| Reference number(s) |
| --- |
| 5717-A |

# Specialty Guideline Management
# Xofigo

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Xofigo | radium Ra 223 dichloride |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications

Xofigo is indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease.

### Compendial Uses

- Prostate Cancer
- Osteosarcoma

All other indications are considered experimental/investigational and not medically necessary.

## Coverage Criteria

### Prostate Cancer

Authorization of 7 months for a total of 6 injections may be granted for treatment of bone metastases for members with castration-resistant prostate cancer when all of the following criteria are met:

- The member has symptomatic bone metastases
- The member does not have visceral metastatic disease
- The member has had a bilateral orchiectomy or will be using the requested medication in combination with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix).

## Osteosarcoma

Authorization of 7 months for a total of 6 injections may be granted for subsequent treatment of osteosarcoma when the member has previously tried at least 2 systemic therapies.

# References

1. Xofigo [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; December 2019.
2. The NCCN Drugs & Biologics Compendium™ © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org Accessed August 12, 2024.
3. 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.