MEDICAL POLICY

POLICY TITLE	**RADIUM RA223 DICHLORIDE (XOFIGO®)**
POLICY NUMBER	**MP-2.180**

Original Issue Date (Created):	**1/1/2014**
Most Recent Review Date (Revised):	**5/15/2020**
Effective Date:	**8/1/2020**

I. POLICY

Radium Ra 223 dichloride (Xofigo®) may be considered **medically necess**ary for treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease.

Note: For patients with late stage metastatic disease (Stage IV), please refer to **MP 2.373** *Step Therapy Treatment in Cancer, Including Treatments for Stage Four, Advanced Metastatic Cancer and Severe Related Health Conditions* for additional guidance.

Policy Guidelines

- Prior to the initial dose, patients should have an absolute neutrophil count ≥1.5 x 10^9/L, platelet count ≥ 100 x 10^9/L, and hemoglobin ≥10g/dL.
- Prior to subsequent doses, patients should have an absolute neutrophil count ≥1 x 10^9/L and platelet count ≥50 x 10^9/L.
- Radium Ra 223 dichloride (Xofigo®) should be discontinued if a delay of 6-8 weeks does not result in return of blood counts to these levels.
- At the present time, except on a clinical trial, radium Ra 223 dichloride (Xofigo®) is not intended to be used in combination with chemotherapy due to potential for additive myelosuppression.

Cross-reference:

MP-2.143 Zoledronic Acid (Reclast® and Zometa®)
MP-2.158 Cabazitaxel (Jevtana®)
MP 2.373 Step Therapy Treatment in Cancer, Including Treatments for Stage Four, Advanced Metastatic Cancer and Severe Related Health Conditions

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO: Refer to FEP Benefit Brochure for information on cancer treatment: https://www.fepblue.org/benefit-plans/benefit-plans-brochures-and-forms

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Note* - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

Note for Medicare Advantage:

"Off-label use of FDA approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen for medically accepted indications may be covered under Medicare if the indications are supported in either one or more Medicare recognized compendia or in peer-reviewed literature. Refer to Medicare Benefit Policy Manual (100-2, Chapter 15, Section 50.4.5- Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen. *http://www.cms.gov/manuals/Downloads/bp102c15.pdf*

III. DESCRIPTION/BACKGROUND TOP

Prostate cancer forms in a gland in the male reproductive system found below the bladder and in front of the rectum. The male sex hormone testosterone stimulates the prostate tumors to grow. According to the National Cancer Institute, it is estimated that there will be 161,360 new cases of prostate cancer and an estimated 26,730 people will die of this disease in 2017.

Radium Ra 223 dichloride Xofigo®) (is a radiopharmaceutical to improve survival in patients with bone metastases from advanced cancer. Radium Ra 223 dichloride Xofigo®) is indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease. "Castrate resistant" means the cancer is still growing despite the fact that hormone therapy (either an orchiectomy or an LHRH agonist or antagonist) is keeping the testosterone in the body at very low, "castrate" levels.

The dose regimen of Radium Ra 223 dichloride (Xofigo®) is 55 kBq (1.49 microcurie) per kg body weight, given at 4-week intervals for 6 injections (intravenously). Safety and efficacy beyond 6 injections with Radium Ra 223 dichloride (Xofigo®) have not been studied. Radium Ra 223 dichloride (Xofigo®) should be received, used, and administered only by authorized persons in designated clinical settings. Radium Ra 223 dichloride (Xofigo®) is usually administered by an approved licensed facility, usually in nuclear medicine or radiation therapy departments. The administration of Radium Ra 223 dichloride (Xofigo®) is associated with potential risks to other persons from radiation or contamination from spills of bodily fluids such as urine, feces, or vomit. Therefore, radiation protection precautions must be taken in accordance with national and local regulations.

The most common adverse drug reactions (≥ 10%) in patients receiving Radium Ra 223 dichloride (Xofigo®) were nausea, diarrhea, vomiting, and peripheral edema. The most common hematologic laboratory abnormalities (≥ 10%) were anemia, lymphocytopenia, leukopenia, thrombocytopenia, and neutropenia. Radium Ra 223 dichloride (Xofigo®) is contraindicated in women who are or may become pregnant. Radium Ra 223 dichloride (Xofigo®) can cause fetal harm when administered to a pregnant woman. The safety and efficacy of Radium Ra 223 dichloride (Xofigo®) in pediatric patients have not been established.

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At the present time, except on a clinical trial, Radium Ra 223 dichloride (Xofigo®) is not intended to be used in combination with chemotherapy due to potential for additive myelosuppression. If chemotherapy, other systemic radioisotopes or hemibody external radiotherapy are administered during the treatment period, Radium Ra 223 dichloride (Xofigo®) should be discontinued.

IV. RATIONALE

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For information on clinical studies for Radium Ra 223 dichloride (Xofigo®), refer to Prescribing Information.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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Covered when medically necessary:

CPT Code							
79101							

HCPCS Code	Description
A9606	Radium RA-223 dichloride, therapeutic, per microcurie

ICD-10-CM Diagnosis Codes	Description
C61	Malignant neoplasm of prostate
C79.51	Secondary malignant neoplasm of bone

IX. REFERENCES

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1. *American Cancer Society. Hormone Therapy for Prostate Cancer. Revised July 18, 2018 [Website]: http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-treating-hormone-therapy Accessed May 15, 2020.*
2. *Centers for Medicare and Medicaid Services (CMS) Medicare Benefit Policy Manual. Publication 100-02. Chapter 15. Section 50.4.5. Off-Label Use of Anti-Cancer Drugs and Biologicals. [Website]: http://www.cms.gov/manuals/Downloads/bp102c15.pdf . Accessed May 15, 2020.*
3. *Centers for Medicare and Medicaid Services (CMS) Medicare Benefit Policy Manual. Publication 100-02. Chapter 15. Sections 50, 50.4.1, 50.4.3. Drugs and Biologicals. Effective 06/08/12. [Website]: http://www.cms.gov/manuals/Downloads/bp102c15.pdf. Accessed May 22, 2019.*
4. *FDA News Release. FDA approves new drug for advanced prostate cancer. May 15, 2013. [Website]: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm352363.htm. Last accessed July 31, 2015.*
5. *National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Prostate Cancer (V.2.2019). [Website]: http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed May 15, 2020.*
6. *National Cancer Institute. Cancer Stat Facts: Prostate Cancer. [Website]: https://seer.cancer.gov/statfacts/html/prost.html. Accessed May 15, 2020.*
7. *Oliver Sartor, A. Bone metastases in advanced prostate cancer: Management. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated May 5, 2020. [Website]: www.uptodate.com. Accessed May 15, 2020.*
8. *XOFIGO prescribing information. Revised 8/ 2018. [Website]: https://www.xofigo-us.com/index.php?utm_source=google&utm_medium=cpc&utm_campaign=Xofigo-Brand_Branded_Patient_%3BS%3BPH%3BBR%3BONC%3BDTC%3BBR&utm_content=Brand+%7C+General+Info+-*

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+Exact&utm_term=Xofigo+prescribing+information&matchtype=e&device=c&adposition=1t1&loc=9006662&gclid=EAIaIQobChMI1qnqyuSv4gIVxJ6zCh3b3ArgEAAYASAAEgK7-_D_BwE&gclsrc=aw.ds. Accessed May 15, 2020.

X. POLICY HISTORY

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MP 2.180	**CAC 9/24/13 New policy**. Radium Ra 223 dichloride (Xofigo®) was FDA approved in May 2013 for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease. Policy coded.
	CAC 9/30/14 Consensus review. References updated. No changes to the policy statements.
	CAC 9/29/15 Consensus review. No change to policy statements. References reviewed. Coding reviewed and updated.
	CAC 9/27/2016 Consensus review. No change to policy statements. References reviewed. Coding reviewed. Variation reformatting.
	CAC 11/28/17 Consensus review. Policy statement unchanged. Lab value criteria within the Policy Guidelines section updated to align with prescribing information. Cross-Reference, Description/Background, Rationale and Reference sections updated. Coding reviewed.
	8/10/18 Consensus review. No change to policy statements. References reviewed. Rationale condensed.
	5/22/19 Consensus review. No change to policy statements. References updated.
	4/10/20 Admin update. Added note for patients with late stage metastatic disease (Stage IV), please refer to MP 2.373 Step Therapy Treatment in Cancer, Including Treatments for Stage Four, Advanced Metastatic Cancer and Severe Related Health Conditions for additional guidance.
	5/15/2020- Consensus review. Policy statement unchanged. References, product variation, benefit variation, and disclaimer updated. Coding reviewed.

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