

ROUTING FORM

First Mechanical ☐

Final Mechanical ☐

Job #: _____

☐ Patient Facing Materials
(requires Euro Legal Review)

Client: _____ Product: _____

Description: _____

☐ Client Comments Received/Transcribed Date: _____ Initials: _____

Operator: _____ Extension: _____ Date: _____ Time: _____

PM: _____ Extension: _____ ArtDir: _____ Extension: _____

SIGN-OFF

INITIALS

DATE

TIME

COMMENTS

Art Director

REVISED

☐ OK ☐ Corrections

Art Supervisor

7:08 pm, Dec 22, 2020

☐ OK ☐ Corrections

Editor

☐ OK ☐ Corrections

Editor 2—Double Read ☐

☐ OK ☐ Corrections

Copywriter

☐ OK ☐ Corrections

Copy Supervisor

☐ OK ☐ Corrections

Creative Director Art

☐ OK ☐ Corrections

Creative Director Copy

☐ OK ☐ Corrections

Assoc. Creative Director

☐ OK ☐ Corrections

Account Executive

☐ OK ☐ Corrections

Account Supervisor

☐ OK ☐ Corrections

Acct. Group Supervisor

☐ OK ☐ Corrections

Sr. Mgmt. Supervisor

☐ OK ☐ Corrections

Medical Director

☐ OK ☐ Corrections

Production

☐ OK ☐ Corrections

Art Buyer

☐ OK ☐ Corrections

NOTES

IMPORTANT SAFETY INFORMATION

Prolia® is contraindicated in women who are pregnant and may cause fetal harm. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment with Prolia®. 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.

Hypersensitivity: Clinically significant hypersensitivity including anaphylaxis has been reported with Prolia®. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of Prolia®.

Osteonecrosis of the Jaw (ONJ): ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving Prolia®. An oral exam should be performed by the prescriber prior to initiation of Prolia®. A dental examination with appropriate preventive dentistry is recommended for all patients with risk factors for ONJ such as invasive dental procedures, diagnosis of cancer, concomitant therapies (e.g. chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and co-morbid disorders. Good oral hygiene practices should be maintained during treatment with Prolia®. The risk of ONJ may increase with duration of exposure to Prolia®.

Atypical Femoral Fractures: Atypical low-energy, or low trauma fractures of the shaft have been reported in patients receiving Prolia®. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with antiresorptive agents.

Multiple Vertebral Fractures (MVF) Following Discontinuation of Prolia® Treatment: Following discontinuation of Prolia® treatment, fracture risk increases, including the risk of multiple vertebral fractures. New vertebral fractures occurred as early as 7 months (on average 19 months) after the last dose of Prolia®. Prior vertebral fracture was a predictor of multiple vertebral fractures after Prolia® discontinuation. Evaluate an individual's benefit/risk before initiating treatment with Prolia®. If Prolia® treatment is discontinued, patients should be transitioned to an alternative antiresorptive therapy.

Serious Infections: In a clinical trial (N = 7808), serious infections leading to hospitalization were reported more frequently in the Prolia® group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear, were more frequent in patients treated with Prolia®.

Endocarditis was also reported more frequently in Prolia®-treated patients. The incidence of opportunistic infections and the overall incidence of infections were similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis.

Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Prolia®, prescribers should assess the need for continued Prolia® therapy.

Dermatologic Adverse Reactions: Epidermal and dermal adverse events such as dermatitis, eczema and rashes occurred at a significantly higher rate with Prolia® compared to placebo. Most of these events were not specific to the injection site. Consider discontinuing Prolia® if severe symptoms develop.

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

Suppression of Bone Turnover: Prolia® resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment are unknown. Monitor patients for consequences, including 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

Reference: 1. Data on file, Amgen; 2020.

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
www.amgen.com
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2 Clarke Drive, Ste 100
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