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 has giant cell tumor of bone, then must be an adult ($\geq$18 years old) or an adolescent at least 12 years of age and skeletally mature, defined by having at least 1 mature long bone (e.g., closed epiphyseal growth plate of the humerus) and a body weight $\geq$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