Xgeva (denosumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Xgeva (denosumab) subcutaneous solution 120 mg/1.7mL (70 mg/mL) vial	1 vial per 28 days*

*Initiation of therapy for giant cell tumor of bone or for hypercalcemia of malignancy:
May allow up to two additional vials (120 mg/1.7 mL) in the first 28 days of treatment.

APPROVAL CRITERIA

Requests for Xgeva (denosumab) may be approved when the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual is using for the prevention of skeletal-related events with one of the following conditions:
    A. Multiple myeloma; **OR**
    B. Bone metastases from solid tumor other than prostate cancer ; **OR**
    C. Bone metastases from castration resistant/recurrent prostate cancer;

OR

III. Individual is 18 years of age or older; **AND**
IV. Individual is using for the treatment of hypercalcemia of malignancy [defined as an albumin-corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L)] and is refractory to recent (within last 30 days) treatment with intravenous bisphosphonate therapy (for example, pamidronate or zoledronic acid);

OR

V. Individual is using for the treatment of localized or metastatic giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity when either or the following criteria below are met:
    A. Individual is 18 years of age or older; **OR**
    B. Individual is a skeletally mature adolescents [defined by at least one mature long bone (for example; closed epiphyseal growth plate of the humerus)].

Request for Xgeva may not be approved when the above criteria are not met and for all other indications.

Key References:

1. 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 – 2020 Update. *Endocrine Practice*. 2020;26(1):1-46.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 8, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2020. Updated periodically.
6. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 5, May 2019, Pages 1595–1622, https://doi.org/10.1210/jc.2019-00221.
7. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update, The Journal of Clinical Endocrinology & Metabolism, Volume 105, Issue 3, March 2020, Pages 587-594.
8. Stopeck AT, et al. Denosumab compared with zoledronic acid for the treatment of bone metastases in patients with advanced breast cancer : a randomized, double-blind study. J Clin Oncol. 2010 ;28 :1-10.
9. Fizazi K, et al. Denosumab versus zoledronic acid for treatment of bone metastases in men with castration-resistant prostate cancer: a randomized, double-blind study. *Lancet*. 2011;377:813-22.
10. Henry DH, Costa L, Goldwasser F, et al. Randomized, Double-Blind Study of Denosumab Versus Zoledronic Acid in the Treatment of Bone Metastases in Patients With Advanced Cancer (Excluding Breast and Prostate Cancer) or Multiple Myeloma. *J Clin Oncol* 2011 ;29 : 1125-1132.
11. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.