PRIOR AUTHORIZATION POLICY

POLICY: Bone Modifiers – Xgeva Prior Authorization Policy
- Xgeva® (denosumab subcutaneous injection – Amgen)

REVIEW DATE: 03/09/2022; selected revision 10/19/2022

OVERVIEW

Xgeva, a receptor activator of nuclear factor kappa-B ligand inhibitor, is indicated for the following uses:[1]

- **Giant cell tumor of bone**, treatment of adults and skeletally mature adolescents with disease that is unresectable or where surgical resection is likely to result in severe morbidity.
- **Hypercalcemia of malignancy**, treatment of, that is refractory to bisphosphonate therapy.
- **Skeletal-related events**, prevention of, in patients with multiple myeloma and in those with bone metastases from solid tumors.

Another injectable formulation of denosumab is available, Prolia® (subcutaneous injection), but it is not included in this policy.[2]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Xgeva. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Xgeva as well as the monitoring required for adverse events and long-term efficacy, approval requires Xgeva to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xgeva is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   Note: Some examples of cancer in this clinical scenario include breast cancer, prostate cancer, and non-small cell lung cancer.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has bone metastases; AND
   C) Patient with prostate cancer must have castration-resistant prostate cancer; AND
   Note: This includes patients who have progressed after treatment with hormonal therapy or after surgical castration (e.g., bilateral orchiectomy). Examples of hormonal therapies for prostate cancer include Lupron Depot (leuprolide for depot suspension), Eligard (leuprolide acetate for injectable suspension), Trelstar (triptorelin pamoate for injectable suspension), or Zoladex (goserelin implant).
   D) The medication is prescribed by or in consultation with a hematologist or an oncologist.
2. **Giant Cell Tumor of Bone.** Approve for 1 year.

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3. **Hypercalcemia of Malignancy.** Approve for 2 months if the patient meets the following criteria (A, B, and C):
   A) Patient has a current malignancy; AND
   B) Patient meets one of the following (i or ii):
      i. Patient has tried at least one intravenous (IV) bisphosphonate therapy; OR
      Note: Examples include zoledronic acid intravenous infusion (Zometa) and pamidronate intravenous infusion (Aredia); OR
      ii. Patient has an estimated calculated creatinine clearance (CrCl) < 30 mL/min; AND
   C) Patient has an albumin-corrected calcium (cCa) ≥ 11.5 mg/dL.

4. **Multiple Myeloma – Prevention of Skeletal-Related Events.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Medication is prescribed by or in consultation with a hematologist or an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Xgeva is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Xgeva® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; June 2020.
2. Prolia® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; May 2021.

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