Reference number(s)
2152-A

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

B. Compendial Uses
1. Second-line therapy for osteopenia/osteoporosis in patients with systemic mastocytosis
2. Thyroid cancer as palliative care for bone metastases

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Multiple myeloma
Authorization of 12 months may be granted for prevention of skeletal-related events in members with multiple myeloma.

B. Bone metastases from a solid tumor
Authorization of 12 months may be granted for either of the following:
1. For prevention of skeletal-related events in members with bone metastases from a solid tumor (e.g., breast cancer, non-small cell lung cancer, thyroid carcinoma, kidney cancer, prostate cancer)
2. As palliative care for bone metastases from thyroid carcinoma

C. Giant cell tumor of bone
Authorization of 12 months may be granted for treatment of giant cell tumor of bone.

D. Hypercalcemia of malignancy
Authorization of 2 months may be granted for treatment of hypercalcemia of malignancy that is refractory to intravenous (IV) bisphosphonate therapy OR there is a clinical reason to avoid IV bisphosphonate therapy (see Appendix).

E. Systemic mastocytosis

Authorization of 12 months may be granted for second-line therapy for osteopenia or osteoporosis in members with systemic mastocytosis that have not responded to therapy with bisphosphonates or who are not candidates for bisphosphonates because of renal insufficiency.

III. CONTINUATION OF THERAPY

A. Hypercalcemia of malignancy

Authorization of 2 months may be granted for continued treatment in members requesting reauthorization for hypercalcemia of malignancy who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

B. All other indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

IV. APPENDIX

Clinical reasons to avoid IV bisphosphonate therapy

- Renal insufficiency (creatinine clearance <35 mL/min)
- Acute renal impairment
- History of intolerance to an IV bisphosphonate

V. REFERENCES

1. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020.
2. The NCCN Drugs & Biologics Compendium™ © 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 6, 2023.
3. Hu M, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. *J Clin Endocrinol Metab*. 2014;99(9):3144-3152.
4. Bisphosphonates. Drug Facts and Comparisons. Facts & Comparisons® eAnswers. Wolters Kluwer Health Inc. Riverwoods, IL. Accessed October 6, 2023. https://online.factsandcomparisons.com