

| | |
|--|---|
| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
| Original Development Date: Original Effective Date: Revision Date: | May 21, 2012 November 23, 2015, October 21, 2019, April 15, 2024 |

Xgeva® (denosumab)

LENGTH OF AUTHORIZATION: Up to six months

REVIEW CRITERIA:

- Patient must be ≥ 18 years old, or ≥ 12 years old for patients with skeletal maturity in unresectable giant cell tumor of the bone.
- Patient must have a documented diagnosis of one of the following (*progress notes or medical records confirming the diagnosis must be provided*):
 - Multiple Myeloma
 - Bone metastases from solid tumors
 - Giant Cell Tumor of the bone that is unresectable or resection will likely cause severe morbidity
 - Hypercalcemia of malignancy refractory to bisphosphonate therapy

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING & ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as a 120 mg/1.7 mL (70 mg/mL) solution in a single-dose vial for injection.