Reference number(s)
2392-A

STANDARD MEDICARE PART B 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 Use
1. Treatment for osteopenia or osteoporosis in patients with systemic mastocytosis
2. Thyroid cancer as palliative care for bone metastases
3. Prevention of skeletal-related events in prostate cancer in patients with bone metastases.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

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 any of the following:
1. For the prevention of skeletal-related events in members with bone metastases from a solid tumor (i.e., 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 the bone**
Authorization of 12 months may be granted for the treatment of giant cell tumor of bone

D. **Hypercalcemia of malignancy**
Authorization of 2 months may be granted for the treatment of hypercalcemia of malignancy

E. Systemic mastocytosis
Authorization of 12 months may be granted for the treatment of osteopenia or osteoporosis in patients with systemic mastocytosis

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

A. Hypercalcemia of malignancy
Authorization for 2 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Xgeva
2. Xgeva is being used to treat hypercalcemia of malignancy
3. The member is receiving benefit from therapy. Benefit is defined as:
    a. Disease stability, or
    b. Disease improvement

B. All other indications
Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Xgeva
2. Xgeva is being used to treat an indication enumerated in Section II other than hypercalcemia of malignancy
3. The member is receiving benefit from therapy. Benefit is defined as:
    a. Disease stability, or
    b. Disease improvement

IV. REFERENCE

1. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020.
2. The NCCN Drugs & Biologics Compendium™ © 2021 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 18, 2022.