



Montana Healthcare Programs
Physician-Administered Drug Coverage Criteria

XGEVA® (denosumab)

I. Medication Description

Xgeva® is a RANK ligand (RANKL) inhibitor indicated for:

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastasis from solid tumors
- 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
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all the following criteria:

- Xgeva® is being used for one of the following indications:
 - Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors
 - 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
 - Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy
- Member is at least 18 years of age, unless has giant cell tumor of bone. If member has giant cell tumor of bone, then must be an adult (≥ 18 years old) or an adolescent at least 12 years of age and skeletally mature, defined by having at least one mature long bone (e.g., closed epiphyseal growth plate of the humerus) and a body weight ≥ 45 kg.
- Member has used an IV bisphosphonate that has been ineffective or not tolerated, unless contraindicated.
 - Exception: If member has giant cell tumor of bone, they do not have to try IV bisphosphonate first.
- Member is not pregnant.
- Member is not taking Prolia®.

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Member has been adherent to Xgeva®.
- Member has experienced a positive clinical response.

V. Quantity Limitations

Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors: Max 120mg SQ every 4 weeks

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: Max 120mg SQ every 4 weeks, with additional 120mg doses on days 8 and 15 of the first month of therapy

Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy: Max 120mg SQ every 4 weeks, with additional 120mg doses on days 8 and 15 of the first month of therapy

VI. Coverage Duration

Initial approval duration: 1 year

Renewal approval duration: 1 year