CareSource

| PHARMACY POLICY STATEMENT<br>**Marketplace** | |
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| DRUG NAME | Prolia (denosumab) |
| BILLING CODE | J0897 |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Office/Outpatient hospital |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Non-Preferred Product)<br>Alternative preferred products include alendronate, risedronate, ibandronate tablet, and zoledronic acid<br>QUANTITY LIMIT— 60 mg every 6 months |
| LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY | Click Here |

Prolia (denosumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

## OSTEOPOROSIS

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Medication is being used to treat **one** the following:
   a) Osteoporosis in postmenopausal women;
   b) Osteoporosis in men;
   c) Glucocorticoid-induced osteoporosis in men and women who have been taking ≥ 7.5 mg of prednisone (or equivalent) daily and will remain on therapy for at least 6 months; AND
3. Member is at high-risk for fracture as evidenced by **one** of the following:[2,6]
   a) Bone mineral density (BMD) T-score –2.5 or below in the lumbar spine, femoral neck, proximal femur, 1/3 radius, or total hip;
   b) History of vertebral (spine) or hip fracture;
   c) T-score between –1 and –2.5 with a fragility fracture of proximal humerus, pelvis, or distal forearm;
   d) T-score between –1 and –2.5 with FRAX score of ≥ 20% for major osteoporotic fracture or ≥ 3% for hip fracture;
   e) Member is taking prednisone ≥30mg/day (or equivalent) and cumulative dose > 5g in the last year;
   f) Member is taking prednisone ≥ 7.5mg/day (or equivalent) for 6 months AND having greater than 10% BMD loss per year or a Z score < -3 at hip or spine; AND
4. Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast), ibandronate), unless not tolerated or contraindicated.
5. **Dosage allowed:** one subcutaneous injection (60 mg) every 6 months.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:
1. Chart notes have been provided showing stable or increase in bone mineral density, with no evidence of new fractures or vertebral fracture progression.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## BONE LOSS (for prostate cancer or breast cancer patients)

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Medication is intended to be used for **one** the following:
   a) Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (e.g., goserelin, leuprolide, bicalutamide) for non-metastatic prostate cancer;
   b) Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy (e.g., anastrozole, letrozole) for breast cancer; AND
3. Member is at high risk for fracture, as defined by **one** of the following:[9,14]
   a) Has two of the following risk factors: Age > 65, T score < -1.5, smoking, BMI < 20, family history of hip fracture, personal history of fragility fracture > 50 years, oral glucocorticoid use > 6 months;
   b) T-score less than -2 in the femoral neck, total hip, or lumbar spine;
   c) Decrease in BMD ≥5% per year;
   d) FRAX score of ≥ 20% for major osteoporotic fracture or ≥ 3% for hip fracture; AND
4. Member has had an inadequate response to 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast)), unless not tolerated or contraindicated.
5. **Dosage allowed:** one subcutaneous injection (60 mg) every 6 months.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:
1. Member continues to be at high risk for fracture due to taking androgen deprivation therapy or aromatase inhibitor therapy; AND
2. Chart notes have been provided showing stable or increase in bone mineral density, with no evidence of new fractures or vertebral fracture progression.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## CareSource considers Prolia (denosumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Bone metastases from solid tumors
- Giant Cell Tumor of Bone
- Multiple Myeloma
- Paget's disease

| DATE | ACTION/DESCRIPTION |
|---|---|
| **07/19/2019** | New policy for Prolia created. |
| **08/13/2020** | For osteoporosis: added age requirement; removed Appendix of risk factors for fracture; added diagnostic criteria for GC-induced; removed exclusions (uncorrected hypocalcemia, dental disease, Xgeva within past 6 months); removed vitamin D & |

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| | calcium requirement; removed reasons oral bisphosphonate cannot be used; changed trial to 12 months of oral or IV bisphosphonate; changed approval length to 12 months.<br>For bone loss due to cancer drugs: added age requirement; redefined diagnostic requirements according to latest guidelines; removed exclusions (uncorrected hypocalcemia, dental disese, Xgeva within past 6 months); removed vitamin D & calcium requirement; trial specified to be 12 months or oral or IV bisphosphonate; changed approval length to 12 months. |

References:


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