

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 Indications¹

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

Compendial Uses²

- Prostate Cancer
- Osteosarcoma

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

Coverage Criteria

Prostate Cancer^{1,2}

Reference number(s)
5717-A

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^{2,3}

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™ © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org> Accessed August 11, 2025.
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.