

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:

STEP
2

Diagnosis	<input type="checkbox"/> Postmenopausal osteoporosis documented by bone densitometry (e.g. DXA)	<input type="checkbox"/> Other (please state): _____
Clinical information	<input type="checkbox"/> Patient failed and/or is intolerant to bisphosphonate therapy (indicate failed therapy(s)): _____	
Supporting Documentation	Diagnosis: ICD-9 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 _____	
Please attach all relevant medical records and test results. Incomplete forms will not be processed.		

STEP
3

I certify that the above is correct and accurate to the best of my knowledge (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.

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.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Medical benefit
Commercial Formulary:	Medical benefit
Medicare Part D coverage:	Part B

COVERAGE CRITERIA

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

- Post-menopausal osteoporosis in women who or either intolerant or have failed bisphosphonates

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)

Required Provider Specialty:

- None required

DOSAGE/ADMINISTRATION:

Postmenopausal osteoporosis

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

Dosage in Renal Failure

- No dose adjustments are needed in patients with renal impairment. Due to an increased risk of hypocalcemia, consider the benefit-risk profile when administering to patients with severe renal impairment or receiving dialysis

PRECAUTIONS:

- Hypocalcemia, pre-existing; 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 (eg, cancer, infection, coagulopathy, anemia, ill-fitting dentures, periodontal, poor oral hygiene, other pre-existing dental disease), concomitant chemotherapy or corticosteroids, or invasive dental procedures (eg, 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 (eg, 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
- Renal impairment, severe (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:

C9399	Unclassified drugs or biologicals
J3590	Unclassified biologics

Associated CPT Coding:

Associated ICD-9 Coding:

733.01	Postmenopausal osteoporosis

COST

- AWP (August 2010): 1 60mg/ml syringe (dosed every 6 months): \$990.00

COMMITTEE APPROVAL:

GUIDELINE UPDATE INFORMATION:

August 2010	Policy created

REFERENCES:

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