

# Xofigo Policy

## Purpose

To describe the CVS Radiation Oncology External Policy for Xofigo.

## Scope

The scope of this document applies to CVS Health clients who have signed up for the CVS Radiation Oncology program under CVS Health Solutions. This document includes the external policy details for the Xofigo policy.

## Policy

Radium Ra 223 Dichloride (Xofigo) Policy

### Criteria for Initial Approval

#### A. *Prostate Cancer*

CVS Health considers a total of 6 injections of radium Ra 223 dichloride (Xofigo) medically necessary 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; and
2. The member does not have visceral metastatic disease; and
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*

CVS Health considers a total of 6 injections of radium Ra 223 dichloride (Xofigo) medically necessary for subsequent treatment of osteosarcoma when the member has previously tried at least 2 systemic therapies.

CVS Health considers all other indications as experimental and investigational (for additional information, see Experimental and Investigational and Background sections).

### Continuation of Therapy

See Dosage and Administration information.

## Procedure

### Dosage and Administration

Xofigo (radium Ra 223 dichloride) is available as a single-dose vial at a concentration of 1,100 kBq/mL (30 microcurie/mL) at the reference date with a total radioactivity of 6,600 kBq/vial (178 microcurie/vial) at the reference date.

The recommended dose regimen of Xofigo is 55 kBq (1.49 microcurie) per kg body weight, given at 4-week intervals for 6 injections. Xofigo is to be administered by slow intravenous injection over 1 minute.

**Note:** Safety and efficacy beyond 6 injections with Xofigo have not been studied.

See Full Prescribing Information for calculation of volume to be administered (mL).

Source: Bayer Healthcare, 2019

### Experimental and Investigational

CVS Health considers more than one course (total of 6 injections) of radium Ra 223 dichloride (Xofigo) experimental and investigational because the safety and efficacy of more than one course has not been established.

CVS Health considers the use of radium Ra 223 dichloride (Xofigo) experimental and investigational for the following indications (not an all-inclusive list) because its effectiveness for these indications have not been established:

- Bone metastasis from breast cancer, kidney cancer, lung cancer, paraganglioma, and medulloblastoma
- Breast cancer
- For use in combination with bortezomib for the treatment of multiple myeloma
- For use in combination with docetaxel or any other chemotherapy
- For use in combination with irreversible electroporation for the treatment of prostate cancer bone metastasis
- Osteosarcoma

## References

The Xofigo policy is based on the following references:

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