AdvancedHealth
Bridging the Future of Healthcare

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Denosumab – Prolia® Drug Use Criteria

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Includes:
Prolia® (Denosumab)

GUIDELINE FOR USE:
Initial Request:

1. Is the member a post-menopausal female with osteoporosis with ONE of the following:
    - Radiographic evidence of an osteoporotic fracture while compliant on an oral bisphosphonate for at least 12 months.
    - Very high risk of fracture (please see Table 1) AND
        - documented adverse event with an oral bisphosphonate despite proper administration, OR
        - contraindication to oral bisphosphonates (previous hypersensitivity, esophageal abnormality, hypocalcemia, inability to stand or sit upright for 30 minutes, history of bariatric surgery)

    a. If yes, continue to 5
    b. If no, continue to 2

2. Does the member have glucocorticoid-induced osteoporosis (on prednisone 7.5mg/day or equivalent for at least 6 months) with ONE of the following?
    - Radiographic evidence of an osteoporotic fracture while compliant on an oral bisphosphonate for at least 12 months.
    - High risk of fracture AND
        - documented adverse event with an oral bisphosphonate despite proper administration, OR
        - contraindication (previous hypersensitivity, esophageal abnormality, hypocalcemia, inability to stand or sit upright for 30 minutes) to oral bisphosphonates.

    a. If yes, go to 5
    b. If no, got to 3

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3. Does the member have a diagnosis of ONE of the following?
    - Non-metastatic prostate cancer and receiving androgen deprivation therapy (ADT).
    - Breast cancer receiving adjuvant aromatase inhibitor (AI) therapy.
    - Male with osteoporosis.

    a. If yes, go to 4
    b. If no, deny as not meeting criteria. Off-label use is not a covered benefit of OHP

4. Is the member at very high risk of fracture (Please see Table 1)?

    a. If yes, go to 5
    b. If no, deny as not meeting criteria.

5. Has the member tried and failed or have contraindications to zoledronic acid?

    a. If yes, go to 6
    b. If no, deny as not meeting criteria. Please trial with preferred least costly alternative, zoledronic acid (Zometa)

6. Has the member had treatment failure or adverse reaction to preferred biosimilar (Jubbonti (denosumab-bbdz)?

    a. If yes, approve for up to 12 months
    b. If no, deny as not meeting criteria. Please change to preferred least costly biosimilar, Jubbonti (denosumab-bbdz)

Table 1. Definition for **Very** High Risk of Fracture

Osteoporosis in post-menopausal women and men at very high risk of fracture with: • Multiple fragility fractures OR • T score of - 2.0 or less, plus a fragility fracture OR • T-score of - 3.0 or less in the absence of fractures OR • Fractures sustained while on approved osteoporosis therapy OR • Fractures while on medications causing skeletal harm (e.g. long-term glucocorticoids) OR • High risk for falls or history of injurious falls and very high fracture probability with a FRAX Score > 30% for major osteoporosis fracture or > 4.5%
Abbreviation: FRAX = Fracture Risk Assessment Tool

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Renewal Criteria:

1. Has the member demonstrated continued benefit from Prolia, such as stable or improved bone mineral density (BMD) or absence of new osteoporotic fractures?

    a. If yes, go to 2
    b. If no deny as not meeting criteria. Reassessment is required

2. Is the member adherent to calcium and vitamin D supplementation and regular laboratory monitoring?

    a. If yes, approve for up to 12 months
    b. If no, deny as not meeting criteria

Rationale: To ensure appropriate, safe, and cost-effective use. Criteria help confirm that Prolia is prescribed within its FDA-approved indications, after failure or intolerance of preferred lower-cost alternatives, and with appropriate monitoring of calcium and vitamin D status. Implementing these criteria promotes clinical value while supporting responsible resource utilization.

Mechanism of Action: Prolia is a monoclonal antibody that binds to RANK ligand (RANKL), a key regulator of osteoclast activity. By inhibiting RANKL, Prolia prevents the formation, function, and survival of osteoclasts, thereby reducing bone resorption and increasing bone mass and strength.

References:

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2. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 2.2024. Accessed June 6, 2025. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
3. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis—2020 Update. Endocr Pract. 2020;26(Suppl 1):1-46. doi:10.4158/GL-2020-0524SUPPL
4. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. Osteoporos Int. 2022;33(10):2049-2102. doi:10.1007/s00198-021-05900-y
5. U.S. Food and Drug Administration. Prolia (denosumab): Drug Safety Communication—FDA Adds Boxed Warning for Increased Risk of Severe Hypocalcemia in Patients with Advanced Chronic Kidney Disease. Published January 19, 2024. Accessed June 6, 2025. https://www.fda.gov/safety/medical-product-safety-information/prolia-denosumab-drug-safety-communication-fda-adds-boxed-warning-increased-risk-severe-hypocalcemia