

Xofigo® (radium Ra 223 dichloride) for Treatment of Castration-Resistant Prostate Cancer

Policy Number: **M20200508036**
 Effective Date: **7/1/2020**
 Sponsoring Department: **Health Care Services**
 Impacted Department(s): **Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐ Confidential ☐ Restricted ☒ Public

Applies to (Line of Business):

- ☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒ MediSource; ☒ MediSource Connect; ☐ Child Health Plus; ☒ Essential Plan
☒ Medicare, if yes, which plan(s): ☒ MAPD; ☐ PDP; ☒ ISNP; ☒ CSNP
☒ Commercial, if yes, which type: ☒ Large Group; ☒ Small Group; ☒ Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No ☒

Purpose and Applicability:

To set forth Independent Health's criteria for **Xofigo®** for the treatment of patients with **castration-resistant prostate cancer (CRPC)**.

Policy:

Commercial, Self-Funded and Medicare Advantage:

Xofigo® is considered medical necessary when ALL of the criteria below are met:

- Patient is 18 years or older; AND
- Must be prescribed by hematologist/oncologist or radiation oncologist; AND

- Medical record documentation provided of castration-resistant prostate cancer with symptomatic bone metastases and no known **visceral metastatic disease**.

Dosage:

- 55 kBq (1.49 microcurie) per kg body weight, given at 4-week intervals for 6 injections.
- Coverage will be provided for six months (6 injections only) and may NOT be renewed.

MediSource, MediSource Connect, Essential Plan

MediSource, MediSource Connect and Essential Plan cover Xofigo® for CRPC utilizing the criteria above.

Background:

Prostate cancer is the most commonly diagnosed solid organ malignancy in US men and remains the second leading cause of cancer deaths for this population. Prostate cancer may be cured when localized, and it frequently responds to treatment when widespread. The approach to treatment is influenced by age and coexisting medical problems. Primary therapy for localized disease consists of either surgical resection or radiation therapy, however, for patients with recurrent or metastatic prostate cancer, treatment consists of androgen deprivation therapy through depletion or blockage of circulating androgens. While initially effective, most men develop castration resistant prostate cancer (CRPC).

The U.S. Food and Drug Administration (FDA) approved radium-223 dichloride, an alpha particle-emitting radioactive agent in May 2013. This first-in-class radiopharmaceutical was approved for treatment of metastatic CRPC in patients with symptomatic bone metastases and no known visceral metastatic disease.

According to the National Comprehensive Cancer Network (NCCN) Radium-223 is administered intravenously once a month for 6 months by an appropriately licensed facility, usually in nuclear medicine or radiation therapy departments. Radium-223 is not intended to be used in combination with chemotherapy due to the potential for additive myelosuppression, except in a clinical trial. Radium-223 is not recommended for use in combination with docetaxel or any other systemic therapy except androgen deprivation therapy (ADT).

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☒ No ☐

Pre-authorization is required for this service.

Definitions

Castration resistance prostate cancer (CRPC) is an advanced prostate cancer which progressed while receiving androgen deprivation therapy (ADT), a first line treatment.

Visceral metastatic disease refers to liver, lung, adrenal, peritoneal, and brain metastases. Soft tissue/lymph node sites are not considered visceral metastases.

Xofigo® is an alpha particle-emitting radioactive therapeutic agent indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral

metastatic disease. The dose regimen of Xofigo is 50 kBq (1.35 microcurie) per kg body weight, given at 4-week intervals for 6 injections.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

Dawson NA, Leger P. Overview of the treatment of castration-resistant prostate cancer (CRPC). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed on April 5, 2024.

Den RB, Doyle LA, Knudsen KE. Practical guide to the use of radium 223 dichloride. Can J Urol. 2014 Apr;21(2 Supp 1):70-6.

Lowrance WT, Breau RH, Chou R, et al. Advanced Prostate Cancer: AUA/ASTRO/SUO Guideline PART I. J Urol. 2021 Jan;205(1):14-21.

Lowrance WT, Breau RH, Chou R, et al. Advanced Prostate Cancer: AUA/ASTRO/SUO Guideline PART II. J Urol. 2021 Jan;205(1):22-29.

National Cancer Institute (NIH) [web site]. Prostate Cancer Treatment (PDQ®)—Health Professional Version. Updated:03/11/2024 . Available at: <https://www.cancer.gov/types/prostate/hp/prostate-treatment-pdq#link/2584> Accessed April 12, 2023.

National Comprehensive Cancer Network (NCCN) [web site]. NCCN Guidelines Version 3.2024 — March 8, 2024 Prostate Cancer. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf Accessed April 3, 2024.

Parker C, Nilsson S, Heinrich D, et al. Alpha emitter radium-223 and survival in metastatic prostate cancer. N Engl J Med. 2013 Jul 18; 369(3):213-22.

Sartor Ao, DiBiase SJ. Bone metastases in advanced prostate cancer: Management. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed on April 3, 2024.

Regulatory References

New York State Department of Health [web site]. New York State Medicaid Program Ordered Ambulatory Procedure Codes. April 2024 . Available at: https://www.emedny.org/ProviderManuals/OrderedAmbulatory/PDFS/OrderedAmbulatory_Procedure_Codes.pdf Accessed April 3, 2024.

United States Food and Drug Administration (FDA) [web site]. New Drug Approval Label Xofigo. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/203971lbl.pdf Accessed April 4, 2024.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

Revision Date	Owner	Notes
6/1/2024	Health Care Services	Reviewed
1/1/2024	Health Care Services	Revised
6/1/2023	Health Care Services	Reviewed
6/1/2022	Health Care Services	Reviewed
6/1/2021	Health Care Services	Reviewed