CareFirst Family of health care plans

CVS caremark™

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 multiple myeloma and in patients with bone metastases from solid tumors
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. Multiple Myeloma and Bone Metastases from a Solid Tumor
Authorization of 24 months may be granted for the prevention of skeletal-related events in members with multiple myeloma or bone metastases from solid tumors.

B. Giant Cell Tumor of Bone
Authorization of 24 months may be granted for the treatment of giant cell tumor of bone.

C. 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) OR there is a clinical reason to avoid IV bisphosphonate therapy (See Appendix A)

III. CONTINUATION OF THERAPY

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

IV. APPENDIX

Appendix A. Clinical reasons to avoid IV bisphosphonate therapy
- Renal insufficiency (creatinine clearance <35 mL/min)
- Acute renal impairment
- History of intolerance to an IV bisphosphonate
- Hypocalcemia

V. REFERENCES

1. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2018.
2. The NCCN Drugs & Biologics Compendium™ © 2015 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 18, 2017.
3. NCCN Clinical Practice Guidelines in Oncology: Bone Cancer. Version 1.2017. Accessed October 18, 2017.
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.
5. Bisphosphonates. *Drug Facts and Comparisons.* F*acts & Comparisons*® *eAnswer*s [online]. 2015. Available from Wolters Kluwer Health, Inc. Accessed October 18, 2017.