



EFFECTIVE DATE: 01|10|2014
POLICY LAST UPDATED: 11|20|2018

OVERVIEW

Xofigo (Radium-223) injection is used for the treatment of symptomatic, metastatic, castration-resistant prostate cancer (mCRCP). Xofigo is radium RA 223 dichloride, an alpha particle-emitting radioactive therapeutic agent. This agent has an anti-tumor effect, which occurs due to energy transfer from the radioactive material to nearby cancer cells. 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 who are 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.

MEDICAL CRITERIA

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

- Diagnosis of metastatic, castration-resistant prostate cancer, (mCRCP); and
- Symptomatic bone metastasis; and
- Radium 223 is not used concomitantly with **ANY** cytotoxic chemotherapy agent (e.g., docetaxel, cabazitaxel, mitoxantrone), abiraterone (Zytiga®), or enzalutamide (Xtandi®); and
- Has progressed despite androgen deprivation (or clinical trial use); and
- No known visceral metastatic disease. The dose does not exceed 1 injection every 28 days for 6 injections

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 above are met.

COVERAGE

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

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 who are 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.

Currently there is an ongoing phase VII clinical trial investigating the use of radium-223 in combination with docetaxel for use in treatment of CRPC and bone metastases. Presently there is insufficient published literature to support the safety and efficacy of radium-223 combined with docetaxel in the treatment of individuals with CRPC and bone metastases.

CODING

The HCPC code listed below is covered when the criteria above has been met.

A9606 Radium ra-223 dichloride, therapeutic, per microcurie

RELATED POLICY

Radiopharmaceuticals

PUBLISHED

Provider Update, February 2018

Provider Update, April 2017

Provider Update, July 2016

Provider Update, July 2015

Provider Update, January 2014

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
4. Xofigo (radium chloride ra-223) [package insert]. Bayer HealthCare. Wayne (NJ): May 2013.
5. AHFS Drug Information. Bethesda (MD): American Society of Health-System Pharmacists, Inc; 2015 [cited 2015 Feb 16]. In: STAT! Ref Online Electronic Medical Library [Internet]. Available from: <http://online.statref.com/>.

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