MEDICAL MUTUAL®

Drug Policy

Policy:	**201416**	**Initial Effective Date: 07/30/2014**
Code(s):	**J0897**	**Annual Review Date: 03/16/2023**
SUBJECT:	**Xgeva® (denosumab injection)**	**Last Revised Date:03/16/2023**

☐Subject to Site of Care

Prior authorization applies to Medicare benefit

Prior approval is required for some or all procedure codes listed in this Corporate Medical.

HCPCS Code J0897 requires prior approval except when utilized for treatment/prevention of osteoporosis.

POLICY STATEMENT

This policy involves the use of Xgeva. Prior authorization is recommended for medical benefit coverage of Xgeva. Coverage is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy, and Labs/Diagnostics** for the diagnosis provided. The requirement that the patient meet the Criteria for coverage of the requested medication applies to the initial authorization only. **Waste Management** applies for all covered conditions. **Conditions not recommended for approval** are listed following the recommended authorization criteria and Waste Management section.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Xgeva as well as the monitoring required for adverse events and long-term efficacy, initial approval for some conditions requires Xgeva to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is required, a response to therapy is required for continuation of therapy.

Recommended Authorization Criteria

Coverage of Xgeva is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumors (e.g., Breast Cancer, Prostate Cancer, Non-Small-Cell Lung Cancer).** Approve for 6 months if the patient meets the following criteria (A, B, C and D):
   - **A)** The patient is aged ≥ 18 years; AND
   - **B)** The agent is prescribed by, or in consultation with, a hematologist or an oncologist; AND
   - **C)** The patient has bone metastases; AND

D) Patients with prostate cancer have received at least one hormonal therapy (e.g., Lupron Depot® [leuprolide for depot suspension], Eligard® [leuprolide acetate for injectable suspension], Trelstar® [triptorelin pamoate for injectable suspension], or Zoladex® [goserelin implant]).

Dosing. Approve 120 mg administered as a subcutaneous (SC) injection once every 4 weeks.

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2. Prevention of Skeletal-Related Events in Patients with Multiple Myeloma.[1] Approve Xgeva for 6 months if the patient meets the following criteria (A and B):

A) The patient is aged ≥ 18 years; AND

B) The agent is prescribed by, or in consultation with, a hematologist or an oncologist.

Dosing. Approve 120 mg administered as a subcutaneous (SC) injection once every 4 weeks.

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3. Giant Cell Tumor of Bone. Approve for 6 months.

Dosing. Approve 120 mg SC once every 4 weeks with loading doses on Day 8 and Day 15 of Month 1.[1,7]

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4. Hypercalcemia of Malignancy. Approve for 2 months if the patient meets the following criteria (A, B, and C):

A) The patient has a current malignancy; AND

B) The patient meets one of the following (i or ii):

i. The patient has tried intravenous (IV) bisphosphonate therapy (e.g., zoledronic acid injection [Zometa], pamidronate injection [Aredia]); OR

ii. The patient has an estimated calculated creatinine clearance (CrCl) < 30 mL/min; AND

C) The patient's albumin-corrected calcium (cCa) is ≥ 11.5 mg/dL.

Dosing. Approve 120 mg SC once every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy.[1]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Xgeva has not been shown to be effective or there are limited or preliminary data, or potential safety concerns, that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions are provided below.

1. Coverage is not recommended for circumstances *not* listed in the *Recommended Authorization Criteria*. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J0897