Xgeva (denosumab)

**POLICY**

**A. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

**FDA-Approved Indications**

1. Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors
2. 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
3. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy
   - Prevention of skeletal-related events in patients with bone metastases from solid tumors
   - Limitation of Use: Not indicated for the prevention of skeletal-related events in patients with multiple myeloma
   - 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

**B. REQUIRED DOCUMENTATION**

The following information is may be necessary to initiate the prior authorization review (where applicable):

- **Initial therapy**
  - Multiple myeloma or Bone metastases from a solid tumor:
  - Documentation of primary cancer (e.g., breast, prostate) from member’s chart notes
  - Hypercalcemia of malignancy: documentation of pre-treatment albumin-corrected serum calcium level

- **Continuation of therapy**
  - Giant cell tumor of the bone:
  - Documentation of clinical notes and active findings such as imaging studies (for continuation of therapy requests only)
  - Hypercalcemia of malignancy:
  - Documentation of pre-treatment albumin-corrected serum calcium level (for new starts only)
C. CRITERIA FOR APPROVAL

1. **Multiple Myeloma and Bone Metastases from a Solid Tumor**
   
   Authorization of 24 months may be granted for the prevention of skeletal-related events in members with multiple myeloma or bone metastases from solid tumors.
   
   2. Indefinite approval may be granted to members who are prescribed Xgeva for the prevention of skeletal-related events when the following criteria are met:
      
      a. Member has bone metastases from a solid tumor.
      b. Member will receive calcium and vitamin D as needed to treat or prevent hypocalcemia.

2. **Giant Cell Tumor of Bone**
   
   Authorization of 24 months may be granted for the treatment of giant cell tumor of bone.
   
   Authorization of 6 months may be granted to members who are prescribed Xgeva for giant cell tumor of bone when the following criteria are met:
   
   a. Member has unresectable disease or surgical resection is likely to result in severe morbidity.
   b. Member will receive calcium and vitamin D as needed to treat or prevent hypocalcemia.

3. **Hypercalcemia of Malignancy**
   
   Initial authorization of 2 months may be granted for the treatment of hypercalcemia of malignancy that is refractory to intravenous (IV) bisphosphonate therapy (e.g., zoledronic acid, pamidronate) OR there is a clinical reason to avoid IV bisphosphonate therapy (See Appendix A). Initial authorization of 2 months may be granted to members who are prescribed Xgeva for hypercalcemia of malignancy when the following criteria are met:
   
   a. Pre-treatment albumin-corrected serum calcium level is greater than 12.5 mg/dL.
   b. The hypercalcemia is refractory to IV bisphosphonate therapy OR member has a contraindication to IV bisphosphonate therapy.

D. CONTINUATION OF THERAPY

1. No previous authorization/precertification:
   
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.

2. Reauthorization:
   
   a. **Giant Cell Tumor of Bone and Multiple Myeloma**
      
      Members who were previously approved for Xgeva by HMSA/CVS may request reauthorizations after their initial approval. Approval for an additional 246 months may be granted when the following information is supplied: documentation shows no progression of disease:
      
      a. A current oncology note documenting the patient’s response to treatment showing no progression of disease
      b. Current imaging studies and other objective measures showing no progression of disease when compared with previous results

   b. **Hypercalcemia of Malignancy**
      
      Authorization of an additional 24 months may be granted to members who are prescribed Xgeva for requesting authorization for continuation of therapy who demonstrate a response to Xgeva therapy defined as albumin-corrected serum calcium level (for continuation of therapy requests only).
level of < 12.5 mg/dL if Xgeva was and were previously authorized by HMSA/CVS and members demonstrate a response to Xgeva therapy defined as albumin-corrected serum calcium level of < 12.5 mg/dL.

E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. ADMINISTRATIVE GUIDELINES

Pre-certification is required. Please refer to the HMSA medical policy web site for the fax form.

G. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. APPENDIX

Appendix A. Clinical reasons to avoid IV bisphosphonate therapy

- Renal insufficiency (creatinine clearance < 35 mL/min)
- Acute renal impairment
- History of intolerance to an IV bisphosphonate
- Hypocalcemia

H.1. REFERENCES


Document History

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<tr>
<td>10/01/2015</td>
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<tr>
<td>03/2016</td>
<td>Revised criteria for bone metastases and hypercalcemia of malignancy</td>
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<td>10/2016</td>
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<td>10/2016</td>
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<td>03/2018</td>
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<td>04/18/2018</td>
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<td>04/2018</td>
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