

# 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

### Pharmacy Information

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

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 card 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...)  
Please provide complete code (see next page for details).  
 Original diagnostic T-score: \_\_\_\_\_ Date: \_\_\_\_\_  
 Other (specify ICD-10 Code): \_\_\_\_\_  
Please provide secondary ICD-10 Code, if applicable: \_\_\_\_\_  
 History of osteoporotic fracture  
**Prior Osteoporosis Therapy (if any):**  
 Generic alendronate  Fosamax® (alendronate sodium)  Actonel® (risedronate sodium)  Boniva® (ibandronate sodium)  
 Other (specify): \_\_\_\_\_  
Reason for discontinuing previous osteoporosis therapy(ies): \_\_\_\_\_  
Contraindications (if any): \_\_\_\_\_  
Patient is currently taking calcium and vitamin D supplements:  Yes  No Calcium level available:  Yes  No  
Other pertinent information: \_\_\_\_\_

\* 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.

### Physician Information

### Order or Prescription Information

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

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 Assist® or [www.amgenassist.com](http://www.amgenassist.com) for insurance verification or any questions regarding coding/billing, claims submission, and other payer requirements. Fosamax® is a registered trademark of Merck & Co., Inc. Boniva® is a registered trademark of Roche Therapeutics Inc. Actonel® is a registered trademark of Warner Chilcott, Inc.

# 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

- ❗ **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.
- ❗ **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