolia® is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating Prolia®. Prolia® is contraindicated in women who are pregnant and may cause fetal harm. Prolia® is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling and urticaria.

Warnings and Precautions: Prolia® contains the same active ingredient (denosumab) found in XGEVA®. Patients receiving Prolia® should not receive XGEVA®.

Clinically significant hypersensitivity including anaphylaxis has been reported with Prolia®. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of Prolia®. Hypocalcemia may worsen with the use of Prolia®, especially in patients with severe renal impairment. Adequately supplement all patients with calcium and vitamin D.

ONJ and atypical femoral fracture have been reported in patients with Prolia®. Patients should be monitored for adverse outcomes. In a clinical trial (N = 7808), serious infections leading to hospitalization were reported more frequently in the Prolia®-treated patient group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear, were more frequent in patients treated with Prolia®. Patients should seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis. Endocarditis was reported more frequently in Prolia®-treated patient group.

Epidermal and dermal adverse events such as dermatitis, rashes, and eczema have been reported. Most of these events were not specific to the injection site. Consider discontinuing Prolia® if severe symptoms develop.

Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking Prolia®. Consider discontinuing use if severe symptoms develop.

Prolia® resulted in significant suppression of bone remodeling. The significance of these findings is unknown. The long-term consequences of the degree of suppression of bone remodeling observed with Prolia® may contribute to adverse outcomes such as ONJ, atypical fractures, and delayed fracture healing.

Adverse Reactions: The most common adverse reactions (> 5% and more common than placebo) are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis. Pancreatitis has been reported with Prolia®.

Prolia® Postmarketing Active Safety Surveillance Program: The Prolia® Postmarketing Active Safety Surveillance Program is available to collect information from prescribers on specific adverse events. Please see www.proliasafety.com or call 1-800-772-6436 for more information about this program.

Please see accompanying Prolia® full prescribing information, including Medication Guide.

In accordance with the PhRMA Code on Interactions with Healthcare Professionals, this program is intended only for healthcare professionals who will find its content clinically relevant to their practice. Accordingly, non-healthcare professionals (ie, spouses and other guests) may not attend. Invitation is extended only to those HCPs whose attendance would not violate compliance with state law requirements in which such HCP is licensed to practice.

This is not an independent medical education program and not eligible for credit toward CME requirements.