VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Bone Modifiers – Xgeva Utilization Management Medical Policy
- Xgeva® (denosumab subcutaneous injection – Amgen)

REVIEW DATE: 03/09/2022

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® (denosumab subcutaneous injection), but it is not included in this policy.[2]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Xgeva. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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 received at least one hormonal therapy; AND
   Note: 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) Medication is prescribed by or in consultation with a hematologist or an oncologist.

Dosing. Approve 120 mg administered as a subcutaneous (SC) injection up to once every 4 weeks.

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2. Giant Cell Tumor of Bone. Approve for 1 year.

Dosing. Approve 120 mg subcutaneous (SC) up to once every 4 weeks with loading doses on Day 8 and Day 15 of Month 1.

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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.

Dosing. Approve 120 mg subcutaneous (SC) up to once every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy.

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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)** The medication is prescribed by or in consultation with a hematologist or an oncologist.

Dosing. Approve 120 mg administered as a subcutaneous (SC) injection up to once every 4 weeks.

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	The following changes were made: **Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events:** The examples of breast cancer, prostate cancer, and non-small-cell lung cancer were moved as examples of cancers from the cited indication to a Note. Regarding the criterion that patients with prostate cancer must have received at least one hormonal therapy, the examples of hormonal therapies for prostate cancer were moved from the criteria to a Note. **Hypercalcemia of Malignancy:** Regarding the criteria that the patient has tried intravenous bisphosphonate therapy, the qualifier of "at least one" bisphosphonate therapy was added and examples were moved from the criteria to a Note.	03/03/2021
Annual Revision	No criteria changes.	03/09/2022