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. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Xgeva.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
3. NCCN Guideline: Prostate cancer
4. NCCN Guideline: Multiple myeloma
5. NCCN Guideline: Bone cancer
6. NCCN Guideline: Non-small cell lung cancer
7. NCCN Guideline: Breast cancer
8. NCCN Guideline: Thyroid carcinoma
9. NCCN Guideline: Kidney cancer
10. NCCN Guideline: Systemic mastocytosis

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Xgeva are covered in addition to the following:
A. Treatment of osteopenia/osteoporosis in patients with systemic mastocytosis
B. Palliative care for bone metastases in thyroid cancer
C. Prevention of skeletal-related events associated with bone metastases from prostate cancer

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Xgeva as treatment for osteopenia or osteoporosis in patients with systemic mastocytosis can be found in the National Comprehensive Cancer Network's guideline for systemic mastocytosis. The NCCN Guideline for systemic mastocytosis supports the use of Xgeva as second-line therapy for osteopenia/osteoporosis in patients with bone pain not responding to bisphosphonates or for patients who are not candidates for bisphosphonates because of renal insufficiency.

Support for using Xgeva as palliative care for bone metastases in patients with thyroid cancer can be found in the National Comprehensive Cancer Network's guideline for thyroid carcinoma. The NCCN Guideline for thyroid carcinoma supports the use of Xgeva as care for bone metastases for the following cancer types: papillary carcinoma, follicular carcinoma, oncocytic carcinoma, medullary carcinoma, and anaplastic carcinoma.

Support for using Xgeva for the prevention of skeletal-related events in patients with bone metastases associated with prostate cancer can be found in the National Comprehensive Cancer Network's guideline for prostate cancer. The NCCN Guideline for prostate cancer supports the use of Xgeva as the preferred agent to prevent skeletal-related events in patients with castration-resistant prostate cancer who have documented bone metastases and creatinine clearance greater than 30 mL/min.

VI. 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.