MODA applies pre-payment claims edits to diagnosis criteria and criteria for maximum units. Prior Authorization criteria *do not apply* for this policy.

OHSUHealthServices

Xofigo® (radium Ra 223 dichloride)
(Intravenous)

Document Number: IC-0172

Last Review Date: 10/01/2026
Date of Origin: 09/05/2013
Dates Reviewed: 06/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 08/2017, 07/2018, 07/2019, 07/2020, 07/2021, 07/2022, 07/2023, 10/2024, 10/2025, 10/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), 6 total injections.
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

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

- Prostate Cancer: 178 billable units every 28 days
- Bone Cancer - Osteosarcoma: 356 billable units every 28 days

III. Initial Approval Criteria

Prior authorization validity is provided in the following conditions:

Prostate Cancer † ‡ [1-3,7]

- Member is at least 18 years of age; **AND**
- Member has castration-resistant disease; **AND**
- Member does not have any known visceral metastatic disease; **AND**
  - Used as a single agent for symptomatic bone metastases **¥**; **OR**
  - Used in combination with enzalutamide **¥**; **AND**
    - Member has bone metastases; **AND**
    - Member has NOT received androgen receptor pathway inhibitor (ARPI) therapy

¥ *Concomitant use of androgen deprivation therapy and denosumab or zoledronic acid is permitted.*

(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.)

Bone Cancer - Osteosarcoma ‡ [2,5,6]

- Member is at least 15 years of age; **AND**

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- Member has relapsed or refractory disease; **AND**
- Used beyond second-line therapy

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

Duration of authorization has not been exceeded *(refer to Section I)*

V. Dosage/Administration [1,6,7]

Indication	Dose
Prostate Cancer	Administer 55 kBq (1.49 microcurie)/kg given as an intravenous injection every 4 weeks for 6 cycles.
Bone Cancer - Osteosarcoma	Administer 100 kBq (2.70 microcurie)/kg given as an intravenous injection every 4 weeks for up to 6 cycles.

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: 50419-0208-xx

VII. References

1. Xofigo [package insert]. Whippany, NJ; Bayer HealthCare Pharmaceuticals Inc.; December 2019. Accessed August 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Radium Ra 223 dichloride. National Comprehensive Cancer Network, 2026. 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 August 2026.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 7.2026. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks

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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 August 2026.

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. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Bone Cancer 1.2027. National Comprehensive Cancer Network, 2026. 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 August 2026.
6. Subbiah V, Anderson PM, Kairemo K, et al. Alpha particle radium 223 dichloride in high-risk osteosarcoma: A phase I dose escalation trial. Clin Cancer Res 2019;25:3802- 3810.
7. Tombal B, Choudhury A, Saad F, et al. Enzalutamide plus radium-223 in metastatic castration-resistant prostate cancer: results of the EORTC 1333/PEACE-3 trial. *Ann Oncol*. 2025;36(9):1058-1067. doi:10.1016/j.annonc.2025.05.011
8. Palmetto GBA. Local Coverage Article for Xofigo Billing Instructions (A54559). Centers for Medicare & Medicaid Services, Inc. Updated on 08/30/2021 with effective date 09/02/2021. Accessed August 2026.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb
C40.01	Malignant neoplasm of scapula and long bones of right upper limb
C40.02	Malignant neoplasm of scapula and long bones of left upper limb
C40.10	Malignant neoplasm of short bones of unspecified upper limb
C40.11	Malignant neoplasm of short bones of right upper limb
C40.12	Malignant neoplasm of short bones of left upper limb
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.21	Malignant neoplasm of long bones of right lower limb
C40.22	Malignant neoplasm of long bones of left lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb
C40.31	Malignant neoplasm of short bones of right lower limb
C40.32	Malignant neoplasm of short bones of left lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate
Z85.830	Personal history of malignant neoplasm of bone

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under

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Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
J, M	A54559	Palmetto GBA

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	Wellpoint Federal
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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	Wellpoint Federal
15	KY, OH	CGS Administrators, LLC

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