

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI #:

If Applicable: Pharmacy Name: _____
Pharmacy Phone: _____

Complete the Clinical Assessment:

Please attach all relevant medical records and test results.

STEP
2

Diagnosis	<input type="checkbox"/> Postmenopausal osteoporosis documented by bone densitometry (e.g. DEXA). <input type="checkbox"/> High risk for fracture with <i>evidence of bone loss documented</i> on bone densitometry (e.g. DEXA) and: <input type="checkbox"/> postmenopausal female receiving adjuvant aromatase inhibitor therapy for non-metastatic breast cancer; or <input type="checkbox"/> male receiving androgen deprivation therapy for non-metastatic prostate cancer	<input type="checkbox"/> Other (please state): _____ _____ _____ _____
Clinical information	For diagnosis of Osteoporosis ONLY (documentation required) <input type="checkbox"/> Patient failed and/or is intolerant to bisphosphonate therapy (indicate failed therapy(s)): _____	
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Prolia [®] (denosumab) Strength _____ Sig _____ Qty _____ Refills _____	
	<p align="center">We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.</p>	

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

Prescriber Signature

Date

STEP 4 **Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk: 970-248-5034**

Name of Person filling out form: _____

Pharmacy Technician Initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 02/13/12

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Denosumab (Prolia™)

CLASSIFICATION

- Monoclonal antibody, anti-resorptive

DESCRIPTION

- Denosumab is a monoclonal antibody that inhibits the development and activity of osteoclasts through binding inhibition of the RANK ligand (RANKL) protein, which inhibits the formation, function, and survival of osteoclasts, leading to decreased bone resorption and increased bone mass and strength in the cortical and trabecular bone
- It is indicated for the treatment of osteoporosis with a high risk of fracture in postmenopausal women, including women with a history of osteoporotic fracture, multiple risk factors for fracture, or women intolerant to other osteoporosis agents.
- Supplemental calcium and vitamin D are required
- Denosumab treatment every 6 months significantly reduced the incidence of new vertebral fracture compared with placebo in postmenopausal women with low bone mineral density (BMD) according to the 36-month, randomized, controlled Fracture Reduction Evaluation of Denosumab in Osteoporosis Every 6 Months (FREEDOM) trial (n=7808)
- Adverse events associated with the use of denosumab with greater frequency compared with placebo include hypocalcemia, serious infections, and osteonecrosis of the jaw.
- It is indicated as a treatment to increase bone mass in women who are at high risk for fracture and receiving adjuvant aromatase inhibitor therapy for breast cancer.
- *Treatment* with denosumab 60 mg administered every 6 months, significantly increased lumbar spine (LS) bone mineral density (BMD) from baseline at 12 months and 24 months in *postmenopausal women with nonmetastatic breast cancer and low bone mass* receiving adjuvant aromatase inhibitor therapy in a multicenter, randomized, double-blind, placebo-controlled phase 3 study (n=252). Evidence of low bone mass is defined as BMD T-scores between -1 to -2.5 at the lumbar spine, femoral neck, and total hip.
- It is indicated as a treatment to increase bone mass in men who are at high risk for fracture and receiving androgen deprivation therapy for *nonmetastatic* prostate cancer.
- *Treatment* with denosumab increased bone mineral density at the lumbar spine, femoral neck, and total hip, as well as reduced the incidence of new vertebral fractures among men receiving androgen-deprivation therapy for nonmetastatic, hormone-sensitive prostate cancer in a multicenter, double-blind, placebo-controlled trial (n=1468). Patients had either a low BMD at baseline (defined as a T score at the lumbar spine, total hip, or femoral neck of less than -1.0) or a history or an osteoporotic fracture.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 6
Commercial Formulary:	Tier 6
Medicare Part D coverage:	Tier 4

COVERAGE CRITERIA

Prolia (denosumab) meets the definition of **medical necessity** for the following:

- Post-menopausal osteoporosis in women who are either intolerant or have failed bisphosphonates. Documentation of osteoporosis diagnosis on bone mass densitometry (e.g. DEXA) required. Documentation supporting trial and failure or intolerance to oral bisphosphonate required.
- As **treatment** to increase bone mass in women who are on adjuvant aromatase inhibitor therapy for nonmetastatic breast cancer and who are at high risk for fracture with *evidence of bone loss documented* on bone densitometry (e.g. DEXA). Evidence of low bone mass is defined as BMD T-scores between -1 to -2.5 at the lumbar spine, femoral neck, and total hip.
- As **treatment** to increase bone mass in men who are on androgen deprivation therapy for nonmetastatic prostate cancer and who are at high risk for fracture with *evidence of bone loss documented* on bone densitometry (e.g. DEXA) with low BMD at baseline defined as a T score at the lumbar spine, total hip, or femoral neck of less than -1.0 **OR** documentation supporting history of an osteoporotic fracture.

Prolia (denosumab) is considered **experimental** for the following:

- Osteopenia
- Bone metastases, associated with breast cancer, multiple myeloma or other malignancies
- In males
- First line therapy for osteoporosis (without documented failure or intolerance of bisphosphonates)
- *Prophylaxis* against loss of bone mass in women at high risk for fracture and receiving an adjuvant aromatase inhibitor for breast cancer.
- *Prophylaxis* against loss of bone mass in men at high risk for fracture and receiving androgen deprivation therapy for nonmetastatic prostate cancer.

Required Provider Specialty:

- None required

DOSAGE/ADMINISTRATION:

1) Postmenopausal osteoporosis;

2) Osteopenia in women at high risk of fracture receiving aromatase inhibitor therapy for nonmetastatic breast cancer;

3) Osteopenia in men at high risk of fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer:

- 60 milligrams (mg) subcutaneously once every 6 months *by a healthcare provider*, plus calcium 1000 mg orally once daily and at least vitamin D 400 international units orally once daily

Dosage in Renal Failure

- Dose adjustments are NOT needed in patients with renal impairment but there is an increased risk of hypocalcemia. Consider the benefit-risk profile when administering to patients with severe renal impairment or receiving dialysis.

PRECAUTIONS:

- Pre-existing hypocalcemia; correct before initiating therapy
- Bone remodeling suppression has been reported; may contribute to osteonecrosis of the jaw, atypical fractures, and delayed fracture healing
- The following conditions may also increased the risk for osteonecrosis of the jaw: Comorbid disorders (e.g. cancer, infection, coagulopathy, anemia, ill-fitting dentures, periodontal, poor oral hygiene, other pre-existing dental disease), concomitant chemotherapy or corticosteroids, or invasive dental procedures (e.g. tooth extraction, dental implants, oral surgery)
- Dermatitis, eczema, and rashes have been reported; discontinue therapy with severe symptoms
- Endocarditis has been reported; assess need for continued therapy
- Hypocalcemia may be exacerbated
- Immunosuppression, pre-existing; increased risk for serious infections
- Mineral metabolism disturbances, pre-existing (e.g. hypoparathyroidism, thyroid or parathyroid surgery, malabsorption syndromes, excision of small intestine); increased risk of hypocalcemia, hypomagnesemia, and hypophosphatemia; monitor serum levels; adequate intake of calcium and vitamin D required during therapy
- Opportunistic infections requiring hospitalization involving the skin, abdomen, urinary tract, and ear have been reported; assess need for continued therapy
- Severe renal impairment (creatinine clearance less than 30 mL/min) or receiving dialysis; significant risk for hypocalcemia; maintain calcium levels with adequate intake of calcium and vitamin D during therapy

Billing/Coding information

Associated HCPCS Codes:

C9272	Injection, denosumab, 1mg
J3590	Unclassified biologics

Associated CPT Coding:

Associated ICD-9 Coding:

733.01	Postmenopausal osteoporosis
E933.6	Oral bisphosphonate causing adverse effects in therapeutic use
V07.52	Prophylactic use of Aromatase inhibitors
V13.51	Personal history of pathological fracture

COST

- AWP (August 2010): 60mg/ml syringe (dosed every 6 months): \$990.00

COMMITTEE APPROVAL:

- May 25, 2011

GUIDELINE UPDATE INFORMATION:

August 2010	Policy created
October 2011	Policy updated for new indications

REFERENCES:

- DRUGDEX®, accessed 08/02/2010, 10/26/11
- Product Information: PROLIA(TM) subcutaneous injection, denosumab subcutaneous injection. Amgen, Inc, Thousand Oaks, CA, 2010.