MEDICATION POLICY

Generic Name: Denosumab

Therapeutic Class or Brand Name: Xgeva®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 1/15/16 **Date Last Reviewed/Revised:** 6/16/16

GPI Code: 30044530002030

Prior Authorization Criteria (may be considered medically necessary when criteria I through II 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 bone metastases from solid tumors AND criterion 1 is met:

1. 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. pamidronate, zoledronic acid).
3. Minimum age requirement: 18 years old.

II. Prescriber must be an oncologist.

Exclusion Criteria:

- Skeletal-related events in patients with multiple myeloma.
- Hypocalcemia.
- Coadministration of Xgeva® with Prolia®.

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.

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Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 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. http://pi.amgen.com/united_states/xgeva/xgeva_pi.pdf.
2. Medi-Span.
3. http://blue.regence.com/trgmedpol/drugs/dru393.pdf.
4. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
5. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.

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Historical Tracking Of Changes Made To Policy	
6/16/2016	1. **Changed** "A. Prevention of skeletal-related events in patients with bone metastases from solid tumors AND criteria 1 and 2 are met: 1. Documented trial and failure of, intolerance to, or contraindication to IV bisphosphonate therapy (i.e. pamidronate, zoledronic acid); B. Minimum age requirement: 18 years old" **to** "A. Prevention of skeletal-related events in patients with bone metastases from solid tumors AND criterion 1 is met: 1. Minimum age requirement: 18 years old" **under Prior Authorization Criteria**. 2. **Added** "https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf" and "https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf" **under References**.

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