Prolia Osteoporosis Prior Authorization with Quantity Limit

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent	Indication	Dosing and Administration
Prolia® (denosumab) Subcutaneous injection	• Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. • Treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. • Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. • 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.	The recommended dose is 60 mg via subcutaneous injection once every 6 months. Denosumab should be administered by a healthcare professional. All patients should receive calcium 1000 mg daily and at least 400 IU of vitamin D daily.

Prolia (denosumab) Prior Authorization and Quantity Limit

TARGET AGENT
Prolia® (denosumab)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target agent will be approved when ALL of the following are met:

1. ONE of the following:
    a. The patient has a diagnosis of osteoporosis and ALL of the following:
        i. ONE of the following:
            A. The patient's sex is male and the patient is over 50 years of age
            OR
            B. The patient's sex is female and is postmenopausal
            OR
            C. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex or age

        AND

        ii. The patient's diagnosis was confirmed by ONE of the following:
            A. A fragility fracture in the hip or spine
            OR
            B. A T-score of -2.5 or lower
            OR
            C. A T-score of -1.0 to -2.5 and ONE of the following:
                1. A fragility fracture of a proximal humerus, pelvis, or distal forearm OR
                2. a FRAX 10-year probability for major osteoporotic fracture of ≥20%
                OR
                3. a FRAX 10-year probability of hip fracture of ≥3%

        AND

        iii. ONE of the following:
            A. The patient is at a very high fracture risk as defined by ONE of the following:
                1. Patient had a recent fracture (within the past 12 months)
                OR
                2. Patient had fractures while on approved osteoporosis therapy
                OR
                3. Patient has had multiple fractures
                OR
                4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids)
                OR
                5. Patient has a very low T-score (less than -3.0)
                OR
                6. Patient is at high risk for falls or has a history of injurious falls
                OR
                7. 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

            OR

            B. ONE of the following:
                1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required)
                OR
                2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required)
                OR
                3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required)

    OR

b. The patient is requesting the agent for osteopenia (osteoporosis prophylaxis) **AND** ALL of the following:
    i. ONE of the following:
        A. The patient's sex is male and the patient is over 50 years of age
        OR
        B. The patient's sex is female is postmenopausal
        OR
        C. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex, age, or menopause status

    AND

    ii. BOTH of the following:
        A. The patient has osteopenia, defined as a T-score between -1.0 to -2.5
        AND
        B. ONE of the following:
            1. A fragility fracture of a proximal humerus, pelvis, or distal forearm
            2. 10-year probability of a hip fracture ≥ 3% per FRAX
            OR
            3. 10-year probability of a major osteoporosis-related fracture ≥ 20% per FRAX

    AND

    iii. ONE of the following:
        A. The patient has tried and had an inadequate response to a bisphosphonate (medical records required)
        OR
        B. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required)
        OR
        C. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required)

OR

c. The patient has a diagnosis of breast cancer **AND** BOTH of the following:
    i. The patient is currently receiving aromatase inhibitor therapy
    AND
    ii. ONE of the following:
        A. The patient has tried and had an inadequate response to a bisphosphonate (medical records required)
        OR
        B. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required)
        OR
        C. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required)

OR

d. The patient has a diagnosis of nonmetastatic prostate cancer **AND** BOTH of the following:
    i. The patient is currently receiving androgen deprivation therapy (ADT)
    AND
    ii. ONE of the following:
        A. The patient has tried and had an inadequate response to a bisphosphonate (medical records required)
        OR
        B. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required)
        OR
        C. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required)

OR

e. The patient has a diagnosis of glucocorticoid-induced osteoporosis and ALL of the following:

i. The patient is either initiating or currently taking glucocorticoids in a daily dosage equivalent to 7.5 mg or higher of prednisone
AND
ii. The patient's expected current course of therapy of glucocorticoids is for a period of at least 6 months
AND
iii. The patient's diagnosis was confirmed by ONE of the following:
    A. A fragility fracture in the hip or spine
    OR
    B. A T-score of -2.5 or lower
    OR
    C. A T-score of -1.0 to -2.5 and ONE of the following:
        1. A fragility fracture of a proximal humerus, pelvis, or distal forearm
        2. a FRAX 10-year probability for major osteoporotic fracture of ≥20%
        OR
        3. A FRAX 10-year probability of hip fracture of ≥3%

AND
iv. ONE of the following:
    A. The patient is at a very high fracture risk as defined by ONE of the following:
        1. Patients had a recent fracture (within the past 12 months)
        OR
        2. Patient had fractures while on approved osteoporosis therapy
        OR
        3. Patient has had multiple fractures
        OR
        4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids)
        OR
        5. Patient has a very low T-score (less than -3.0)
        OR
        6. Patient is at high risk for falls or has a history of injurious falls
        OR
        7. 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

    OR
    B. ONE of the following:
        1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required)
        OR
        2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required)
        OR
        3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required)

AND

2. The patient will NOT be using the requested agent in combination with a bisphosphonate, SERM, Evenity (romosozumab-aqqg), another form of denosumab(i.e., Xgeva), or a parathyroid hormone analog (i.e., abaloparatide, teriparatide)
AND
3. If patient has a diagnosis of advanced chronic kidney disease (eGFR less than 30 mL/min/1.73^2 including dialysis-dependent patients), then BOTH of the following:

    A. Prior to initiating therapy with the requested agent, the patient will be evaluated for the presence of chronic kidney disease-mineral bone disorder (CKD-MBD) AND

B. If the patient has CKD-MBD, the prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND

4. The patient does not have any FDA labeled contraindications to the requested agent
   AND
5. ONE of the following:
   a. The requested quantity (dose) is less than or equal to the program quantity limit
      OR
   b. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose
         AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

      OR
   c. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
         AND
      iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. The patient has had clinical benefit with the requested agent AND
3. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 12 months