



MRN: _____

DOB: _____

Phone: 1-800-809-1265 Fax: 1-866-872-8920

STANDARD Prolia® (denosumab) PLAN OF TREATMENT

(Re) Certification Period From _____ to _____

NOTE: Patient ***may be ineligible*** to receive Prolia® if serum calcium levels are sub-therapeutic, receiving antibiotics for active infectious process, antifungal therapy, active fever and/or suspected infection. Treat hypocalcemia, hypovitaminosis D, and other disturbance of bone and mineral metabolism before starting therapy.

1. Patient Name: _____ Height (inches): _____ Weight (lbs): _____

2. Allergies: _____

3. Diagnosis: * Please complete the 2nd and 3rd digits to complete the ICD-10 code for billing

- M81.0 Age-related Osteoporosis without current fractures C61 Malignant neoplasm of the Prostate
- C50.____ Breast Cancer Other **ICD-10 Code:** _____ **Diagnosis description:** _____
- Z79.818 Long-term use of agents affecting estrogen receptors and estrogen levels
- Z79.899 Long-term current use of other medications

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4. History: Is the patient on Calcium and Vitamin D replacement? Yes No

(It is recommended that patients receive 1000 mg of supplemental calcium and at least 400 IU of vitamin D daily, treatment will not be administered if the serum calcium is sub-therapeutic.)

Orders: Obtain weight each visit. Monitor pre-injection vital signs and then may discharge after each injection. Instruct patient/caregiver on medications and signs/symptoms of adverse reaction. Assess patient for response to therapy. Supplies needed to complete prescribed therapy. **Pharmacist to perform clinical drug monitoring. If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES.** Utilize existing central line or initiate a peripheral IV as needed for treatment of Adverse Reactions. Sodium Chloride 0.9% flush 3-10 ml and/or Heparin flush 100 units/ml 1-5 ml per line type if needed for treatment of Adverse Reactions.

5. Dose/Frequency:

- Prolia® (denosumab) 60mg subcutaneously every 6 months
(Administer as subcutaneous injection only to upper arm, upper thigh, or abdomen)

Lab Orders: ***BMP prior to each dose; hold dosing if serum Calcium sub-therapeutic.***
Pharmacist will perform clinical lab monitoring, preferred results within 14-30 days of each dose.

Special orders: _____

6. Physician's Signature: _____ / _____ Date: _____
No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials: _____

7. Fax updated supporting clinical MD notes with each order renewal or change in orders
Infusion order forms available at www.palmettoinfusion.com



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Guidelines for Prescribing Prolia® (denosumab)

(Required documentation with all initial referrals)

Patient Name: _____

Referral Date: _____

___ Include signed and completed **Plan of Treatment**. (MD must complete sections 1-7)
(Infusion order forms & Standard Adverse Reactions orders are available at www.palmettoinfusion.com under Agency/MD tab)

___ Include patient demographic information and insurance information. (Copy of insurance cards if available)

___ **Supporting clinical MD notes to include any past tried and/or failed therapies, intolerance, outcomes or contraindications to conventional therapy. Include any lab results and/or tests to support diagnosis.**

- Prolia® is indicated for: • Treatment of postmenopausal women with osteoporosis at high risk for fracture • Treatment to increase bone mass in men with osteoporosis at high risk for fracture • Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer • Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer
- **Please include documentation regarding treatment history to include: Inadequate response or intolerance to oral bisphosphonates, presence or history of osteoporotic fractures, low bone mass (T-score more than 2.0 standard deviations below premenopausal mean; 2.5 for Medicare patients)**

___ If patient is switching bisphosphonate therapies, then MD must specify wash-out period prior to starting Prolia® as specified of _____ weeks. Last known therapy: _____ and last date received: _____.

___ Other as requested: _____

Pre-Screening:

___ BMP results required within last 30 days

**** Warnings/Precautions:** Patients receiving Prolia® should not receive XGEVA® • **Hypersensitivity:** including anaphylactic reactions may occur. Discontinue permanently if a clinically significant reaction occurs • **Hypocalcemia:** Must be corrected before initiating therapy. May worsen, especially in patients with renal impairment. • **Osteonecrosis of the jaw:** Has been reported with Prolia®. Monitor for symptoms • **Atypical femoral fractures:** Have been reported. Evaluate patients with thigh or groin pain to rule out a femoral fracture • **Multiple vertebral fractures:** have been reported following therapy discontinuation, consider transitioning to another antiresorptive agent if Prolia® is discontinued • **Serious infections** including skin infections: May occur, including those leading to hospitalization. Advise patients to seek prompt medical attention if they develop signs or symptoms of infection, including cellulitis • **Dermatologic reactions:** Dermatitis, rashes, and eczema have been reported. Consider discontinuing, if severe symptoms develop • **Severe bone, joint, muscle pain:** may occur, discontinue use if severe symptoms develop • **Suppression of bone turnover:** Significant suppression has been demonstrated, monitor for consequences of bone over suppression. **Renal impairment:** No dose adjustment is necessary in patients with renal impairment. Patients with creatinine clearance < 30 mL/min or receiving dialysis are at risk for hypocalcemia. **Pregnancy:** Prolia® is contraindicated in women who are pregnant. See full prescribing information.

Palmetto Infusion Services will complete insurance verification and submit all required clinical documentation to the patient's insurance company for eligibility. Our office will notify you if any further information is required. We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.

Please fax all information to 1-866-872-8920 or call 1-800-809-1265 for assistance.