

SPECIALTY GUIDELINE MANAGEMENT

XGEVA (denosumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Prevention of skeletal-related events in patients with bone metastases from solid tumors
Limitation of Use: Not indicated for the prevention of skeletal-related events in patients with multiple myeloma
2. 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
3. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Bone Metastases from a Solid Tumor (excluding prostate cancer)**

Authorization of 24 months may be granted for the prevention of skeletal-related events in members with bone metastases from solid tumors other than prostate cancer.

B. **Prostate Cancer**

Authorization of 24 months may be granted for the prevention of skeletal-related events in members with bone metastases for castration recurrent prostate cancer.

C. **Giant Cell Tumor of Bone**

Authorization of 24 months may be granted for the treatment of giant cell tumor of bone.

D. **Hypercalcemia of Malignancy**

Initial authorization of 2 months may be granted for the treatment of hypercalcemia of malignancy that is refractory to intravenous (IV) bisphosphonate therapy (e.g., zoledronic acid, pamidronate).

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2015 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed October 24, 2016.
3. NCCN Clinical Practice Guidelines in Oncology: Bone Cancer. Version 1.2017. Accessed October 24, 2016.
4. Hu M, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. *J Clin Endocrinol Metab*. 2014; 99(9):3144-3152.

