

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Medication	Comments
Xofigo (Radium Ra 223 Dichloride)	N/A

VERRIDE(S)

Prior Authorization of Benefits

APPROVAL DURATION

1 Year

APPROVAL CRITERIA

Xofigo (Radium Ra 223 Dichloride) may be approved for individuals who meet **all** the following criteria:

- I. Age 18 years or older with symptomatic bone metastasis from castrate-resistant prostate cancer (CRPC); **AND**
- II. Planned course of six monthly injections; **AND**
- III. 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**
- IV. 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 Xofigo (Radium Ra 223 dichloride); **AND**
- V. No known history or presence of visceral metastatic disease; **AND**
- VI. Eastern Cooperative Oncology Group (ECOG) performance-status score of 0 to 2; **AND**
- VII. No evidence of imminent or established spinal cord compression; **AND**
- VIII. Has not received systemic radiotherapy with radioisotopes within the previous 24 weeks; **AND**
- IX. Has not been treated with chemotherapy or biologic therapy within the previous 4 weeks; **AND**
- X. Will not be used concurrently with other chemotherapy or biologic therapy (**Note:** this does not include androgen-ablation therapy or other hormonal therapy) for prostate cancer.

Investigational and may not be approved:

Xofigo (Radium Ra 223 Dichloride) is considered **investigational and not be approved** when the above criteria are not met, including but not limited to **any** of the following:

- 1. Has imminent or established spinal cord compression;

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

2. Has received systemic radiotherapy with radioisotopes within the previous 24 weeks;
3. Was treated with chemotherapy or biologic therapy within the previous 4 weeks;
4. Has received a previous course of Radium Ra 223 dichloride;
5. Reason for treatment other than diagnoses of CRPC.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.