PROLIA® SPECIALTY PHARMACY NETWORK

Helping appropriate patients start and stay on Prolia®

Prolia® FDA-Approved Indication

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.

Contraindications

Prolia® is contraindicated in patients with hypocalcemia, women who are pregnant, and patients with a history of systemic hypersensitivity to any component of the product.

Please see Important Safety Information on back cover and accompanying Prolia® full Prescribing Information, including Medication Guide.

prolia® (denosumab) injection

prolia® (denosumab) injection

Why Use the Prolia® Specialty Pharmacy Network?

Specialty pharmacies in the Prolia® network help your appropriate patients *start* and *stay* on track with their Prolia® therapy. They can:

- Investigate benefits and facilitate prior authorization (PA) process
- Connect patients with financial assistance programs
- Ship on demand directly to your office or your patient's home
- Remind your office and patients when the next Prolia® injection is due

Please see Important Safety Information on back cover and accompanying Prolia® full Prescribing Information, including Medication Guide.

How to Get Started:

Identify & Submit

Your office will:

- Identify clinically appropriate patients
- Complete Patient Information Form
- Have patient review the Privacy Statement/Instruction Sheet and sign the Patient Information Form
- Fax completed Patient Information Form to selected Specialty Pharmacy

Fill & Ship

Specialty Pharmacy will:

- Investigate insurance coverage and facilitate the PA process
- Arrange for delivery and coordinate payment from the patient
- Ship prescription to your office or directly to your patient

Inject & Remind

Your office will:

- Administer Prolia® to patient
- Schedule appointment for the next injection

Specialty Pharmacy will:

- Remind office and patient when the next injection is due
- Refill prescription

prolia® (denosumab) injection

Specialty Pharmacy Patient Information Form

Patient Information

Patient Name: _____ Today's Date: _____
Fill out entirely OR ❑ **attach Face/Demographic Information Sheet**
Date of Birth: _____ Social Security Number: _____ M ❑ F ❑ **Patient Preferred Language:** _____
Address: _____ City: _____ State: _____ ZIP Code: _____
Work Phone: _____ Cell Phone: _____ E-mail: _____

Prescription Drug Insurance Information

Fill out entirely OR ❑ **fax a copy of insurance card front AND back.**

Primary Insurance: _____ Secondary Insurance: _____
Insured: _____ Insured: _____
Phone: _____ Phone: _____
Policy #: _____ Policy #: _____
RxBIN: _____ RxPCN: _____ RxBIN: _____ RxPCN: _____
Pharmacy Benefits: _____

Pertinent Medical Information*

Diagnosis Code*:

❑ 733.00 Osteoporosis, unspecified ❑ 733.01 Senile osteoporosis, postmenopausal osteoporosis ❑ Other (specify ICD-9-CM): _____

Risk Factors for Osteoporotic Fracture

❑ Lowest DXA Score (T-Score: _____) ❑ History of osteoporotic fracture
Other risk factors for osteoporotic fracture (if any): _____

History of 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): _____
Other pertinent medical information (eg, calcium and vitamin D supplementation): _____

* 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, payor requirements, practice patterns, and the services rendered.

Prescriber Information

Date Shipment Needed: _____ ❑ Ship to Physician Office ❑ Ship to Patient
Site Name: _____ Office Contact: _____
Address: _____
City: _____ State: _____ ZIP Code: _____ Phone: _____ Fax: _____

Prescription Information

Product Name/Strength: Prolia® 60 mg prefilled syringe Directions: 60 mg SC every 6 months Refill: _____
Physician Name: _____ NPI #: _____
I authorize the Specialty Pharmacy and its representatives to act as an agent to initiate and execute the insurance prior authorization process.

Prescriber Signature: ✗ _____ Date: _____

Specialty Pharmacy Option

❑ **Avella Specialty Pharmacy**
P: 1-877-546-5779
F: 1-877-546-5780

❑ **BioCure**
P: 1-855-497-7956
F: 1-855-497-7957

❑ **Diplomat Specialty Pharmacy**
P: 1-866-311-9966
F: 1-877-301-8207

❑ **Pharmacy Advantage**
P: 1-800-456-2112
F: 1-888-400-0109

❑ **Senderra Rx**
P: 1-888-777-5547
F: 1-888-777-5645

❑ **Total Life Care (TLC)**
P: 1-888-355-4191
F: 1-888-355-4192

Patient Consent (I have read and agree to the terms set forth in the Program and Privacy Information Form)

❑ I authorize Amgen and its contractors to enroll me in the Prolia® Specialty Pharmacy Network and Prolia® Patient Support Programs. I authorize the use and/or disclosure of my personal (included health-related) information for the purposes of these programs. I understand that I am authorizing Amgen and its contractors to contact me to provide reminders on future injections.
I understand that Healthcare Companies (such as the Specialty Pharmacy) may receive direct or indirect compensation from Amgen for the use or disclosure of my personal information for the purpose of the programs listed above.

Patient Signature: ✗ _____ Date: _____
My signature above certifies that I have read, understand, and agree to the terms set forth in the Program and Privacy Information Form (provided separately) regarding releasing my protected health information to Amgen and its contractors.

Key safety considerations for Prolia® include: hypersensitivity including anaphylaxis, hypocalcemia, osteonecrosis of the jaw, atypical femoral fractures, serious infections, dermatologic adverse events, musculoskeletal pain, and long-term suppression of bone remodeling.

NOTE TO PROVIDER: Prior to transmittal of any personal health information ("PHI"), obtain the legally required Patient Authorizations for verification services.

USA-162-104289

Program and Privacy Information Form

Dear Patient,

Your Prolia® prescription is being processed through the Prolia® Specialty Pharmacy Network. Below is information you should know about your prescription.

Payment

To fill your prescription, the specialty pharmacy (ie, Avella Specialty Pharmacy, BioCure, Diplomat Specialty Pharmacy, Pharmacy Advantage, Senderra Rx, Total Life Care [TLC]) may call you to obtain additional information, such as:

- Additional insurance information
- Payment for any out-of-pocket expenses (may require credit card)

A timely response to the specialty pharmacy may help you obtain Prolia® more quickly.

Delivery

Most often, your prescription will be sent to your doctor's office. If the prescription will be sent directly to you, please make sure you store the product as directed by the product labeling.

Privacy and Patient Support Programs

Amgen respects the privacy of your personal health information. Please read the following privacy notice and indicate your agreement by signing the patient authorization in the Patient Information Form (provided separately).

Prolia® Specialty Pharmacy Network Patient Program and Prolia® Patient Support Program

By signing the authorization in the Patient Information Form, I authorize Amgen and its contractors to use and/or disclose my personal (included health-related) information to enroll me in the **Prolia® Specialty Pharmacy Network Patient Program and Prolia® Patient Support Program**. I also authorize any healthcare providers, healthcare insurers, and pharmacies that have provided treatment, payment, or services to me or on my behalf (together, "Healthcare Companies") to use my personal information, including health-related information and information on insurance coverage and payment for Prolia® and/or to disclose my personal information to and among Healthcare Companies and Amgen.

I authorize Amgen to use and disclose my personal information for the following purposes:

- to provide me with educational or informational materials;
- to improve or develop products, services, and programs;
- to provide me with marketing and advertising materials relating to Prolia®;
- to evaluate, or ask for my opinion on, the services, programs, and materials provided to me and about my condition or Prolia® treatment;
- to enroll me in the Prolia® Patient Support Program, which includes all now-existing reimbursement services, nursing services, and ongoing disease management support; and
- to enroll me in the Prolia® Specialty Pharmacy Network Patient Program, which will contact me to provide reminders about when my next refill of Prolia® is due.

I understand the above-mentioned services and materials may be provided to me by Amgen and its contractors through e-mail, direct mail, and/or telephone calls. I also agree that my personal information may be used and disclosed under this authorization to contractors providing services on behalf of Amgen in addition to recipients as required by law.

I understand that the Healthcare Companies may receive direct or indirect compensation from Amgen for the use or disclosure of my personal information for the above-stated purposes.

Further, I understand that Amgen and their contractors will not sell nor rent my personal information. I am aware the Prolia® Privacy Policy is available at www.prolia.com.

I understand that Healthcare Companies must not condition my medical treatment, payment, or enrollment or eligibility for insurance benefits on my providing this authorization. However, if I do not provide my authorization, I cannot participate in these Programs. Once my information is disclosed by the Healthcare Companies to Amgen, and/or their contractors pursuant to this authorization, federal privacy laws may no longer protect the information from further disclosure. Amgen will take reasonable steps designed to protect the confidentiality of my personal information.

This authorization will expire 10 years from the date of my signature. I may cancel this authorization at any time by calling the specialty pharmacy that I fill the prescription with and the Prolia® Patient Support Program at the below telephone numbers. If I cancel this authorization, I will not continue receiving services under these Programs. Once entity receives and processes my cancellation, entity will not use my personal information going forward. I understand that cancelling my authorization will not affect any use of my information that occurred before my request was processed. I am entitled to receive a copy of this authorization at any time by sending a letter to Amgen, PO Box 781046, Indianapolis, IN 46268.

Specialty Pharmacy and Prolia® Patient Support Program contact telephone numbers:

- ❑ **Prolia® Patient Support Program: 1-800-917-1622**
- ❑ **Avella Specialty Pharmacy: 1-877-546-5779**
- ❑ **BioCure: 1-855-497-7956**
- ❑ **Diplomat Specialty Pharmacy: 1-866-311-9966**
- ❑ **Pharmacy Advantage: 1-800-456-2112**
- ❑ **Senderra Rx: 1-888-777-5547**
- ❑ **Total Life Care (TLC): 1-888-355-4191**

Important Safety Information

- **Contraindications:** Prolia® (denosumab) 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.
- **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, clinical monitoring of calcium and mineral levels is highly recommended within 14 days of Prolia® injection. 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®.

  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 anti-resorptive 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.
- **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® groups. 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.
- **Prolia® Postmarketing Active Safety Surveillance Program:** The 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.

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

AMGEN®

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