MRN:_____

DOB: _____

STANDARD Prolia® (denosumab) PLAN OF TREATMENT

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

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.)

Pharmacist to perform clinical drug monitoring.

If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES.

5. Dose/Frequency:

Prolia® (denosumab) 60mg subcutaneously every 6 months

(Administer as subcutaneous injection only to upper arm, upper thigh, or abdomen)

6. Lab Orders: Calcium ***prior to first dose, then annually. Hold dosing if serum Calcium sub-therapeutic.***

Pharmacist will perform clinical lab monitoring.

Special orders: _____

7. Physician's Signature:_____/_____ Date: _____

No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials: _____

MRN: _____

DOB: _____

Guidelines for Prescribing Prolia® (denosumab)

(Required documentation with all initial referrals)

Patient Name: _____ **Referral Date:** _____

☐ Include signed and completed **Plan of Treatment**.

☐ 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:

☐ Calcium results required before the first injection then annually.

** **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.

Checklist for referrals to AccuRX Infusion Center:

Fax referral to 1-866-990-3192

- Patient demographics – address, phone number, SS#, etc.
- Insurance Information – copy of the card(s) if possible
- Plan of Treatment/Orders
- Most recent physician office notes to include tried and failed therapies – all insurance companies that require a pre-authorization require the note. This includes Medicare/Medicaid HMOs
- Any lab results or other diagnostic procedures to support the diagnosis

AccuRx Infusion Center 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.