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DENOSUMAB (XGEVA® AND PROLIA®)
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 #:

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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

Prescribed in consultation with a specialist? ☐ 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: Start Date: __/__/__ End Date __/__/__	**Dosing Information:** Dose: Strength: Frequency: Quantity requested per month:

<u>Attach documentation demonstrating the medical nessicity of the requested drug.</u> 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.)

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Has the patient had **medical testing** completed for use of this drug? (labs, imagining) ☐ 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:
Does the patient have any FDA labeled contraindication(s) to the requested drug? ☐ Yes ☐ No Does the requested quantity (dose) exceed the program quantity limit? ☐ Yes ☐ No Does the requested quantity (dose) exceed the FDA labeled dose for the requested indication? ☐ Yes ☐ No Can the requested quantity (dose) be achieved with a lower quantity of a higher strength that does not exceed the limit? ☐ Yes ☐ No Has the prescriber provided information in support of therapy with a higher dose for the requested indication? ☐ Yes ☐ No
Patient's diagnosis: ☐ Multiple myeloma ☐ Prostate cancer with documented bone metastases ☐ Breast Cancer with documented bone metastases ☐ Another solid tumor cancer (e.g., thyroid, non-small cell lung cancer, kidney cancer, breast cancer) with documented bone metastases ☐ Systemic mastocytosis ☐ Giant cell tumor of bone ☐ Hypercalcemia of malignancy ☐ Osteoporosis ☐ Osteopenia (osteoporosis prophylaxis) ☐ Breast cancer ☐ Nonmetastatic prostate cancer ☐ Glucocorticoid-induced osteoporosis ☐ Other: Specify:_____

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For Continuation of Therapy:

- Is the patient currently being treated with the requested drug? ☐ Yes ☐ No
- If yes, is the patient at risk if they change therapy? ☐ Yes ☐ No
- Has the patient tried and had an inadequate response to zoledronic acid or pamidronate? ☐ Yes ☐ No
- Does the patient have an intolerance, hypersensitivity, or FDA labeled contraindication to zoledronic acide or pamidronate? ☐ Yes ☐ No
- Is the requested agent a NCCN category 2a or above preferred agent for the requested indication? ☐ Yes ☐ No
- Does the patient have stage four, advanced metastatic cancer or a severe adverse health condition experienced as a result of stage four, advanced metastatic cancer? ☐ Yes ☐ No

For a diagnosis of Multiple Myeloma:

- Will the requested drug be used for the prevention of skeletal-related events? ☐ Yes ☐ No

For another solid tumor cancer diagnosis (e.g., thyroid, non-small cell lung cancer, kidney cancer, breast cancer) with documented bone metastases:

- Has the patient tried and had an inadequate response to zoledronic acid? ☐ Yes ☐ No
- Does the patient have an intolerance, hypersensitivity, or FDA labeled contraindication to zoledronic acid? ☐ Yes ☐ No

For a diagnosis of Systemic Mastocytosis:

- The patient has tried zoledronic acid **and** has persistent bone pain? ☐ Yes ☐ No
- Does the patient have an intolerance, hypersensitivity, or FDA labeled contraindication to zoledronic acid? ☐ Yes ☐ No

For a diagnosis of Giant Cell Tumor of Bone:

- Is the patient an adult or skeletally mature adolescent (must be ≥ 12 years of age)? ☐ Yes ☐ No
- Is the tumor recurrent, unresectable, or resection is likely to result in severe morbidity? ☐ Yes ☐ No

For a diagnosis of Hypercalcemia of Malignancy:

- Has the patient had a least 2 doses of intravenous bisphosphonate therapy? ☐ Yes ☐ No
- Has the patient failed or is refractory to intravenous bisphosphonate therapy (i.e., albumin-corrected calcium of ≥ 12.0 mg/dL [3.0mmol/L)? ☐ Yes ☐ No
- Does the patient have an intolerance, hypersensitivity, or FDA labeled contraindication to IV bisphosphonate therapy? ☐ Yes ☐ No

Questions that may pertain to more than one of the above listed patient diagnoses:

- Does the patient have renal insufficiency? ☐ Yes ☐ No
- Does the patient have documented bone metastases? ☐ Yes ☐ No
- Has the patient tried and had an inadequate response to zoledronic acid **or** pamidronate? ☐ Yes ☐ No
- Does the patient have an intolerance or hypersensitivity to pamidronate **or** zoledronic acid? ☐ Yes ☐ No
- Does the patient have an FDA labeled contraindication to **both** pamidronate **and** zoledronic acid? ☐ Yes ☐ No
- Is the requested agent a NCCN category 2a or above, preferred agent in NCCN guidelines for the requested diagnosis? ☐ Yes ☐ No
- Does the patient have stage four, advanced metastatic cancer or a severe adverse health condition experienced as a result of stage four, advanced metastatic cancer? ☐ Yes ☐ No
- Will the patient be using the requested agent in combination with Prolia? ☐ Yes ☐ No

Prolia®

Questions that may pertain to one or more of the above listed patient diagnoses:

- Is the patient's sex a male who is over 50 years of age? ☐ Yes ☐ No

- Is the patient postmenopausal? ☐ Yes ☐ No
- Has the prescriber provided information that the requested agent is medically appropriate for the patient's sex? ☐ Yes ☐ No
- Was the patient's diagnosis confirmed by a fragility fracture in the hip or spine? ☐ Yes ☐ No
- If applicable, what is the patient's T-score? _____
- Does the patient have a 10-year probability of a hip fracture ≥3% or a 10-year probability of a major osteoporosis-related fracture ≥20% based on U.S. adopted WHO absolute fracture risk model (FRAX)? ☐ Yes ☐ No
- Is the patient at a **very high** fracture risk as defined by one of the following:
  - o Patient had a recent fracture (within the past 12 months)
  - o Patient had fractures while on approved osteoporosis therapy
  - o Patient has had multiple fractures
  - o Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids)
  - o Patient is at a high risk for falls or has a history of injurious falls
  - o Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture >30%, hip fracture >4.5%) or by other validated fracture risk algorithm

  ☐ Yes ☐ No
- Has the patient tried and had an inadequate response to a bisphosphonate, has an intolerance or hypersensitivity to a bisphosphonate, or has an FDA labeled contraindication to ALL bisphosphonates? ☐ Yes ☐ No
- Is the patient currently receiving aromatase inhibitor therapy? ☐ Yes ☐ No
- Does the patient have stage four, advanced metastatic cancer or a severe adverse health condition experienced as a result of stage four, advanced metastatic cancer? ☐ Yes ☐ No
- Is the patient currently receiving androgen deprivation therapy? ☐ Yes ☐ No
- Is the patient either initiating or currently taking glucocorticoids in a daily dosage equivalent to 7.5 mg or higher of prednisone? ☐ Yes ☐ No
- Is the patient's expected current course of therapy of glucocorticoids for a period of at least 6 months? ☐ Yes ☐ No
- Will the patient be using the requested agent in combination with a bisphosphonate, SERM, Evenity (romosozumab-aqqg), Xgeva (denosumab), or parathyroid hormone analog (i.e., abaloparatide, teriparatide)? ☐ 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.