Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Xgeva (denosumab)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2011 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *March 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Xgeva (denosumab).

Xgeva (denosumab) is indicated for:

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.
- 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

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Xgeva (denosumab), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Multiple Myeloma or bone metastases from solid tumors:**
   - Must be prescribed by an oncologist or a hematologist
   - Must be age 18 years or older
   - Must be used for the prevention of skeletal-related events
   - Must not be used concurrently with denosumab (Prolia)

2. **Giant cell tumor of bone:**
   - Must be prescribed by an oncologist or a hematologist
   - Must be age 13 years or older. If age less than 18, member must be skeletally mature.
   - Must have a diagnosis of giant cell tumor of bone
   - Must have disease that is unresectable or where surgical resection is likely to result in severe morbidity

3. **Hypercalcemia of malignancy:**
   - Must be prescribed by an oncologist or a hematologist
   - Must be age 18 years or older
   - Must have a diagnosis of hypercalcemia of malignancy
   - Must have a trial and failure of intravenous (IV) bisphosphonate therapy. Failure is defined as an albumin-corrected calcium > 12.5mg/dL (3.1 mmol/L) despite recent treatment with an IV bisphosphonate.

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Xgeva [package insert]. Thousand Oaks, CA:Amgen.; January 2018.
2. Stopeck AT, et al: Denosumab compared with zoledronic acid for the treatment of bone metastases in patients with advanced breast cancer: a randomized, double-blind study. American Society of Clinical Oncology 28: 5131-139.
3. Denosumab in the treatment of bone metastases from advanced cancer or multiple myeloma (MM): Analyses from a phase III randomized trial. Meeting: 2010 ASCO Annual Meeting Abstract No: 9042 First Author: S. Vadhan-Raj Category: Patient and Survivor Care
4. A randomized phase III trial of denosumab versus zoledronic acid in patients with bone metastases from castration-resistant prostate cancer. Meeting: 2010 ASCO Annual Meeting Abstract No: LBA4507 First Author: K. Fizazi Category: Genitourinary Cancer
5. Thomas DM. RANKL, denosumab, and giant cell tumor of bone. *Curr Opin Oncol* 2012;24:397- 403
6. Thomas D, Henshaw R, Skubitz K,, et al. Denosumab in patients with giant-cell tumour of bone: an open-label, phase 2 study. *Lancet Oncol* 2010;11:275-80

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED

Annual review	*02/16, 02/17, 02/18*
New Indication	*03/18*