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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/13/2025

Xofigo[®] (radium Ra 223 dichloride)

HCPCS: A9606

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Medically or surgically castration resistant prostate cancer with bone metastases defined by a serum testosterone level of less than 50 mg/dL and one of the following:
 - i. Sequential rise of prostate specific antigen (PSA) levels OR
 - ii. Worsening of existing bone metastases or development of new bone metastases on a bone scan performed within the past 60 days despite androgen-deprivation therapy
 - b. No evidence of visceral metastases or bulky regional lymph nodes greater than 3 cm on imaging performed within the past 30 days
 - c. Member has received and exhausted all medical or surgical-ablative hormonal treatments. The member may remain on their ablative hormonal treatment to maintain a castrate level in accordance with NCCN guidelines
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: 6 months
 - c. Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Xofigo is an alpha particle-emitting radioactive therapeutic agent indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases, and no known visceral metastatic disease.
- The 2024 NCCN treatment guidelines for prostate cancer state castrate-resistant prostate cancer is defined as prostate cancer that progresses clinically, radiographically, or biochemically despite castrate levels of serum testosterone of less than 50 ng/dL. Any increase in prostate specific antigen or the development of or worsening of existing bone metastasis while the patient has a testosterone level less than 50 ng/dL would be considered resistant.
- The NCCN guidelines state visceral disease refers to metastases to the liver, lung, adrenal gland, peritoneal cavity, and the brain. Soft tissue and lymph node sites are not considered visceral disease. Patients were excluded from the clinical trial of Xofigo if they had malignant lymphadenopathy exceeding 3 cm.
- NCCN guidelines recommend multiple first-line hormonal-ablative therapies for use in prostate cancer. All these therapies are category 1 and none are preferred over the other when making treatment decisions. All of these therapies should be tried to control the spread of prostate cancer and maintain the patient's testosterone level below 50 ng/dL.

References:

1. Xofigo [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; December 2019.
2. National Comprehensive Cancer Network. Prostate cancer (Version 1.2025). 2024 Dec 4. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed on December 12, 2024.
3. Hoskin P, Sartor O, O'Sullivan JM, et al. Efficacy and safety of radium-223 dichloride in patients with castration-resistant prostate cancer and symptomatic bone metastases, with or without previous docetaxel use: a prespecified subgroup analysis from the randomized, double-blind, phase 3 ALSYMPCA trial. *Lancet Oncol*. 2014 Nov; 15 (12): 1397 – 1406.
4. Parker C, Nilsson S, Heinrich D, et al. Alpha emitter radium-223 survival in metastatic prostate cancer. *N Engl J Med*. 2013 Jul 18; 369 (3): 213 – 23.

Policy History												
#	Date	Change Description										
1.6	Effective Date: 02/13/2025	Annual review of criteria was performed, no changes were made										
1.5	Effective Date: 02/08/2024	Annual review of criteria was performed, no changes were made										
1.4	Effective Date: 02/02/2023	Annual review of criteria was performed, no changes were made										
1.3	Effective Date: 02/10/2022	Annual review of criteria was performed, no changes were made										
1.2	Effective Date: 02/04/2021	Annual review of criteria was performed, no changes were made										
1.1	Effective Date: 02/06/2020	Annual review of criteria was performed, no changes were made										
1.0	Effective Date: 02/14/2019	<div>New Policy<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></div>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.