Denosumab (Xgeva®)	Place of Service Office Administration Home Infusion Administration Self-Administration Outpatient Facility Infusion Administration Infusion Center Administration HCPCS: J0897 per 1mg

Condition listed in policy (*see criteria for details*)

- Hypercalcemia of malignancy, refractory
- Prevention of skeletal-related events in bone metastases from solid tumors
- Prevention of skeletal-related events in multiple myeloma
- Treatment of giant cell tumor of bone

AHFS therapeutic class: Bone resorption inhibitor

Mechanism of action: Denosumab is a monoclonal antibody that inhibits RANK ligand activity and prevents osteoclast formation, leading to decreased bone resorption and increased bone mass.

(1) Special Instructions and pertinent Information

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Xgeva® (denosumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Hypercalcemia of malignancy, refractory

1. Diagnosis of hypercalcemia of malignancy, **AND**
2. Inadequate response, intolerance, or contraindication to intravenous bisphosphonate therapy given 7 to 30 days prior to the initiation of Xgeva (denosumab)

Covered Doses
Up to 120 mg SC every 4 weeks with additional doses given on days 8 and 15 of the first month of therapy

Coverage Period
Indefinite

ICD-10:
E83.52

Prevention of skeletal related events in bone metastases

1. Diagnosis of bone metastases from solid tumors, **AND**
2. Documentation of metastatic bone disease by scan or x-ray

Covered Doses
Up to 120 mg SC every 4 weeks

Coverage Period
Indefinite

ICD-10:
C79.51-C79.52

Prevention of skeletal related events in multiple myeloma

Covered Doses
Up to 120 mg SC every 4 weeks

Coverage Period
Indefinite

ICD-10:
C90.00 - C90.02

Treatment of giant cell tumor of bone

1. Patient is ≥ 18 years of age OR an adolescent whose bones have matured, **AND**
2. Tumor is unresectable, metastatic, recurrent, or resectable with unacceptable morbidity

Covered Doses
Up to 120 mg SC every 4 weeks with additional doses given on days 8 and 15 of the first month of therapy

Coverage Period
Indefinite

ICD-10:
D48.0

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Xgeva® (denosumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 120 mg/1.7 mL (single dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Xgeva (denosumab) [Prescribing information]. Thousand Oaks, CA: Amgen Inc.; 6/2020.
- Fuleihan G, Clines G, Hu M, et al. Treatment of Hypercalcemia of Malignancy in Adults: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism, 2023, 108:507-528.

(7) Policy Update

Date of last review: 4Q2023

Date of next review: 4Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.