

Xofigo® (radium Ra 223 dichloride) (Intravenous)

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I. Length of Authorization

Coverage will be provided for 6 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 ¹⁻³

Coverage is provided in the following conditions:

Prostate Cancer †

- Patient is at least 18 years of age; **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); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria

Coverage is not renewable.

V. Dosage/Administration ¹

| Indication | Dose |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Prostate Cancer | Administer 55 kBq (1.49 microcurie) per kg body weight at 4 week intervals for 6 intravenous injections. <i>*Note: 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

HCPSC 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: 50419-0208-xx

VII. References

1. Xofigo [package insert]. Whippany, NJ; Bayer HealthCare Pharmaceuticals Inc.; December 2019. Accessed May 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Radium Ra 223 dichloride. National Comprehensive Cancer Network, 2023. 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 May 2023.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 1.2023. National Comprehensive Cancer Network, 2023. 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 May 2023.
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 08/03/2021 with effective date 09/02/2021. Accessed June 2023.

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|--------|--------------------------------|
| C61 | 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:

<https://www.cms.gov/medicare-coverage-database/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/LCA/LCD Document (s): A54559 |
| https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=A54559&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP | |

| 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 GBA, 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. |

Medicare Part B Administrative Contractor (MAC) Jurisdictions

| Jurisdiction | Applicable State/US Territory | Contractor |
|---------------------|--------------------------------------|------------------------------------------|
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |