Reference number(s)
5717-A

SPECIALTY GUIDELINE MANAGEMENT

XOFIGO (radium Ra 223 dichloride)

POLICY

I. 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.

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

B. Compendial Use
1. Prostate Cancer
2. Osteosarcoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. 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:
1. The member has symptomatic bone metastases
2. The member does not have visceral metastatic disease
3. The member has had a bilateral orchiectomy or will be using the requested medication in combination with a GnRH agonist or degarelix.

B. 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.

III. REFERENCES

1. Xofigo [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; December 2019.
2. The NCCN Drugs & Biologics Compendium™ © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org Accessed August 10, 2023.
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.