

PHARMACY POLICY STATEMENT

Marketplace

| | |
|-------------------------|------------------------------|
| DRUG NAME | Prolia (denosumab) |
| BILLING CODE | J0897 |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Office/Outpatient Hospital |
| STATUS | Prior Authorization Required |

Prolia (denosumab) was initially approved by the FDA in 2010. It is a monoclonal antibody that inhibits the RANK ligand (RANKL) and is approved for the treatment of postmenopausal women with osteoporosis at high risk for fracture, treatment to increase bone mass in men with osteoporosis at high risk for fracture, and treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture. It is also approved to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and for treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Prolia (denosumab) will be considered for coverage when the following criteria are met:

Osteoporosis in Postmenopausal Women

For **reauthorization**:

1. Member continues to be at high risk for fracture due to receiving 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.

