Denosumab

(Prolia®) J0897 (1mg)

Covered with prior authorization

Treatment of osteoporosis (males >50 years & postmenopausal females)

Initial Therapy (Based on Bone Mineral Density measurements taken within last 12 months)

- Diagnosis of Osteoporosis; **AND**
- **One** of the following: (Very High Risk)
    - Bone mineral density (BMD) T-score < -3.0 based on measurements from
        - lumbar spine (at least two vertebral bodies), **OR**
        - hip (femoral neck, total hip), **OR**
        - radius (one-third radius site); **OR**
    - Fragility fracture (including: Vertebral compression fracture; Fracture of the hip; Fracture of the distal radius; Fracture of the pelvis; Fracture of the proximal humerus) in the past 12 months or multiple fragility fractures; **OR**
    - Fractures while on osteoporotic treatment or drugs that can cause skeletal harm (i.e. glucocorticoids); **OR**
    - FRAX© 10-year probability is at least 30% for major osteoporotic fracture or 4.5 % for hip fracture;

  OR
- **Both** of the following: (High Risk)
    - BMD T-score less than or equal to -2.5 in the:
        - lumbar spine (at least two vertebral bodies), **OR**
        - hip (femoral neck, total hip); **OR**
        - radius (one-third radius site) prior to start of therapy;

      OR
    - BMD T-score between -1.0 and -2.5 in the:
        - lumbar spine (at least two vertebral bodies); **OR**
        - hip (femoral neck, total hip); **OR**
        - radius (one-third radius site) prior to start of therapy;

          AND
        - hip or vertebral fragility fracture prior to start of therapy;

      OR
    - BMD T-score between -1 and -2.5 based on measurements from:
        - lumbar spine (at least two vertebral bodies); **OR**
        - hip (femoral neck, total hip); **OR**
        - radius (one third radius site) prior to start of therapy;

          AND
        - One of the following:

- FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more; **OR**
- FRAX 10-year fracture probabilities: hip fracture at 3% or more;

AND

- Unable to tolerate, contraindication or inadequate response to bisphosphonates (alendronate, risedronate, zoledronic acid); **OR**
- History of maxillofacial skeleton resorption, in particular the tooth-bearing areas. Denosumab may be an alternative with close monitoring by an oral surgeon, and limited duration of therapy, as these areas may become necrotic and exposed to the oral cavity.

AND

- Prolia® dosing is 60 mg every 6 months

Reauthorization/Continuation of Care Criteria

- For patients currently on Prolia® for the treatment of postmenopausal patients with osteoporosis, or to increase bone mass in patients with osteoporosis at high risk or very high risk for fracture, continued use will be approved based on the following criteria:
  - Bone Mineral Density measurements obtained within last two (2) years; **AND**
  - Prolia® dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; **AND**
  - Authorization is for no more than 12 months.

Treatment of Drug-induced Bone Loss in Breast Cancer or Non-metastatic Prostate Cancer

Initial Therapy

- Documentation of one (1) of the following:
  - Patient is receiving aromatase inhibitor therapy; **OR**
  - Patient is receiving androgen deprivation therapy;

AND

- One of the following:
  - Both of the following:
    - History of intolerance to oral bisphosphonate therapy; **AND**
    - History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); **OR**
  - History of failure or contraindication to oral bisphosphonate therapy; **OR**
  - History of failure, contraindication, or intolerance to IV bisphosphonate therapy;

AND

- Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; **AND**
- Authorization is for no more than 12 months.

Reauthorization/Continuation of Care Criteria

- For patients currently on Prolia to increase bone mass in patients at high risk for fracture* receiving androgen deprivation therapy for non-metastatic prostate cancer or receiving adjuvant

aromatase inhibitor therapy for breast cancer, continued use will be approved based on the following criteria:
- Patient is receiving androgen deprivation therapy; **OR**
- Patient is receiving adjuvant aromatase inhibitor therapy; **AND**
- Provider attests to a positive clinical response; **AND**
- Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; **AND**
- Authorization is for no more than 12 months.

***High risk for fractures as defined by ANY of the following**:
- History of fragility (non-traumatic) or osteoporotic fracture; **OR**
- BMD T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip; **OR**
- T-score between -1.0 and -2.5 if the FRAX© 10-year probability for major osteoporotic fracture is at least 20% or the 10-year probability of hip fracture is at least 3%.

Treatment of Glucocorticoid-Induced Osteoporosis

Initial Therapy

- Diagnosis of glucocorticoid-induced osteoporosis; **AND**
- Documentation the patient is initiating or continuing treatment with a medium or high dose systemic glucocorticoid (for example, greater than or equal to 7.5mg/day oral prednisone); **AND**
- Individual is expected to remain on therapy for at least 6 months with recent documentation of any of the following:
  - BMD T-score less than or equal to -2.5 in the lumbar spine (at least two vertebral bodies), femoral neck or total hip prior to start of therapy; **OR**
  - History of beneficial clinical response with denosumab (Prolia©); **OR**
  - Failure or inadequate response to at least one oral or IV bisphosphonate product trial of at least 1 year; **OR**
  - Contraindication per FDA label, intolerance, inability to take, or not a candidate for bisphosphonate therapy; **OR**
  - History of maxillofacial skeleton resorption, in particular the tooth-bearing areas. Denosumab may be an alternative with close monitoring by an oral surgeon, and limited duration of therapy, as these areas may become necrotic and exposed to the oral cavity;

  AND
- Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; **AND**
- Authorization is for no more than 12 months.

Reauthorization/Continuation of Care Criteria

- For patients currently on Prolia to treat glucocorticoid-induced osteoporosis in patients at high risk for fracture*, continued use will be approved based on the following criteria:
  - Patient is receiving corticosteroid therapy; **AND**
  - Provider attests to a positive clinical response; **AND**
  - Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; **AND**

- Authorization is for no more than 12 months.
  High risk for fractures as defined by ANY of the following:
  - History of fragility (non-traumatic) or osteoporotic fracture; **OR**
  - BMD T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip; **OR**
  - T-score between -1.0 and -2.5 if the FRAX© 10-year probability for major osteoporotic fracture is at least 20% or the 10-year probability of hip fracture is at least 3%.

Exclusion criteria

- Any diagnosis other than osteoporosis; or individual is not concurrently receiving either aromatase inhibitors or glucocorticoids
- Patient has a history of a hypersensitivity reaction or contraindication to denosumab;
- If patient is receiving XGEVA©, they should not receive Prolia©, as it contains the same medicine as XGEVA© (denosumab);
- Concurrent therapy with IV bisphosphonate;
- Patients who are pregnant or plan to become pregnant.

Step/Alternative Therapies:

Preferred Product(s) [No PA Required]	Non-Preferred Product(s) [PA Required]
Alendronate oral	Denosumab (Prolia®, Xgeva®) J0897
Ibandronate oral	
Risedronate oral, Risedronate IV J1740	
Pamidronate IV J2430	
Zoledronic acid (Reclast®, Zometa®, geq) J3489	

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.
Prolia is a RANK ligand (RANKL) inhibitor indicated for:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture;
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture;
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture;
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer;

- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

References:

Prolia® (denosumab) label. (2018, May). Accessdata.fda.gov. Retrieved June 16, 2022 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125320s186lbl.pdf

Camacho P, Petak S, Binkley N, Harris S, Hurley D, Kelly J, et al. American association of clinical endocrinologists/american college of endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis-2020 update. Endocrine Practice 202;26(Suppl 1):1-46.

Ellis GK, Bone HG, Chlebowski R, Paul D, Spadafora S, et al. Randomized trial of denosumab in patients receiving adjuvant aromatase inhibitors for nonmetastatic breast cancer. J Clin Oncol 2008; 26:4875-4882.

Black D, Rosen C. Postmenopausal osteoporosis. New Engl J Med 2016;374:254-262.

Saag K, et al. Denosumab versus risedronate in glucocorticoid-induced osteoporosis: a mutlicentre, randomized, double-blind, active controlled, double-dummy, non-inferiority study. Lancet Diabetes Endocrinol 2018; 6: 445-54.

Prolia (denosumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; May 2021.

Criteria History/ Revision Information:

Date	Summary of Changes
January 2022	Developed by Ambulatory Care Expert Review Panel
January 2022	Approved by Ascension Ambulatory Care Steering Committee
February 2022	Approved by Ascension Therapeutic Affinity Group
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 18, 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group
June 2022	Criteria for use summary updated by Ascension Medical Specialty Prior Authorization Team
July 2022	Revised criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.