



Updated: 04/2019
PARP Approved: 04/2019

Prior Authorization Criteria
Xgeva (denosumab), Prolia (denosumab)

All requests for Xgeva (denosumab), Prolia (denosumab) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Xgeva® (denosumab), Prolia® (denosumab) all of the following criteria must be met:

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be prescribed by on in consultation with an oncologist or hematologist (Xgeva only)
- An attestation of the following:
 - The member is receiving routine dental exams due to the risk of osteonecrosis of the jaw (ONJ).
 - The member does not have hypocalcemia
 - Ongoing monitoring of calcium levels during therapy and adequate supplementation with calcium and vitamin D

Requests for Xgeva® (denosumab):

Coverage may be provided with a diagnosis for prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors

Coverage may be provided with a diagnosis of giant cell tumor of bone and the following criteria is met:

- Members must be 12 years of age or older
- Members must be skeletally mature
- The tumor must be unresectable or surgical resection is likely to result in severe morbidity

Coverage may be provided with a diagnosis of hypercalcemia of malignancy and the following criteria is met:

- Documentation of an albumin-corrected calcium of $> 12.5\text{mg/dl}$ (3.1 mmol/L) despite treatment with IV bisphosphonate therapy within the previous 30 days

Requests for Prolia® (denosumab)

For all requests for Prolia® (denosumab) all of the following criteria must be met:

- The member must be at moderate or high risk for fracture defined by one of the following:
 - A documented T-score between -1.0 and -2.5 at the lumbar spine, total hip, femoral neck, or 33% radius and one of the following:
 - Is on an aromatase inhibitor
 - Is on androgen deprivation therapy
 - History of osteoporotic fracture
 - The 10-year probability for major osteoporotic fracture is $\geq 20\%$ or the 10-year probability of hip fracture is $\geq 3\%$ based on the U.S. adapted World Health Organization (WHO) algorithm (also known as FRAX)
 - History of a fragility fracture as an adult
 - The member is on prednisone $\geq 7.5\text{mg/day}$ (or equivalent) and planning to continue therapy for at least 6 months and has one of the following:

- A z score <-3 at hip or spine
- A $\geq 10\%$ per year bone loss of BMD at hip or spine
- The member must currently be on or recently (within the last year) taken a glucocorticoid steroid and have one of the following:
 - FRAX (glucocorticoid-adjusted) 10 year risk for major osteoporotic fracture $\geq 10\%$
 - FRAX (glucocorticoid-adjusted) 10 year risk for hip fracture $> 1\%$
- The member was recently on (within the past year) prednisone ≥ 30 mg/day and a cumulative dose of > 5 gm
- A documented T-score of less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or 33% radius
- Must have tried (for at least 1 year each) and failed one oral bisphosphonate therapy and intravenous zoledronic acid unless contraindicated, intolerant, or member is experiencing an increased amount of fractures while on therapy

Coverage may be provided with a diagnosis of decreasing bone mass in women with breast cancer

Coverage may be provided with a diagnosis of glucocorticoid-induced osteoporosis and the following criteria is met:

- The member must currently be on or recently (within the last year) taken a glucocorticoid steroid

Coverage may be provided with a diagnosis of decreasing bone mass in men with non-metastatic prostate cancer

Coverage may be provided with a diagnosis of decreasing bone mass in men with osteoporosis

Coverage may be provided with a diagnosis of postmenopausal osteoporosis in women

- **Initial Duration of Approval:** 12 months
- **Reauthorization Criteria:**
 - For Xgeva
 - For hypercalcemia of malignancy:
 - Documentation the member has corrected serum calcium ≤ 11.5 mg/dL (2.9 mmol/L)
 - For all other diagnoses there is chart documentation of clinical improvement or stabilization of disease
 - For Prolia:
 - Documentation of clinical improvement or stabilization of disease
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.



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**XGEVA (DENOSUMAB), PROLIA (DENOSUMAB)
PRIOR AUTHORIZATION FORM**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway HealthSM Pharmacy Services. **FAX:** (888) 245-2049

If needed, you may call to speak to a Pharmacy Services Representative.

PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE: _____)

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐ Giant Cell Tumor of Bone ☐ Hypercalcemia of Malignancy ☐ Osteoporosis ☐ Other: _____
ICD-10 Code: _____

For Giant Cell Tumor of Bone is the member skeletally mature? ☐ Yes ☐ No

Is the tumor unresectable or surgical resection is likely to result in severe morbidity? ☐ Yes ☐ No

For Hypercalcemia of Malignancy please provide the member's albumin-corrected calcium: _____

Did the member have a bone density test performed? ☐ Yes ☐ No

If yes, T-score result: _____

10-year probability score: _____

Do any of the following apply to the member (check all that apply):

- ☐ History of an osteoporotic fracture
- ☐ History of a fragility fracture
- ☐ The member is on an aromatase inhibitor
- ☐ The member is on androgen deprivation therapy

Is the member on prednisone ≥ 7.5 mg/day (or equivalent) and planning to continue therapy for at least 6 months ☐ Yes ☐ No

If yes please provide one of the following:

Z score: _____

% bone loss per year _____

FRAX (glucocorticoid-adjusted) 10 year risk for major osteoporotic fracture _____

FRAX (glucocorticoid-adjusted) 10 year risk for hip fracture _____

Was the member recently on (within the past year) prednisone ≥ 30 mg/day and a cumulative dose of > 5 gm?

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

If the member has hypercalcemia of malignancy please provide the member's corrected serum calcium _____

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No

Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature

Date

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