

Policy: MBP 81.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Prolia (denosumab)

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

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) the service or benefit 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 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**
- Physician provided documentation of previous osteoporotic fracture or 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 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 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**
- Physician provided documentation of previous osteoporotic fracture or 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**
- Medical record documentation of previous osteoporotic fracture or 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 $\geq 3\%$ probability of hip fracture OR $\geq 20\%$ probability of major osteoporosis-related fracture; **OR**
- Medical record documentation of a failure on, intolerance to, or contraindication to one oral bisphosphonate

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.

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)

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