MEDICATION POLICY:

Xgeva®

Generic Name: Denosumab

Therapeutic Class or Brand Name: Xgeva®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/15/2016

Date Last Reviewed / Revised: 8/15/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I and III are met)

I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:

   A. Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors AND criteria 1 through 2 are met:

      1. Documented trial and failure of, intolerance to, or contraindication to IV bisphosphonate therapy (i.e., pamidronate, zoledronic acid, etc.)
      2. Minimum age requirement: 18 years old.

   B. Treatment of giant cell tumor of bone AND criteria 1 through 3 are met:

      1. Tumor is unresectable or surgical resection is contraindicated.
      2. Patient is an adult or skeletally mature adolescent (defined by at least 1 mature long bone (i.e. closed epiphyseal growth plate of the humerus).
      3. Minimum age requirement: 13 years old.

   C. Treatment of hypercalcemia of malignancy AND criteria 1 through 3 are met:

      1. Patient has a documented albumin-corrected calcium of greater than 12.5 mg/dL (3.1 mmol/L).
      2. Documented trial and failure of, intolerance to, or contraindication to IV bisphosphonate therapy (i.e. ibandronate, pamidronate, zoledronic acid).
      3. Minimum age requirement: 18 years old.

II. Treatment must be prescribed by or in consultation with an oncologist.

III. Refer to plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Skeletal-related events in patients with multiple myeloma.
- Hypocalcemia.

- Coadministration of Xgeva® with Prolia®

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Multiple Myeloma and Bone Metastasis from Solid Tumors: One 120 mg injection every 28 days.
- Giant Cell Tumor of Bone or Hypercalcemia of Malignancy: Three 120 mg injections for the 28 days, then one 120mg injection every 28 days

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. Xgeva. Prescribing information. Amgen Inc.; 2020. Accessed August 15, 2023. https://pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/xgeva/xgeva_pi.pdf.
2. NCCN Clinical Practice Guidelines in Oncology. Prostate Cancer V.3.2022. Updated January 10, 2022. Accessed September 15, 2022. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
3. NCCN Clinical Practice Guidelines in Oncology. Breast cancer V.2.2022. Updated December 20, 2021. Accessed September 15, 2022. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.