

Xofigo® (radium Ra 223 dichloride) (Intravenous)

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I. Length of Authorization

Coverage will be provided for six months (6 injections only) and may NOT be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

– N/A

B. Max Units (per dose and over time) [HCPCS Unit]:

- 178 billable units every 28 days

III. Initial Approval Criteria^{1,2,3}

Coverage is provided in the following conditions:

Prostate Cancer †

- Patient is 18 years or older; **AND**
- Patient has castration-resistant disease; **AND**
- Patient has symptomatic bone metastases; **AND**
- Patient does not have any known visceral metastatic disease; **AND**
- Must be used as a single agent

(Note: data from the ERA-223 trial demonstrated an increased risk of fracture and death when used in combination with abiraterone plus prednisone/prednisolone compared to placebo in combination with abiraterone plus prednisone/prednisolone. This combination should not be used outside of a clinical trial)

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage is not renewable.

V. Dosage/Administration¹

Indication	Dose
Prostate Cancer	55 kBq (1.49 microcurie) per kg body weight, given at 4 week intervals for 6 injections. <i>Xofigo should be received, used and administered only by authorized persons in designated clinical settings. The receipt, storage, use, transfer and disposal of Xofigo are subject to the regulations and/or appropriate licenses of the competent official organization. Xofigo should be handled by the user in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.</i>

VI. Billing Code/Availability Information

HCPCS code:

A9606 – Radium ra-223 dichloride, therapeutic, per microcurie: 1 billable unit = 1 microcurie

NDC:

Xofigo (radium Ra 223 dichloride injection) is supplied in single-use vials containing 6 mL of solution at a concentration of 1,100 kBq/mL (30 microcurie/mL) with a total radioactivity of 6,600 kBq/vial (178 microcurie/vial) at the reference date (NDC 50419-0208-xx).

VII. References

1. Xofigo [package insert]. Whippany, NJ; Bayer HealthCare; December 2019. Accessed June 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) radium ra 223 chloride. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2020.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 2.2019. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2020.
4. Smith M, Parker C, Saad F, et al. Addition of radium-223 to abiraterone acetate and prednisone or prednisolone in patients with castration-resistant prostate cancer and bone metastases (ERA 223): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2019 Mar;20(3):408-419.
5. Palmetto GBA. Local Coverage Article for Xofigo Billing Instructions (A54559). Centers for Medicare & Medicaid Services, Inc. Updated on 09/26/2019 with effective date 10/03/2019. Accessed June 2020.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at:

<http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD):

Jurisdiction(s): J, M	NCD/LCD Document (s): A54559
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A54559&bc=gAAAAAAAAAAAAAA ==	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC