Geisinger

# POLICIES AND PROCEDURE MANUAL

**Policy: MBP 81.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Prolia (denosumab)**

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**I. Policy:**
Prolia (denosumab)

**II. Purpose/Objective:**
To provide a policy of coverage regarding Prolia (denosumab)

**III. Responsibility:**
A. Medical Directors
B. Medical Management
C. Pharmacy Department

**IV. Required Definitions**
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

**Medicaid Business Segment**
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

**DESCRIPTION:**
Prolia (denosumab) is a human IgG2 monoclonal antibody (fully human, lab-produced antibody) that inactivates the body's bone-breakdown mechanism by targeting a chemical signal called RANK ligand, an essential part of the body's natural process for breaking down bone.

**CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee**

Prolia (denosumab) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

1. **For post-menopausal women at high risk for fractures:**
   - Physician provided documentation of a diagnosis of post-menopausal osteoporosis **AND**
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture **OR**
     - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) **OR**
     - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

2. **For increasing bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer:**
   - Physician provided documentation that patient is receiving adjuvant aromatase inhibitor therapy for breast cancer **AND**
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture* **OR**
     - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture)

   **AND**
   - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

3. **For increasing bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer:**
   - Physician provided documentation that patient is receiving androgen deprivation therapy for non-metastatic prostate cancer **AND**
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture* **OR**
     - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture)

   **AND**
   - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

4. **For the treatment of men at high risk for fractures:**
   - Physician provided documentation of a diagnosis of osteoporosis **AND**
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture **OR**
     - Physician provided documentation of high risk of fracture (defined as spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) **OR**
     - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

5. **For the treatment of glucocorticoid-induced osteoporosis:**
   - Medical record documentation of a diagnosis of glucocorticoid-induced osteoporosis **AND**
   - Medical record documentation that the patient is initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone **AND**

- Medical record documentation that the patient is going to remain on systemic glucocorticoid therapy for at least 6 months **AND**
- One of the following:
    - Medical record documentation of previous osteoporotic fracture **OR**
    - Medical record documentation of high risk of fracture defined as DXA T-score of less than or equal to -2.0 at the lumbar spine, total hip, or femoral neck, supporting clinical factors and/or FRAX calculation showing a ≥3% probability of hip fracture OR ≥20% probability of major osteoporosis-related fracture; **OR**
    - Medical record documentation of a failure on, intolerance to, or contraindication to one oral bisphosphonate

*Note:
Per the American Association of Clinical Endocrinologists/American College of Endocrinology
Osteoporotic fracture (low-trauma fracture, fragility fracture) - A fracture usually sustained from force similar to a fall from a standing position or less that would not have occurred in healthy bone, excepting fractures of the skull, face, fingers, and toes.

Per UpToDate
Osteoporotic fracture (fragility fracture) – Fracture at the spine, hip, wrist, humerus, and pelvis, without measurement of BMD. Fractures occurring from a fall from a standing height or less, without major trauma such as a motor vehicle accident. Fractures at some skeletal sites (including the skull, cervical spine, hands, and feet) are not considered fragility fractures. Stress fractures are also not considered fragility fractures as they are due to repetitive injury, often in individuals with otherwise healthy bones. Rib fractures may present as fragility fractures but more commonly result from trauma.

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Prolia (denosumab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

1. **For post-menopausal women at high risk for fractures:**
    - Physician provided documentation of a diagnosis of post-menopausal osteoporosis **AND**
    - One of the following:
        - Physician provided documentation of previous osteoporotic fracture* **OR**
        - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) **OR**
        - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

2. **For increasing bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer:**
    - Physician provided documentation that patient is receiving adjuvant aromatase inhibitor therapy for breast cancer **AND**
    - One of the following:
        - Physician provided documentation of previous osteoporotic fracture* **OR**
        - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) **OR**
        - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

3. **For increasing bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer:**
    - Physician provided documentation that patient is receiving androgen deprivation therapy for non-metastatic prostate cancer **AND**
    - One of the following:
        - Physician provided documentation of previous osteoporotic fracture* **OR**
        - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) **OR**
        - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

4. **For the treatment of men at high risk for fractures:**
   - Physician provided documentation of a diagnosis of osteoporosis **AND**
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture* **OR**
     - Physician provided documentation of high risk of fracture (defined as spine or hip DXA T-score of less than or equal to -2.0, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) **OR**
     - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

5. **For the treatment of glucocorticoid-induced osteoporosis:**
   - Medical record documentation of a diagnosis of glucocorticoid-induced osteoporosis **AND**
   - Medical record documentation that the patient is initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone **AND**
   - Medical record documentation that the patient is going to remain on systemic glucocorticoid therapy for at least 6 months **AND**
   - One of the following:
     - Medical record documentation of previous osteoporotic fracture* **OR**
     - Medical record documentation of high risk of fracture defined as DXA T-score of less than or equal to -2.0 at the lumbar spine, total hip, or femoral neck, supporting clinical factors and/or FRAX calculation showing a ≥3% probability of hip fracture OR ≥20% probability of major osteoporosis-related fracture **OR**
     - Medical record documentation of a failure on, intolerance to, or contraindication to one oral bisphosphonate

*Note:
Per the American Association of Clinical Endocrinologists/American College of Endocrinology
Osteoporotic fracture (low-trauma fracture, fragility fracture) - A fracture independent of the T-score value, usually sustained from force similar to a fall from a standing position or less that would not have occurred in healthy bone, excepting fractures of the skull, face, fingers, and toes.

Per UpToDate
Osteoporotic fracture (fragility fracture) – Fracture at the spine, hip, wrist, humerus, and pelvis, without measurement of BMD. Fractures occurring from a fall from a standing height or less, without major trauma such as a motor vehicle accident. Fractures at some skeletal sites (including the skull, cervical spine, hands, and feet) are not considered fragility fractures. Stress fractures are also not considered fragility fractures as they are due to repetitive injury, often in individuals with otherwise healthy bones. Rib fractures may present as fragility fractures but more commonly result from trauma.

**LINE OF BUSINESS:**
**Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.**

**REFERENCES:**

1. Prolia [prescribing information]. Thousand Oaks, CA: Amgen Inc; January 2023.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/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 [cited 2023 Dec 26]. Available from: https://www.sciencedirect.com/science/article/pii/S1530891X20428277
3. Rosen HN, Lewiecki EM, Rosen CJ, et al. Overview of the management of low bone mass and osteoporosis in postmenopausal women. UpToDate. 2024 Mar 26 [cited 2024 Jun 3]. Available from: https://www.uptodate.com/contents/overview-of-the-management-of-low-bone-mass-and-osteoporosis-in-postmenopausal-women?search=age%20related%20osteoporosis&source=search_result&selectedTitle=1%7E150&usage_type=default&display_rank=1

This policy will be revised as necessary and reviewed no less than annually**.**

**Devised:** 9/8/10

**Revised:** 10/11 (indications added); 1/13 (indication added), 9/18/18 (glucocorticoid, criteria updated), 5/16/23 (male high risk fracture T-score, Medicaid business segment), 6/3/24 (LOB carve out, added references, added high risk & facture definition from Dec 2023 P&T)

**Reviewed:** 1/14, 1/20/15, 11/6/15, 3/16, 3/30/17, 3/29/18, 9/15/19, 9/10/20, 9/8/21, 9/7/22

**MA UM Committee approval:** 12/31/23