MONTANA HEALTHCARE PROGRAMS
Prior Authorization Criteria

Version 2, 1/11/18

Xgeva® Denosumab

Xgeva® is a RANK Ligand inhibitor

Indications[1]: Xgeva® is used for**:**

1) Prevention of skeletal-related events in patients with bone metastases from solid tumors and 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 Approval[1]:

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 and multiple myeloma: 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.

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.