Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

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) Alternative preferred products include alendronate, ibandronate and zoledronic acid QUANTITY LIMIT— 60 mg every 6 months
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Prolia (denosuab) 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. Medication is intended to be used for one the following (see *Appendix* for details on risk factors for fracture for all indications):
   a) Treatment of postmenopausal women with osteoporosis at high risk for fracture;
   b) Treatment to increase bone mass in men with osteoporosis at high risk for fracture;
   c) Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture (member has been taking ≥ 5 mg of prednisone (or equivalent) daily for ≥ 3 months); AND
2. Member's osteoporosis evidenced by one of the following:
   a) Bone mineral density (BMD) T-score –2.5 or below in the lumbar spine, femoral neck, total, and/or 33% (one-third) radius;
   b) Low-trauma spine or hip fracture (regardless of BMD);
   c) Osteopenia or low bone mass (T-score between –1 and –2.5) with a fragility fracture of proximal humerus, pelvis, or possibly distal forearm;
   d) Osteopenia or low bone mass and high FRAX® fracture probability (a 10-year probability for major osteoporotic fracture is ≥ 20% or the 10-year probability of hip fracture is ≥ 3%); AND
3. Member does **not** have ANY of the following:
   a) Uncorrected hypocalcemia;
   b) Dental disease;
   c) History of receiving Xgeva within the past 6 months; AND
4. Member was instructed to take calcium 1,000 mg daily and at least 400 IU of vitamin D daily; AND
5. Member cannot take oral bisphosphonate therapies (i.e., alendronate and/or ibandronate) as evidenced by one or more of the following:
   a) Esophogeal dysmotility or varices;
   b) Member is unable to stand or sit upright for 30-60 minutes;
   c) Presence of anatomic or functional esophageal abnormalities that might delay tablet transit (e.g., achalasia, stricture, or dysmotility);

   d) Presence of documented or potential GI malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.);
   e) Member has experienced intolerance to or treatment failure of one or more bisphosphonate medications;
   f) Member has a history of non-adherence to oral bisphosphonate medications; AND
6. Member has had a documented trial and inadequate response to zoledronic acid.
7. **Dosage allowed:** 60 mg every 6 months.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member meets all initial criteria; AND
2. Chart notes have been provided that show the member has shown an increase in bone mineral density.

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

BONE LOSS (for nonmetastatic prostate cancer or for breast cancer)

For **initial** authorization:
1. Medication is intended to be used for one the following (see *Appendix* for details on risk factors for fracture for all indications):
   a) Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (e.g., goserelin, leuprolide, bicalutamide) for nonmetastatic 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;
2. Member has a bone mineral density (BMD) T-score at the lumbar spine, total hip, or femoral neck –1 or less; AND
3. Member does **not** have ANY of the following:
   a) Uncorrected hypocalcemia;
   b) Dental disease;
   c) History of receiving Xgeva within the past 6 months; AND
4. Member was instructed to take calcium 1,000 mg daily and at least 400 IU of vitamin D daily; AND
5. Member cannot take oral bisphosphonate therapies (i.e., alendronate and/or ibandronate) as evidenced by one or more of the following:
   a) Esophogeal dysmotility or varices;
   b) Member is unable to stand or sit upright for 30-60 minutes;
   c) Presence of anatomic or functional esophageal abnormalities that might delay tablet transit (e.g., achalasia, stricture, or dysmotility);
   d) Presence of documented or potential GI malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.);
   e) Member has experienced intolerance to or treatment failure of one or more bisphosphonate medications;
   f) Member has a history of non-adherence to oral bisphosphonate medications.
6. **Dosage allowed:** 60 mg every 6 months.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member meets all initial criteria; AND
2. Chart notes have been provided that show the member has shown an increase in bone mineral density.

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.

References:

1. Prolia (denosumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; June 2018.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2016. *Endocr Pract*. 2016;22(Suppl 4). Doi: 10.4158/EP161435.GL.
3. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2012;97(6):1802-1822. Doi: 10.1210/jc.2011-3045.
4. Buckley L, Guyatt G, Fink HA, et al. 2017 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. *Arthritis Rheumatol*. 2017;69(8):1521-1537. Doi: 10.1002/art.40137.
5. Bienz M, Saad F. Androgen-deprivation therapy and bone loss in prostate cancer patients: a clinical review. *Bonekey Rep*. 2015;4:Article 716. Doi: 10.1038/bonekey.2015.85.
6. Hadji P, Aapro MS, Body JJ, et al. Management of aromatase inhibitor-associated bone loss (AIBL) in postmenopausal women with hormone sensitive breast cancer: Joint position statement of the IOF, CABS, ECTS, IEG, ESCEO, IMS, and SIOG. *J Bone Oncol*. 2017;7:1-12. Doi: 10.1016/j.jbo.2017.03.001.
7. Mohler JL, Lee RJ, Antonarakis ES, et al. Prostate cancer – NCCN Guidelines Version 4.2018. National Comprehensive Cancer Network. Updated August 15, 2018. Accessed February 27, 2019. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
8. Gradishar WJ, Anderson BO, Abraham J, et al. Breast Cancer – NCCN Guidelines Version 4.2018. National Comprehensive Cancer Network. Updated February 8, 2019. Accessed February 27, 2019. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.

Effective date: 09/26/2019
Revised date: 07/19/2019

Humana.

CareSource™

Appendix. Risk Factors for Fracture:

1. Prior fracture;
2. Age ≥ 65;
3. Low body weight (< 57.6 kg [127 lb]);
4. Family history of osteoporosis or fractures;
5. Smoking;
6. Early menopause;
7. Excessive alcohol intake (≥ 3 drinks daily);
8. Rheumatoid arthritis (confirmed diagnosis);
9. Secondary osteoporosis (e.g., type 1 diabetes, hypothyroidism, chronic liver disease);
10. Height loss (including unexplained) or kyphosis;
11. Patient's reliability, understanding, and willingness to accept interventions;
12. Glucocorticoid therapy equivalent to ≥ 5 mg prednisone daily for 3 months or more;
13. Risk factors for falling*

*Risk factors for falling can be any of the following:

- Neurologic disorders (e.g., Parkinson disease, seizure disorder, peripheral neuropathy, prior stroke, dementia, impaired gait and/or balance, autonomic dysfunction with orthostatic hypotension);
- Impaired vision;
- Impaired hearing;
- Frailty and deconditioning;
- Proximal myopathy;
- Sarcopenia;
- Medications (e.g., sedatives and hypnotics, antihypertensive agents, narcotic analgesics);
- Environmental factors (e.g., poor lighting, stairs, slippery floors, wet, icy, or uneven pavement, uneven roadways, electric or telephone cords, walking large dogs, being tripped up by small dogs, throw rugs, positioning in a wet or dry bathtub).