

**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 Number:

**If Applicable:** Pharmacy Name: \_\_\_\_\_  
 Pharmacy Phone: \_\_\_\_\_

**Complete the Clinical Assessment:  
 Please attach all relevant medical records and test results.**

Diagnosis	<input type="checkbox"/> Risk of skeletal-related events in patient with bone metastases from solid tumor cancer (documentation required). <input type="checkbox"/> Patient <b>does not</b> have a diagnosis of Multiple Myeloma	<input type="checkbox"/> Other (please state): _____ _____ _____
Clinical Consideration	<input type="checkbox"/> Preexisting hypocalcemia corrected <input type="checkbox"/> Patient will receive calcium and vitamin D as needed to treat or prevent hypocalcemia	
Physician Specialty	Diagnosis made by: <input type="checkbox"/> Oncologist <input type="checkbox"/> Other (please state): _____	
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: Xgeva <sup>®</sup> (denosumab) Strength _____ Sig _____ Qty _____ Refills _____	
	<p align="center"><b>We will not process incomplete forms.          If we do not receive the completed form &amp; all relevant medical records &amp; test results within 10 calendar days of this request, it will be denied.</b></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:**

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## RMHP Formulary Coverage Policy

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

### Xgeva® (Denosumab)

#### 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
- Denosumab is indicated for prophylaxis of skeletal-related events (SRE) in patients with bone metastases associated with solid tumors.
- It is not indicated for the prevention of skeletal-related events in patients with multiple myeloma. A subgroup analysis in patients with Multiple Myeloma (n=180) showed a higher rate of mortality with Xgeva.
- In an international, randomized, double-blind, active-controlled, phase 3, noninferiority trial (n=2046), denosumab was superior to zoledronic acid for delay of time to first SRE in patients with bone metastasis from advanced breast cancer.
- In an international, randomized, double-blind, double-dummy, active-controlled trial (n=1901), denosumab was superior to zoledronic acid for delay of time to first SRE in men with bone metastasis from castrate-resistant prostate cancer.
- In an international, randomized, double-blind, double-dummy, active-controlled noninferiority trial (n=1776), denosumab was noninferior to zoledronic acid in delaying time to first SRE in patients with solid tumors other than breast and castrate-resistant prostate cancer with bone metastasis and multiple myeloma.
- Monitor calcium, phosphorus, and magnesium levels during therapy, especially in patients predisposed to hypocalcemia and disturbances of mineral.
- Supplemental calcium and vitamin D are required.
- Adverse events associated with the use of denosumab with greater frequency greater or equal to 25% include fatigue/asthenia, hypophosphatemia, and nausea.

#### FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 6
Commercial Formulary:	Tier 6
Medicare Part D coverage:	Part B if administration is “incident to a physician’s service” otherwise Part D (Tier 5)

#### COVERAGE CRITERIA

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

- Patient with bone metastases from a solid tumor cancer to prevent skeletal-related events (documentation required).
  - Patient **does not** have a diagnosis of Multiple Myeloma

- Preexisting hypocalcemia is a contraindication to use of Xgeva and must be corrected prior to therapy
- Patient will receive calcium and vitamin D as necessary to treat or prevent hypocalcemia

Xgeva® (denosumab) is considered **experimental** for the following:

- Any indication that is not FDA approved or Compendia supported.

Required Provider Specialty:

- Oncologist

## DOSAGE/ADMINISTRATION:

### Prevention of skeletal-related events in patients with bone metastasis associated with solid tumors

- 120 milligrams (mg) subcutaneously once every 4 weeks *by a healthcare provider*.

### 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 must be corrected before initiating therapy.
- Bone remodeling suppression has been reported and may contribute to osteonecrosis of the jaw, atypical fractures, and delayed fracture healing.
- The following conditions may also increase the risk for osteonecrosis of the jaw: Comorbid disorders (e.g. cancer, infection, coagulopathy, anemia, ill-fitting dentures, periodontal, poor oral hygiene, and 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. Severe symptoms warrant discontinuation of Xgeva therapy.
- Endocarditis has been reported and necessitates assessment for continued therapy.
- Hypocalcemia may be exacerbated.
- Pre-existing immunosuppression increases the 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; evaluate need for continued therapy.
- Severe renal impairment (creatinine clearance less than 30 mL/min) or receiving dialysis; increases risk for hypocalcemia significantly; maintain calcium levels with adequate intake of calcium and vitamin D during therapy.

## Billing/Coding information

### Associated HCPCS Codes:

J0897	Injection, denosumab, 1mg (For billing prior to 1/1/12 use J3590 or C9272)
J3590	Unclassified biologics

### Associated CPT Coding:


### Associated ICD-9 Coding:

198.5	Secondary malignant neoplasm

### COST

- AWP (August 2011): 120mg/1.7ml single-use vial: \$1980.00

### COMMITTEE APPROVAL:

- May 25, 2011

### GUIDELINE UPDATE INFORMATION:

November 14, 2011	Coverage policy creation

### REFERENCES:

- DRUGDEX®, accessed November 14, 2011.
- Product Information: Xgeva™ (denosumab) subcutaneous injection. Amgen, Inc, Thousand Oaks, CA, 2010.