	<b>Johns Hopkins HealthCare LLC</b> <b>Pharmacy Public</b> <b>Medical Management Drug Policies</b>	<i>Policy Number</i>	MMDP075
		<i>Effective Date</i>	06/01/2022
		<i>Review Date</i>	05/19/2022
	<i>Subject</i> <b>Xgeva</b>	<i>Revision Date</i>	05/19/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

**Keywords:** Xgeva


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## **I. POLICY**

- A. Xgeva (denosumab) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

## **II. POLICY CRITERIA**

- A. **Xgeva** may be approved for patients who meet the following:
1. Multiple myeloma
    - a. Documentation has been submitted showing that Xgeva will be used for prevention of skeletal-related events in a patient with multiple myeloma
  2. Solid Tumor Bone Metastases
    - a. Documentation has been submitted showing that Xgeva will be used for prevention of skeletal-related events in a patient with bone metastases from a solid tumor
  3. Giant cell tumor of bone
    - a. Documentation has been submitted showing that the patient has a diagnosis of giant cell tumor of bone
  4. Hypercalcemia of malignancy
    - a. Documentation has been submitted showing the patient has a diagnosis of hypercalcemia of malignancy and one of the following:
      - I. Patient's disease is refractory to intravenous (IV) bisphosphonate therapy
      - II. Patient has one of the following clinical reasons to avoid IV bisphosphonate therapy:
        - i. Renal insufficiency (creatinine clearance < 35 mL/min)
        - ii. Acute renal impairment
        - iii. History of intolerance to an IV bisphosphonate
  5. Systemic mastocytosis
    - a. Documentation has been submitted showing the following:
      - I. Xgeva will be used as second-line therapy for osteopenia or osteoporosis in a patient with systemic mastocytosis and one of the following:
        - i. Patient has not responded to previous therapy with bisphosphonates

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- ii. Patient is not a candidate for bisphosphonates because of renal insufficiency

### **III. AUTHORIZATION PERIOD/LIMITATIONS**

- A. Initial approval will be limited to 12 months of therapy
1. Diagnosis-specific limitation: Initial approval will be limited to 2 months for treatment of hypercalcemia of malignancy
- B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient is continuing to have a clinical benefit to therapy, evidenced by disease stability, or improvement
1. Diagnosis-specific limitation: Continuation approval will be limited to 2 months for treatment of hypercalcemia of malignancy

### **IV. EXCLUSIONS**

- A. Xgeva will not be covered for the following:
1. Any indications or uses that are not FDA-approved, or guideline-supported

### **V. RECOMMENDED DOSAGE**

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

### **VI. CODES**

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**Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.**


Medication	HCPCS/CPT Code
<b>Injection, denosumab, 1 mg</b>	<b>J0897</b>

### **VII. REFERENCES**

1. Xgeva [prescribing information]. Thousand Oaks, CA: Amgen Inc.; June 2020.
2. The NCCN Drugs & Biologics Compendium™ © 2022National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 19, 2022.
3. Hu M, Glezerman IG, Lebouilleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. J Clin Endocrinol Metab. 2014; 99(9):3144-3152.

### **VIII. APPROVALS**

Signature on file at JHHC

 <b>JOHNS HOPKINS</b> <small>M E D I C I N E</small> <small>JOHNS HOPKINS HEALTHCARE</small>	<b>Johns Hopkins HealthCare LLC</b> <b>Pharmacy Public</b> <b>Medical Management Drug Policies</b>	<i>Policy Number</i>	MMDP075
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DATE OF REVISION	SUMMARY OF CHANGE
5/19/2022	Policy Creation

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