MEDICAL MUTUAL®

Drug Policy

Policy:	**201416**	**Initial Effective Date: 07/30/2014**
Code(s):	**J0897**	**Annual Review Date: 03/20/2025**
SUBJECT:	**Xgeva® (denosumab injection)**	**Last Revised Date: 03/20/2025**

Subject to: ☐Site of Care
☐Medication Sourcing

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.

Covered Diagnosis Codes

ICD-10 CM	Description	FDA/ Off-Label
C79.51	Secondary malignant neoplasm of bone	FDA
D48.0	Neoplasm of uncertain behavior of bone and articular cartilage	FDA
E83.52	Hypercalcemia	FDA
M80.00	Age-related osteoporosis with current pathological fracture, unspecified site	FDA
M80.011	Age-related osteoporosis with current pathological fracture, right shoulder	FDA
M80.012	Age-related osteoporosis with current pathological fracture, left shoulder	FDA
M80.019	Age-related osteoporosis with current pathological fracture, unspecified shoulder	FDA
M80.021	Age-related osteoporosis with current pathological fracture, right humerus	FDA
M80.022	Age-related osteoporosis with current pathological fracture, left humerus	FDA
M80.029	Age-related osteoporosis with current pathological fracture, unspecified humerus	FDA
M80.031	Age-related osteoporosis with current pathological fracture, right forearm	FDA
M80.032	Age-related osteoporosis with current pathological fracture, left forearm	FDA
M80.039A	Age-related osteoporosis with current pathological fracture, unspecified forearm, initial encounter for fracture	FDA
M80.039D	Age-related osteoporosis with current pathological fracture, unspecified forearm, subsequent	FDA

	encounter for fracture with routine healing	
M80.039	Age-related osteoporosis with current pathological fracture, unspecified forearm	FDA
M80.041	Age-related osteoporosis with current pathological fracture, right hand	FDA
M80.042A	Age-related osteoporosis with current pathological fracture, left hand, initial encounter for fracture	FDA
M80.042	Age-related osteoporosis with current pathological fracture, left hand	FDA
M80.049	Age-related osteoporosis with current pathological fracture, unspecified hand	FDA
M80.051	Age-related osteoporosis with current pathological fracture, right femur	FDA
M80.052	Age-related osteoporosis with current pathological fracture, left femur	FDA
M80.059D	Age-related osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with routine healing	FDA
M80.059G	Age-related osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with delayed healing	FDA
M80.059K	Age-related osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with nonunion	FDA
M80.059P	Age-related osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with malunion	FDA

M80.059	Age-related osteoporosis with current pathological fracture, unspecified femur	FDA
M80.061	Age-related osteoporosis with current pathological fracture, right lower leg	FDA
M80.062	Age-related osteoporosis with current pathological fracture, left lower leg	FDA
M80.069	Age-related osteoporosis with current pathological fracture, unspecified lower leg	FDA
M80.071	Age-related osteoporosis with current pathological fracture, right ankle and foot	FDA
M80.072	Age-related osteoporosis with current pathological fracture, left ankle and foot	FDA
M80.079	Age-related osteoporosis with current pathological fracture, unspecified ankle and foot	FDA
M80.08	Age-related osteoporosis with current pathological fracture, vertebra(e)	FDA
M80.0AX	Age-related osteoporosis with current pathological fracture, other site,	FDA
M80.8AX	Other osteoporosis with current pathological fracture, other site, initial encounter for fracture	FDA
M81.0	Age-related osteoporosis without current pathological fracture	FDA
M81.8	Other osteoporosis without current pathological fracture	FDA
M85.9	Disorder of bone density and structure, unspecified	FDA
T38.0X5S	Adverse effect of glucocorticoids and synthetic analogues, sequela	FDA
Z13.820	Encounter for screening for osteoporosis	FDA

Z79.818	Long term (current) use of other agents affecting estrogen receptors and estrogen levels	FDA
Z79.899	Other long term (current) drug therapy	FDA

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

Edits and Denials:

Prior Approval: Prior approval is required for Xgeva **(HCPCS Code J0897)** except when utilized for treatment/prevention of osteoporosis. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within the Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Code J0897** will edit with **Remark Code M3M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary. A provider may bill a member for charges denied as investigational.

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Drug Policy

HCPCS Code(s):	
J0897	Injection, denosumab, 1 mg