Xgeva (denosumab)

**Line(s) of Business:**
- Original Effective Date: 10/01/2015
- HMO; PPO; QUEST Integration
- Current Effective Date: 10/01/2016
- Akamai Advantage

**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**

- 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 may be necessary to initiate the prior authorization review (where applicable):

- Bone metastases from a solid tumor:
  - Documentation of primary cancer (eg, breast, prostate) from member’s chart notes
- Hypercalcemia of malignancy:
  - Documentation of pre-treatment albumin-corrected serum calcium level
  - Documentation of current albumin-corrected serum calcium level (for renewal requests only)

**C. CRITERIA FOR APPROVAL**

1. **Bone Metastases from a Solid Tumor**

1.1 **Prostate Cancer**

Authorization of 24 months may be granted to members who are prescribed Xgeva for the prevention of skeletal-related events in members with bone metastases from prostate cancer when ALL of the following criteria are met:

- Member has castration-recurrent prostate cancer
- Member will receive calcium and vitamin D as needed to treat or prevent hypocalcemia.
1.2 All Other Solid Tumor Types

Authorization of 24 months may be granted to members who are prescribed Xgeva for the prevention of skeletal-related events in members with bone metastases from solid tumors other than prostate cancer when the following criterion is met:

a. 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 to members who are prescribed Xgeva for giant cell tumor of bone when **ALL** of 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 to members who are prescribed Xgeva for hypercalcemia of malignancy when the following criteria are met:
   a. Member’s condition is refractory to intravenous (IV) bisphosphonate therapy (e.g., zoledronic acid, pamidronate) Pre-treatment defined as albumin-corrected serum calcium level is greater than or equal to > 12.5 mg/dL
   b. The hypercalcemia is refractory to despite IV bisphosphonate therapy OR member has a contraindication to IV bisphosphonate therapy.

D. **CONTINUATION OF THERAPY**
   All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

   Hypercalcemia of malignancy:
   - For renewals only: authorization of 24 months may be granted to members who 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. **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’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.
G. REFERENCES


5. Revised: March 2016.