

JURISDICTION SPECIFIC MEDICARE PART B

XGEVA (denosumab)

POLICY

I. COVERED USES

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

- A. Giant Cell Tumor of Bone
- B. Hypercalcemia of Malignancy
- C. Bone Metastases from Solid Tumors
- D. Osteoporosis with Systemic Mastocytosis

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. EXCLUSIONS

The following are exclusions to therapy:

- A. Combination use of bisphosphonate and a monoclonal antibody for the treatment of osteoporosis during an episode of care
- B. Hypocalcemia, hypovitaminosis D, and other disturbances of bone and mineral metabolism
- C. Patients receiving Prolia
- D. Hypersensitivity to Xgeva

III. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

- A. All documentation must be maintained in the patient's medical record and made available to the contractor upon request
- B. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient
- C. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed
- D. Criteria for the diagnosis of osteoporosis
- E. History of treatment as related to progression of disease and ongoing risk factors

- F. Description of treatment failure, or contraindication, or adverse side effects, of oral or self-administered drugs for osteoporosis as applicable to the member that supports monoclonal antibodies via SQ injection therapy in lieu of standard oral treatment protocol

IV. CRITERIA FOR APPROVAL

A. Giant Cell Tumor of Bone

Authorization of 12 months may be granted for the treatment of giant cell tumor of bone when all of the following criteria are met:

1. The member is taking calcium and vitamin D supplements as necessary to treat or prevent hypocalcemia
2. Giant cell tumor of bone is one of the following:
 - i. Unresectable
 - ii. Surgical resection likely to result in severe morbidity

B. Hypercalcemia of Malignancy

Authorization of 12 months may be granted for the treatment of hypercalcemia of malignancy when all of the following criteria are met:

1. The member is taking calcium and vitamin D supplements as necessary to treat or prevent hypocalcemia
2. The member has tried and failed bisphosphonate therapy

C. Bone Metastases from Solid Tumors

Authorization of 12 months may be granted for the prevention of skeletal-related events (SRE) with bone metastases from solid tumors for a member that is taking calcium and vitamin D supplements as necessary to treat or prevent hypocalcemia

D. Osteoporosis with Systemic Mastocytosis

Authorization of 12 months may be granted for the treatment osteoporosis in a member with systemic mastocytosis when all of the following criteria are met:

1. The member is taking calcium and vitamin D supplements as necessary to treat or prevent hypocalcemia
2. The member has bone pain and one of the following:
 - i. Tried and failed bisphosphonate therapy
 - ii. Member cannot use bisphosphonate therapy due to renal insufficiency

V. REFERENCES

1. Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications (L33270) Version R14. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed October 18, 2022.
2. Billing and Coding: Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications (A57603) Version R2. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed October 18, 2022.
3. Xgeva [package insert]. Thousand Oaks, CA: Amgen, Inc; June 2020.

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5251-A

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