DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Bone Modifiers – Xgeva Drug Quantity Management Policy – Per Rx
- Xgeva® (denosumab subcutaneous injection – Amgen)

REVIEW DATE: 01/23/2023

OVERVIEW

Xgeva, a receptor activator of nuclear factor kappa-B ligand inhibitor, is indicated for the following uses[1]:

- **Giant cell tumor of bone**, treatment of adults and skeletally mature adolescents with disease that is unresectable or where surgical resection is likely to result in severe morbidity.
- **Hypercalcemia of malignancy**, treatment of, that is refractory to bisphosphonate therapy.
- **Skeletal-related events**, prevention of, in patients with multiple myeloma and in those with bone metastases from solid tumors.

Another injectable formulation of denosumab, Prolia®, is available, but it is not included in this policy.[2]

Dosing

Xgeva is given as a subcutaneous injection as follows:[1]

- **Giant Cell Tumor of Bone and Hypercalcemia of Malignancy:** 120 mg given by subcutaneous injection once every 4 weeks with additional doses of 120 mg on Days 8 and 15 of the first month of therapy.
- **Skeletal-related events:** 120 mg given by subcutaneous injection once every 4 weeks.

Availability

Xgeva is available as a 120 mg/1.7 mL single-dose vial.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Xgeva. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Xgeva® (denosumab subcutaneous injection)	120 mg/1.7 mL single-dose vial	1.7 mL (1 vial)	5.1 mL (3 vials)

CRITERIA

1. If the patient has giant cell tumor of bone and is initiating therapy, approve a one-time override for the requested quantity, not to exceed 5.1 mL (3 vials) at retail or home delivery.

2. If the patient has hypercalcemia of malignancy and is initiating therapy or is repeating treatment (up to six times per year), approve a one-time override for the requested quantity, not to exceed 5.1 mL (3 vials) at retail or home delivery.

REFERENCES

1. Xgeva® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; June 2020.
2. Prolia® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; January 2023.