Treatment Referral Form

■ Dear Doctor/Medical Office:
I am referring my patient to you for administration of Prolia® injection (60 mg subcutaneous in the upper arm, upper thigh, or abdomen every 6 months).

■ Dear Pharmacy:
Attached is a prescription for the patient listed below.

Treatment Site Information

Physician Name: _____
Specialty: _____
Site Name: _____
Address: _____
City: _____ State: _____ ZIP Code: _____
Phone: _____ Fax: _____
Office Contact: _____

Pharmacy Information

Pharmacy Name: _____
Address: _____
City: _____
State: _____ ZIP Code: _____
Phone: _____
Fax: _____
Contact: _____

Patient Information

Fill out entirely OR ■ **attach Face/Demographic Information Sheet**

Patient Name: _____ Date of Birth: _____ Social Security Number: _____ M ❑ F ❑
Address: _____ City: _____ State: _____ ZIP Code: _____
Work Phone: _____ Cell Phone: _____ Email: _____

Insurance Information

Fill out entirely OR ■ **fax a copy of insurance cards front AND back.**

Primary Insurance: _____ Secondary Insurance: _____
Insured: _____ Insured: _____
Phone: _____ Phone: _____
Policy #: _____ Email: _____

Patient Medical Information*

❑ M81.0 (Age-related osteoporosis without current pathological fracture)
❑ M80.0 _____ (Age-related osteoporosis with current pathological fracture...)
❑ Other (specify ICD-10 Code): _____
Please provide secondary ICD-10 Code, if applicable: _____

** A copy of this information can be given to the patient to bring to his/her appointment. The sample diagnosis codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for Prolia®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered FDA-approved indications for Prolia®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.*

OPTIONAL: Affordability Screening

To see if the patient is eligible for additional affordability options, please complete the questions below

Residency:
Patient has lived in the U.S. or its territories (American Samoa, Guam, Puerto Rico, or U.S. Virgin Islands): ❑ Greater than 6 months ❑ Less than 6 months

Patient household income: $ _____ ❑ Monthly ❑ Annually
(Gross income includes all individuals in the household. This includes wages, Social Security, Social Security disability, unemployment, pensions, and any other income. They may be asked to provide proof of income.)

How many people live in the patient's household (including the patient)?: ■ 1 ❑ 2 ❑ 3 ❑ 4 ❑ Other _____
Household size includes all individuals reported on the patient's U.S. Tax Return. If the patient did not file a tax return please include all individuals that live with them.

Physician Information

Physician Name: _____ NPI #: _____
Specialty: _____ Site Name: _____
Address: _____
City: _____ State: _____ ZIP Code: _____
Phone: _____ Fax: _____
Office Contact: _____

Order or Prescription Information

Product Name/Strength: Prolia® 60 mg pre-filled syringe
Directions: 60 mg SC every 6 months
Refill: ❑ x1 ❑ x2 ❑ x3 ❑ x4
For prescription, ship to: ❑ Physician ❑ Office Patient
Prescriber Signature: X _____ Date: _____

ACTION: FAX BACK INJECTION CONFIRMATION FROM TREATING SITE. Please update the referring physician by faxing back this form.

Prolia® Treatment Status at Our Facility:

Was the patient injected with Prolia®? If yes, provide the date. Yes/No Date: _____
Has the patient's appointment been scheduled for their next Prolia® injection? If yes, provide the date. Yes/No Date: _____

Administering Healthcare Professional's Comments: _____

Please contact Amgen SupportPlus or www.MyAmgenPortal.com for insurance verification or any questions regarding coding/billing, claims submission, and other payer requirements.

Please see Indications and Important Safety Information on Page 2.

Indications and Important Safety Information

Indications:

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.

Prolia is indicated for treatment to increase bone mass in men 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.

Important Safety Information

- **SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE:**

  Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following Prolia administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiating Prolia in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with Prolia in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

- **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. 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.
- **Severe Hypocalcemia and Mineral Metabolism Changes:** Prolia can cause severe hypocalcemia and fatal cases have been reported. Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia. Adequately supplement all patients with calcium and vitamin D.

  In patients without advanced chronic kidney disease who are predisposed to hypocalcemia and disturbances of mineral metabolism (e.g. treatment with other calcium-lowering drugs), assess serum calcium and mineral levels (phosphorus and magnesium) 10 to 14 days after Prolia injection.
- **Same Active Ingredient:** Prolia® contains the same active ingredient (denosumab) found in XGEVA®. Patients receiving Prolia® should not receive XGEVA®.
- **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®.
- **Hypocalcemia:** Hypocalcemia may worsen with the use of Prolia®, especially in patients with severe renal impairment. In patients predisposed to hypocalcemia and disturbances of mineral metabolism, including treatment with other calcium-lowering drugs, clinical monitoring of calcium and mineral levels is highly recommended within 14 days of Prolia® injection. Concomitant use of calcimimetic drugs may worsen hypocalcemia risk and serum calcium should be closely monitored. Adequately supplement all patients with calcium and vitamin D.
- **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 prior to treatment in 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®.

  For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of Prolia® should be considered based on individual benefit-risk assessment.
- **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.

  During Prolia® treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be evaluated to rule out an incomplete femur fracture. Interruption of Prolia® therapy should be considered, pending a risk/benefit assessment, on an individual basis.
- **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) in women with postmenopausal osteoporosis, 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:** In the same clinical trial in women with postmenopausal osteoporosis, 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:** In clinical trials in women with postmenopausal osteoporosis, 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) in women with postmenopausal osteoporosis are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis.

  The most common adverse reactions (>5% and more common than placebo) in men with osteoporosis are back pain, arthralgia, and nasopharyngitis. Pancreatitis has been reported with Prolia®.

  In women with postmenopausal osteoporosis, the overall incidence of new malignancies was 4.3% in the placebo group and 4.8% in the Prolia® group. In men with osteoporosis, new malignancies were reported in no patients in the placebo group and 4 (3.3%) patients in the Prolia® group. A causal relationship to drug exposure has not been established. Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

Please see Prolia® full Prescribing Information, including Medication Guide.

AMGEN®
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prolia® (denosumab) injection