

MONTANA HEALTHCARE PROGRAMS
Prior Authorization Criteria

Version 2, 01/11/2018

Xgeva[®] Denosumab

Xgeva[®] is a RANK Ligand inhibitor

Indications¹: Xgeva[®] is used for:

- 1) Prevention of skeletal-related events in patients with bone metastases from solid tumors; however, Xgeva[®] is not indicated for the prevention of skeletal-related events in patients with multiple myeloma;
- 2) Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity;
- 3) Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

Criteria for Approval¹:

- A) Member has one of the three approved indications listed above.
- B) Member has used an IV bisphosphonate, pamidronate or zoledronic acid, that has been ineffective, contraindicated, or not tolerated.
- C) Member is not taking Prolia.
- D) Serum Creatinine clearance is 30 mL/min or greater.

Administration

Xgeva[®] is administered by the subcutaneous route.

Quantity Limit:

- For Bone Metastasis from solid tumors: 120 mg every four weeks as subcutaneous injection.
- For Giant Cell Tumor of Bone, 120 mg every four weeks with additional loading doses on day 8 and 15 of the first month of therapy administered by subcutaneous injection.
- For hypercalcemia of Malignancy 120 mg every four weeks with loading doses on day 8 and 15 of the first month of therapy administered by subcutaneous injection.

Criteria for Renewal Authorization Approval:

- Member has been compliant and adherent to this regimen and continued to take calcium and vitamin D.

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Criteria for Denial (Any of the following):

- The member does not have the indicated diagnoses.
- The member has discontinued use of calcium and Vitamin D.
- Member has severe hypophosphatemia (serum phosphorus less than 2 mg/dL).
- Member has experienced osteonecrosis of the jaw.
- Female member is pregnant.

Clinical Monitoring

- Monitor serum chemistries including calcium, phosphorus, Vitamin D.

References:

1. Xgeva[®] [package insert] Thousand Oaks, CA; Amgen Inc.; 5/2017, Accessed November 15, 2017.