Xofigo (Radium Ra 223 Dichloride)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Xofigo (Radium Ra 223 Dichloride)

APPROVAL CRITERIA

Requests for Xofigo (Radium Ra 223 Dichloride) may be approved if the following criteria are met (Label, NCCN Prostate Cancer Guideline):

I. Individual has a diagnosis of castration-resistant prostate cancer (CRPC) with symptomatic bone metastasis; **AND**
II. Age 18 years or older; **AND**
III. Individual has a planned course of six monthly injections; **AND**
IV. Individual has serum testosterone level is less than or equal to 50 ng per deciliter ([1.7 nmol per liter] after bilateral orchiectomy or during maintenance treatment consisting of androgen-ablation therapy with a luteinizing hormone-releasing hormone agonist or polyestradiol phosphate); **AND**
V. Individual has prostate-specific antigen (PSA) level is 5 ng per milliliter or higher with evidence of progressively increasing PSA values (two consecutive increases over the previous reference value) or objective evidence of progression of osseous metastases on imaging studies at time of initiation of Radium Ra 223 dichloride; **AND**
VI. Individual is using in combination with denosumab or zoledronic acid (NCCN Prostate Cancer Guidelines V4.2023); **AND**
VII. No known history or presence of visceral metastatic disease; **AND**
VIII. Individual does not have bulky lymph mode metastases (>3-4 cm); **AND**
IX. Eastern Cooperative Oncology Group (ECOG) performance-status score of 0 to 2; **AND**
X. Individual will not use concurrently with other chemotherapy or biologic therapy (**Note:** this does not include androgen-ablation therapy or other hormonal therapy) for prostate cancer.

Requests for Xofigo (Radium Ra 223 Dichloride) is may **not** be approved for the following (Label, NCCN Prostate Cancer Guideline):

I. Individual has imminent or established spinal cord compression; **OR**
II. Individual is using in combination with Zytiga (abiraterone acetate) plus prednisone/prednisolone; **OR**
III. Individual has received systemic radiotherapy with radioisotopes within the previous 24 weeks; **OR**
IV. Individual was treated with chemotherapy or biologic therapy within the previous 4 weeks; **OR**
V. Used in combination with docetaxel or any other systemic therapy except ADT; **OR**

VI. Individual has received a previous course of Radium Ra 223 dichloride; **OR**
VII. Individual is being treated for a diagnosis other than CRPC; **OR**
VIII. When the above criteria are not met and for all other indications.

Key References:

1. Anderson PM, Subbiah V, Rohren E. Bone-seeking radiopharmaceuticals as targeted agents of osteosarcoma: Samarium-153-EDTMP and Radium-223. Adv Exp Med Biol 2014; 804: 291-304.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 18, 2024.
6. Prostate Cancer. V4.2023. Revised September 7, 2023.
    a. Bone Cancer. V1.2024. Revised August 7, 2023.
7. 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.
8. Xofigo® (radium Ra 223 dichloride) [product information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc. August 2018.