Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Xofigo (radium Ra 223 dichloride)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***June 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 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 Xofigo (radium Ra 223 dichloride)

Xofigo (radium Ra 223 dichloride) is indicated for the treatment of patients with castration-resistant prostate-cancer, symptomatic bone metastases and no known visceral metastatic disease.

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, Xofigo (radium Ra 223 dichloride), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a hematologist or oncologist
- Must have a diagnosis of castration-resistant prostate cancer
- Must be age 18 years or older
- Must have two or more symptomatic bone metastases
- Must not have evidence of visceral metastases
- Must have the following laboratory values:
    - Absolute neutrophil count (ANC) ≥ 1.5 x 109/L
    - Platelet count ≥ 100 x 109/L
    - Hemoglobin ≥ 10 g/dL
- Must not be used in combination with chemotherapy [e.g. Taxotere® (docetaxel) and Jevtana® (carbazitaxel)], other systemic radioisotopes (e.g. strontium-89 and samarium-153), or hemibody external radiotherapy

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	1 course of therapy (6-doses given at 4-week intervals) per lifetime
Reauthorization	N/A
Quantity Level Limit	
Xogifo	1 course (6 injections) per lifetime

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

REFERENCES

1. Xofigo [package insert]. Wayne, NJ: Bayer HealthCare Pharmaceutics Inc.; May 2013
2. Parker C, Nilsson S, Heinrich D, et al. Alpha emitter radium-223 and survival in metastatic prostate cancer. N Engl J Med 2013;369-213-23
3. Nilsson S, Sartor O, Bruland O, et al: Pain Analysis from the Phase 3 Randomized ALSYMPCA study with Radium 223 Dichloride in Castration-Resistant Prostate Cancer (CRPC) Patients with Bone Metastases. Poster presented at the American Society of Clinical Oncology Genitourinary Cancer. Orlando, FL. February 2013.
4. Nilsson S, Franzen L, Parker C, et al. Bone-targeted radum-223 in symptomatic, hormone-refractory prostate cancer: a randomized, multecentre, placebo-controlled phase II study. *Lancet Oncol* 2009;8:587-94
5. Kantoff PW, Mohler JL. New developments in the management of prostate cancer. *J Natl Compr Canc Netw* 2013;11:653-657

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	*02/17, 02/18*