CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Xgeva (denosumab)
BILLING CODE	J0897
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
STATUS	Prior Authorization Required

Xgeva (denosumab) was initially approved by the FDA in 2010 and is a monoclonal antibody that inhibits the RANK ligand (RANKL). It is indicated for the prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors, and for the treatment of hypercalcemia of malignancy. It is also indicated for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone (GCTB) that is unresectable or where surgical resection is likely to result in severe mobility.
Giant cell tumor of bone is an intermediate, locally aggressive primary bone tumor, most commonly occurring in long bones. At presentation, 15%–20% of patients have a pathologic fracture. Malignant transformation is uncommon but possible. The main problem in the management of GCTB is local recurrence after surgical treatment. The clinical challenge in GCTB treatment is to improve local control and broaden indications for intralesional surgery, providing optimal functional and oncological results. This may be aided by targeted therapy with denosumab.

Xgeva (denosumab) will be considered for coverage when the following criteria are met:

Giant Cell Tumor of Bone

For **initial** authorization:
1. Member is 12 years of age or older; AND
2. Xgeva is prescribed by or in consult with an oncologist; AND
3. Member has a confirmed diagnosis of giant cell tumor of bone (radiographs, MRI, or histology); AND
4. Member's tumor is either recurrent (came back after surgery), unresectable (cannot be removed by surgery), or surgery is likely to result in severe morbidity (i.e., limb amputation or joint resection).
5. **Dosage allowed/Quantity limit:** 120 mg (1 injection) subQ every 28 days, with additional 120mg doses on days 8 and 15 of the first month of therapy
   QL: total 3 vials for the initial 28 days, followed by 1 vial (1.7 mL) per 28 days thereafter

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document reduction of tumor size or lack of tumor progression from baseline.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

Multiple Myeloma, Bone Metastasis from Solid Tumors, and Hypercalcemia of Malignancy

Any request for cancer or hypercalcemia of malignancy must be submitted through NantHealth/Eviti portal.

CareSource considers Xgeva (denosumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/13/2020	New policy for Xgeva created
04/26/2022	Transferred to new template. Added QL. Updated references. Added specialist and diagnostic confirmation. Modified wording of renewal criteria. Shortened initial approval duration from 12 mo to 6 mo.

References:

1. Xgeva [prescribing information]. Thousand Oaks, CA: Amgen Inc.; June, 2020.
2. van der Heijden L, Dijkstra PD, van de Sande MA, et al. The clinical approach toward giant cell tumor of bone. *Oncologist*. 2014;19(5):550-561. doi:10.1634/theoncologist.2013-0432.
3. van der Heijden L, Dijkstra S, van de Sande M, Gelderblom H. Current concepts in the treatment of giant cell tumour of bone. *Curr Opin Oncol*. 2020;32(4):332-338. doi:10.1097/CCO.0000000000000645

Effective date: 10/01/2022
Revised date: 4/26/2022