SmartHealth

Ascension

Denosumab

(Xgeva®) J0897

Denosumab (Xgeva®) may be authorized when the following criteria are met:

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

OR

- Individual is 18 years of age or older; **AND**
- 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 (such as pamidronate or zoledronic acid).

OR

- 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 and meets **one** of the following:
    - Individual is 18 years of age or older; **OR**
    - Individual is a skeletally mature adolescent (defined by at least one mature long bone [for example; closed epiphyseal growth plate of the humerus]).

AND

- Dosing is
    - 120 mg every 4 weeks for Multiple Myeloma and Bone Metastasis from Solid Tumors; **OR**
    - 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy for Hypercalcemia of Malignancy; **OR**
    - 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy for Giant Cell Tumor of Bone.

Exclusion:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization is up to 12 months.

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Xgeva® is a RANK ligand (RANKL) inhibitor indicated for the prevention of skeletal-related events in patients with bone metastases from solid tumors and 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.

References:
Amgen. (2020, June). *XGEVA (denosumab)* [prescribing information]. Thousand Oaks, CA. https://www.xgevahcp.com/prescribing-xgeva/starting-xgeva
Xgeva® (denosumab) label. (2020, February). Accessdata.fda.gov. Retrieved April 23, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125320s201lbl.pdf
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.
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.

Criteria History/ Revision Information:

Date	Summary of Changes
April 2022	Criteria for Use developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.