DENOSUMAB: PROLIA®; XGEVA®
Preauthorization Request
(Preauthorization is not a guarantee of payment)

SECTION I – General Information	
Today's Date: / /	☐ New request
Fax completed form to:**1-866-805-4150 toll free**	☐ Re-Authorization

Level of Urgency:

Standard Request (Routine Care)—Care/treatment that is not emergent, urgent, or preventive in nature.

Expedited Request—Care/treatment that is emergent or the application of the timeframe for making Standard/Routine or nonlife-threatening care determinations:

- Could seriously jeopardize the life, health, or safety of the member or others, due to the member's psychological state, or
- In the opinion of the practitioner with knowledge of the member's medical or behavioral condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request.

For Expedited Request, Please Explain:

SECTION II – Member Information		
Patients Name:	Member ID:	**Patient Information**: DOB:__/__/__ Sex: Age: Weight: ☐ lbs. ☐ Kg Will the patient self-administer the requested medication? ☐ Yes ☐ No
Patients Address:	Is CBC primary payer: ☐ Yes ☐ No	

Plan Type:

☐ PPO ☐ POS ☐ KHPC ☐ CHIP (aka Capital Cares 4Kids)

☐ Traditional ☐ Comprehensive ☐ Special Care ☐ Other* _____

NOTE: For all Medicare Advantage products, please contact Prime Therapeutics at https://www.covermymeds.com/main or via phone at 1-866-260-0452.

SECTION III – Provider Information Required	
Requesting Provider Name: **Address**:	**Requesting Provider CBC #**_____ **NPI #** _____
Telephone #:	Secure Fax #:
Office Contact Name:	Office Contact Telephone #:
Is the Rendering/Servicing provider different? ☐ No ☐ Yes – Complete rendering provider information below.	
Rendering Provider Name: **Address**: **Telephone:**	**Rendering Provider CBC #**_____ **NPI #** _____
Site of Service: ☐ MD Office ☐ Home Health ☐ Non-hospital affiliated, outpatient infusion center ☐ Hospital affiliated, outpatient infusion center ☐ Other: Specify _____ **Please refer to MP 3.016 for Site of Service requirements.*	**Check all that apply and include all applicable documentation:** ☐ There are contraindications to a less intensive site of care. ☐ A less intensive site of care is not appropriate for the patient's condition. ☐ Patient is being treated with a drug that cannot be administered in a less intensive site of care concurrently. ☐ Less intensive site of care is not available. **Please include all applicable documentation.*
SECTION IV – Preauthorization Requirements and Clinical Criteria	
Is the prescriber a specialist in the area of the patient's diagnosis or has the prescriber consulted with a specialist in the area of the patient's diagnosis? ☐ Yes Specialty: _____ ☐ No	
☐ New to therapy ☐ Continuing therapy*: Initial start __/__/__ ☐ Reinitiating therapy: Last treatment __/__/__ *Please include documentation for changes in dose.	**Route of Administration:** ☐ Intravenous (IV) ☐ Injection (Sub Q or IM) ☐ Oral (PO) or Enteral ☐ Other: Specify _____
HCPC Code(s):	**Diagnosis Code(s)**:
Medication requested:	**Indication:**

Does the patient have late stage metastatic disease? ☐ Yes ☐ No

For patients with late stage metastatic disease (Stage IV), please refer to MP 2.373 Step Therapy Treatment in Cancer, Including Treatments for Stage Four, Advanced Metastatic Cancer and Severe Related Health Conditions for additional guidance.

Type of drug requested: ☐ Brand name ☐ Generic ☐ Biosimilar ☐Other: Specify _____

Initial start date of therapy: __/__/__	Anticipated date of **next administration:** __/__/__

Dosing period for request:	**Dosing Information:**
Start Date: __/__/__ End Date __/__/__	Dose: Strength: Frequency: Quantity requested per month:

Attach documentation demonstrating the medical necessity of the requested drug. Please list all reasons for selecting the requested medication, strength, dosing schedule, and quantity over alternatives (e.g., contraindications, allergies, history of adverse drug reactions to alternatives, lower dose has been tried, information supporting dose over FDA max.)

Has the patient had **medical testing** completed for use of this drug? (labs, imaging) ☐ Yes ☐ No

Results:_____

Is drug being requested for an "**off label" indication**? ☐ Yes ☐ No

If yes, please see Medical Policy 2.103 and include any applicable documentation.

Please list any previous medications that were **tried and failed**. Include reason for discontinuation (intolerance, hypersensitivity, inadequate response etc.). Please attach documentation.

Drug(s) and strength:

Documentation of failure:

Check drug being prescribed and please answer all universal criteria questions

☐ **Prolia**

- Is the patient supplementing with 1,000mg of calcium and at least 400IU of vitamin D daily? ☐ Yes ☐ No
- Does the patient have hypocalcemia? ☐ Yes ☐ No
- Is the patient at least 18 years of age? ☐ Yes ☐ No
- Is the patient at high risk* for fracture? ☐ Yes ☐ No
- If patient is of child-bearing potential, has pregnancy been ruled out? ☐ Yes ☐ No

*High risk for fractures include, but are not limited to, one or more of the following: history of an osteoporotic fracture as an adult, parental history of hip fracture, low BMI, rheumatoid arthritis, alcohol intake of 3 or more drinks per day, current smoker, or history of oral glucocorticoids greater than or equal to 5mg/d of prednisone (or equivalent) for greater than 3 months.

☐ **Xgeva**

- Will patient be taking calcium and vitamin D as necessary to treat or prevent hypocalcemia? ☐ Yes ☐ No

COMPLETE BELOW FOR RELEVANT INDICATION

Prolia

☐ **Osteoporosis in Men and Women**

- Women only: Is patient post-menopausal? ☐ Yes ☐ No
- Does the patient have a documented diagnosis of osteoporosis indicated by one or more of the following? ☐ Yes ☐ No
  - Hip/femur DXA (femoral neck or total hip) or lumbar spint T-score less than or equal to -2.5 and/or forearm DXA 33% (one-third) radius site;
  - T-score less than or equal to -1 or low bone mass and a history of fragility fracture to the hip or spine;
  - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture greater than or equal to 20% or hip fracture great than or equal to 3%
- Is there documented treatment failure or ineffective response* to a minimum (12) month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, resedronate, ibandronate, or zoledronic acid? ☐ Yes ☐ No
- Does the patient have a documented contraindication** or intolerance to BOTH oral bisphonates and intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid? ☐ Yes ☐ No

☐ **Glucocorticoid-Induced Osteoporosis**

- Patient will be initiating or is continuing systemic glucocorticoid therapy at a daily dosage equivalent to greater than or equal to 7.5mg of prednisone and is expected to remain on glucocorticoid therapy for at least 6 months? ☐ Yes ☐ No
- Is there documented treatment failure or ineffective response* to a minimum (12) month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, resedronate, ibandronate, or zoledronic acid? ☐ Yes ☐ No
- Does the patient have a documented contraindication** or intolerance to BOTH oral bisphonates and intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid? ☐ Yes ☐ No

☐ **Osteoporosis treatment and prevention in prostate cancer patients**

- Does the patient have documented hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -1 (or patient meets the diagnostic criteria for osteoporosis as listed above in the 1st indication)?
  ☐ Yes ☐ No
- Is the patient receiving androgen deprivation therapy for non-metastatic prostate cancer? ☐ Yes ☐ No

☐ **Osteoporosis treatment and prevention in breast cancer patients**

- Is the patient receiving adjuvant aromatase inhibitor therapy for breast cancer? ☐ Yes ☐ No

*Ineffective response is defined as one or more of the following: decrease in T-score in comparison with baseline T-score from DXA scan and/or patient has a new fracture while on bisphosphonate therapy.

**Examples of contraindications to oral bisphosphonate therapy include the following: documented inability to sit or stand upright for at least 30 minutes and/or documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia.

Xgeva

□ **Prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors**

- Is the patient at least 18 years of age? □ Yes □ No
- Has the patient tried and had an inadequate response, contraindication***, or intolerance to at least a three (3) month trial of Zoledronic acid? □ Yes □ No
- Does the patient have metastatic breast cancer, metastatic castration-resistant prostate cancer, or metastatic lung cancer (both SCLC and NSCLC)? □ Yes □ No

□ **Giant Cell Tumor of the Bone**

- Is the patient an adult or at least 12 years of age and skeletally mature? □ Yes □ No
- Is the disease unresectable or surgical resection is likely to result in severe morbidity? □ Yes □ No
- Is the disease localized, recurrent, or metastatic? □ Yes □ No
- If yes to the above question, will the drug be used as a single agent or used in combination with interferon alpha, serial embolization, or radiation therapy? □ Yes □ No

□ **Hypercalcemia of malignancy**

- Is the patient at least 18 years of age with a diagnosis of cancer (malignancy)? □ Yes □ No
- Does the patient have a diagnosis of refractory hypercalcemia of malignancy defined as an albumin-corrected calcium of greater than 12.5 mg/dL (3.1 mmol/L) despite treatment with a minimum seven (7) day trial on previous therapy with intravenous (IV) bisphosphonates such as ibandronate or zoledronic acid? □ Yes □ No
- Does the patient have a documented contraindication*** or intolerance to intravenous (IV) bisphosphonates such as ibandronate or Zoledronic acid? □ Yes □ No

□ **Systemic Mastocytosis**

- Does the patient have osteopenia or osteoporosis and coexisting bone pain? □ Yes □ No
- Is this drug being used as second line therapy? □ Yes □ No
- Is the patient responding to bisphosphonate therapy? □ Yes □ No
- Is the patient unable to take bisphosphonate therapy due to renal insufficiency? □ Yes □ No

*** Examples of contraindication to injectable bisphosphonate therapy include the following: documented pre-existing hypocalcemia and disturbances of mineral metabolism, documented pre-existing renal insufficiency defined as creatinine clearance < 35mL/min

RENEWAL CRITERIA (You will also need to complete the indication section above to show that patient continues to meet indication-specific relevant criteria)

Has the patient experienced unacceptable toxicity* from the drug. □ Yes □ No

**Examples of unacceptable toxicity include the following: severe symptomatic hypocalcemia, osteonecrosis of the jaw, atypical femoral fractures, dermatological adverse reactions, severe infection, severe hypersensitivity/anaphylaxis, musculoskeletal pain, etc.*

Prolia

- Has the patient shown disease response as indicated by one or more of the following: absence of fractures and/or increase in bone mineral density compared to pretreatment baseline? □ Yes □ No

□ **Osteoporosis in men and women ONLY:**

- After 5 years of treatment, will the patient have a repeat DXA performed? □ Yes □ No
- If the patient has low to moderate risk disease, will his/her therapy be changed to an oral or IV bisphosphonate unless there is a contraindication or intolerane to both dosage forms? □ Yes □ No

Xgeva

Disease response as indicated by the following:

□ **Multiple Myeloma or bone metastases from solid tumors**

- Has the patient experienced an absence/delay in skeletal-related events (e.g., pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression)? □ Yes □ No

□ **Giant Cell Tumor of the Bone**

- Has the patient experienced a stabilization of disease or decrease in size of tumor or spread of tumor? □ Yes □ No

□ **Hypercalcemia of Malignancy**

- Does the patient have a corrected serum calcium less than or equal to 11.5 mg/dL (2.9 mmol/L)? □ Yes □ No

□ **Systemic Mastocytosis**

- Has the patient experienced improvement or resolution of bone pain as compared to pretreatment baseline? □ Yes □ No

Please use a separate form for each drug.

To fill out form type or write using blue or black ink

Please fax this form to: 1-866-805-4150

Telephone: 1-800-471-2242

Prior authorization is not a guarantee of payment; benefits and eligibility will apply at the time of claim adjudication.

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