# MEDICATION POLICY

**Generic Name:** Denosumab

**Therapeutic Class or Brand Name:** Prolia®

**Applicable Drugs** (if Therapeutic Class)**:** N/A

**Date of Origin:** 1/15/16 **Date Last Reviewed/Revised:** 05/29/18

**GPI Code:** 30044530002020

**Prior Authorization Criteria (may be considered medically necessary when criteria I through V are met):**

I. Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis:

A. Treatment of postmenopausal women with osteoporosis AND criterion 1 is met:

1. Documented baseline bone mineral density (BMD) T-score at of -2.5 or less.

B. Treatment to increase bone mass in men with osteoporosis AND criterion 1 is met:

1. Documented baseline bone mineral density (BMD) T-score at of -2.5 or less.

C. Treatment of glucocorticoid induced osteoporosis in both women and men AND criterion 1 thru 3 are met:

1. Documented baseline bone mineral density (BMD) T-score at -2.5 or less.
2. Documentation treatment is being continued or is being initiated with prednisone daily dose equivalent ≥ 7.5 mg
3. Documentation that treatment duration with glucocorticoids will be 6 months or longer

D. Treatment to increase bone mass in men receiving androgen deprivation therapy for nonmetastatic prostate cancer.

E. Treatment to increase bone mass in women receiving adjuvant aromatase inhibitor therapy for breast cancer.

II. Documented trial and failure of (i.e. progression of bone loss as recorded by bone mineral density measurements or occurrence of an osteoporotic fracture after a minimum of a 12 month trial), intolerance to, or contraindication to bisphosphonate therapy.

III. Documentation that patient is at high risk for fracture (i.e. history of osteoporotic fracture, multiple risk factors for fracture, etc.).

IV. Documentation that patient will also take calcium 1000 mg daily and at least 400 IU vitamin D daily.

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V. Minimum age requirement: 18 years old.

**Exclusion Criteria:**

- Hypocalcemia.
- Pregnancy.
- Coadministration of Prolia® with Xgeva®.

**Other Criteria:**

- N/A

**Quantity/Days Supply Restrictions:**

- One 60 mg injection every 6 months.

**Approval Length:**

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

**Appendix:**

N/A

**References:**

1. http://pi.amgen.com/united_states/prolia/prolia_pi.pdf.
2. http://annals.org/aim/fullarticle/2625385/treatment-low-bone-density-osteoporosis-prevent-fractures-men-women-clinical.
3. Medi-Span.
4. http://blue.regence.com/trgmedpol/drugs/dru223.pdf.

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| *Historical Tracking Of Changes Made To Policy* | |
|---|---|
| *5/29/2018* | 1. **Added** "Treatment of glucocorticoid induced osteoporosis in both women and men AND criterion 1thru 3 are met: 1. Documented baseline bone mineral density (BMD) T-score at -2.5 or less. 2. Documentation treatment is being continued or is being initiated with prednisone daily dose equivalent ≥ 7.5 mg 3. Documentation that treatment duration with glucocorticoids will be 6 months or longer **under Prior Authorization Criteria**. |
| *11/20/2017* | 1. **Added** "http://annals.org/aim/fullarticle/2625385/treatment-low-bone-density-osteoporosis-prevent-fractures-men-women-clinical" **under References**.<br>2. **Removed** "http://nof.org/files/nof/public/content/file/2791/upload/919.pdf" **and** "http://www.summacare.com/libraries/documents/prolia_pa_criteria_medicare_only.sflb.ashx" **under References** (links no longer valid). |
| *6/16/2016* | 1. **Changed** "II. Documentation that patient is at high risk…III. Documented trial and failure of…" **to** "II. Documented trial and failure of…III. Documentation that patient is at high risk…" **under Prior Authorization Criteria**. |