

**EFFECTIVE DATE:** 1/7/14

**POLICY LAST UPDATED:** 10/29/2013

## OVERVIEW

This policy documents the coverage guidelines for use of Xofigo (Radium-223) for the treatment of symptomatic, metastatic, castration-resistant prostate cancer, (mCRCP). Xofigo is radium RA 223 dichloride, an alpha particle-emitting radioactive therapeutic agent. It binds with minerals in the bone to deliver radiation directly to bone tumors, limiting damage to the surrounding normal tissues.

Xofigo is used to treat patients with prostate cancer that is resistant to medical or surgical treatments that lower testosterone. This condition is otherwise known as metastatic castration-resistant prostate cancer, or mCRPC. Patients should also have symptomatic bone metastases and no known visceral metastatic disease.

## PRIOR AUTHORIZATION

Prior Authorization is required for BlueCHiP for Medicare and recommended for all other commercial products.

## POLICY STATEMENT

Xofigo is considered medically necessary for the treatment of men with symptomatic, metastatic, castration-resistant prostate cancer when all of the medical criteria below is met.

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for applicable radiation therapy benefits.

## MEDICAL CRITERIA

Radium-223, Xofigo is covered when all of the following criteria is met;

- o Diagnosis of metastatic, castration-resistant prostate cancer, (mCRCP); and
- o Symptomatic bone metastasis; and
- o Has progressed despite androgen deprivation (or clinical trial use); and
- o No known visceral metastatic disease; and
- o Failed trial of Docetaxal or contraindication to Docetaxal

## BACKGROUND

Xofigo is radium RA 223 dichloride, an alpha particle-emitting radioactive therapeutic agent. The active component is the alpha particle-emitting isotope radium 223, which mimics calcium and forms complexes with the bone mineral hydroxyapatite at areas of increased bone turnover, such as bone metastases. It binds with minerals in the bone to deliver radiation directly to bone tumors, limiting damage to the surrounding normal tissues.

Xofigo is used to treat patients with prostate cancer that is resistant to medical or surgical treatments that lower testosterone. This condition is otherwise known as metastatic castration-resistant prostate cancer, or mCRPC. Patients should also have symptomatic bone metastases and no known visceral metastatic disease.

Xofigo is given by slow IV injection over one minute. The dose regimen of Xofigo is 50 kBq (1.35 microcurie) per kg body weight, given at four week intervals for six injections. Safety and efficacy beyond six injections with Xofigo have not been studied.

The most common adverse drug reactions ( $\geq 10\%$ ) in patients receiving Xofigo were nausea, diarrhea, vomiting, and peripheral edema. The most common hematologic laboratory abnormalities ( $\geq 10\%$ ) were anemia, lymphocytopenia, leukopenia, thrombocytopenia, and neutropenia.

Bone marrow suppression may occur. Blood counts should be measured prior to treatment initiation and before every dose of Xofigo. Use of Xofigo should be discontinued if hematologic values do not recover within six to eight weeks after the last administration of Xofigo.

The safety and effectiveness of radium Ra 223 dichloride have not been established in conditions other than bone metastases from castration-resistant prostate cancer.

#### **COVERAGE**

Benefits vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable radiation therapy services and services not medically necessary coverage.

#### **CODING**

There is not specific HCPCS code for this drug so claims should be filled with the following unlisted code; A9699: Radiopharmaceutical, therapeutic, not otherwise classified

#### **RELATED POLICIES**

Unlisted Claim Process

#### **PUBLISHED**

Provider Update	Mar 2013
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#### **REFERENCES**

1. Blue Cross Blue Shield Of Alabama: <https://www.bcbsal.org/providers/policies/final/529>.)
2. American Society of Clinical Oncology: <http://www.asco.org/advocacy/fda-approves-xofigo-castration-resistant-prostate-cancer>
3. Aetna: [www.aetna.com/cpb/medical/data/800\\_899/0874.html](http://www.aetna.com/cpb/medical/data/800_899/0874.html)
4. <https://www.bcbsri.com/sites/default/files/polices/UnlistedProcedures.pdf>

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