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

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## 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  $\geq$  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) <u>DO NOT</u> 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.

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### 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 <a href="http://www.lexi.com">http://www.lexi.com</a>
- 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.

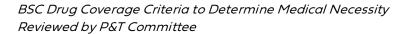
# (7) Policy Update

Date of last review: 4Q2023 Date of next review: 4Q2024

Changes from previous policy version:

• No clinical change to policy following routine annual review.

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