ALASKA MEDICAID
Prior Authorization Criteria

Prolia®, Xgeva®
(denosumab)

FDA INDICATIONS AND USAGE[1,2]

Prolia® is a RANK ligand (RANKL) inhibitor indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with osteoporosis at high risk for fracture, treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture, increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, and to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.
Xgeva® is a RANK ligand (RANKL) inhibitor indicated for the Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors, treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity and the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

APPROVAL CRITERIA[1,2,3,4,5,6,7,8,9]

Prolia®

1. Patient is 18 years of age or older **AND**;
2. Patient has the diagnosis of **one** of the following:
    a. decreasing bone mass in women with breast cancer **OR;**
    b. glucocorticoid-induced osteoporosis **OR;**
    c. decreasing bone mass in men with non-metastatic prostate cancer **OR;**
    d. decreasing bone mass in men with osteoporosis **OR;**
    e. postmenopausal osteoporosis in women **AND**;
3. Chart notes have been submitted with baseline labs showing **one** of the following:
    a. A documented T-score between -1.0 and -2.5 at the lumbar spine, total hip, femoral neck, or 33% radius and one of the following:
        i. Is on an aromatase inhibitor **OR;**
        ii. Is on androgen deprivation therapy **OR;**
        iii. History of osteoporotic fracture **OR;**
    b. The 10-year probability for major osteoporotic fracture is ≥20% or the 10-year probability of hip fracture is ≥3% based on the U.S. adapted World Health Organization (WHO) algorithm (also known as FRAX) **OR;**
    c. T-score less than or equal to -2.5 **AND**;
4. Patient has had an inadequate response to, or is unable to tolerate therapy with at least two of the traditional osteoporosis treatments oral or IV (i.e., alendronate, calcitonin, ibandronate, raloxifene, risedronate, zoledronic acid), one of which must be a bisphosphonate.

Xgeva®

1. Patient is 12 years of age or older with ALL of the following:
    a. Has the diagnosis of giant cell tumor of bone **AND**;
    b. Patient must be skeletally mature **AND**;
    c. The tumor must be unresectable or surgical resection is likely to result in severe morbidity **AND**;
2. Patient is 18 years of age or older with the following:
    a. Has the diagnosis for prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors **OR**;
    b. Has the diagnosis of hypercalcemia of malignancy documented by an albumin-corrected calcium greater than 12.5 mg/dL (3.1 mmol/L) **AND**;
    c. Patient has had an inadequate response to or is unable to tolerate therapy with at least one bisphosphonate.

DENIAL CRITERIA [1,2]

1. Failure to meet approval criteria **OR**;
2. Patient will be taking concurrently with another RANK ligand inhibitor **OR**;
3. Patient has pre-existing hypocalcemia that has not been corrected with adequate supplementation with calcium and vitamin D **OR**;

CAUTIONS[1]

- See package inserts:
    - https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/prolia/prolia_pi.pdf
    - https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/xgeva/xgeva_pi.pdf

DURATION OF APPROVAL

- Initial Approval: up to 6 months
- Reauthorization Approval: up to 12 months if:
    - Patient has bone improvement and/or stabilization.

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QUANTITY LIMIT

- Prolia 60 mg/1 mL single-use prefilled syringe: 1 syringe every 6 months
- Xgeva 120 mg/1.7 mL single-use vial:

    Load: 4 vials per 28 days x 1 dose

    Maintenance: 1 vial monthly
- HCPCS - J0897

REFERENCES / FOOTNOTES:

1. Prolia® [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2021. Accessed December 2021.
2. Xgeva® [package insert]. Thousand Oaks, CA; Amgen, Inc.; June 2020. Accessed December 2021.
3. Langdahl BL, Teglbjærg CS, Ho PR, et al. A 24-month study evaluating the efficacy and safety of denosumab for the treatment of men with low bone mineral density: results from the ADAMO trial. J Clin Endocrinol Metab. 2015 Apr;100(4):1335-42.
4. Hu MI, Glezerman I, Leboulleux S, et al. Denosumab for patients with persistent or relapsed hypercalcemia of malignancy despite recent bisphosphonate treatment. J Natl Cancer Inst. 2013 Sep 18;105(18):1417-20.
5. Thomas D, Henshaw R, Skubitz K, et al. Denosumab in patients with giant-cell tumor of bone: an open-label, phase 2 study. Lancet Oncol. 2010 Mar;11(3):275-80.
6. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014.
7. Branstetter DG, Nelson SD, Manivel JC, et al. Denosumab induces tumor reduction and bone formation in patients with giant-cell tumor of bone. Clin Cancer Res. 2012 Aug 15;18(16):4415-24.
8. Cummings SR, San Martin, J, McClung MR, et al. Denosumab for prevention of fractures in postmenopausal women with osteoporosis. N Engl J Med. 2009 Aug 20; 361(8): 756-65.
9. CGS Administrators, LLC. Local Coverage Article: Denosumab (Prolia ®, Xgeva ®) - (A52424). Centers for Medicare & Medicaid Services, Inc. Updated on 03/16/2018 with effective date 02/01/2018. Accessed December 2021.