Scott&White HEALTH PLAN
PART OF BAYLOR SCOTT & WHITE HEALTH

MEDICAL COVERAGE POLICY	
SERVICE:	**Xofigo**
Policy Number:	**212**
Effective Date:	**07/01/2019**
Last Review:	**04/25/2019**
Next Review Date:	**04/25/2020**

Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website.

SERVICE: Xofigo

PRIOR AUTHORIZATION: Required. This policy provides guidelines for medical review when that review is NOT performed by vendor Oncology Analytics.

POLICY: Administration of Xofigo may be considered medically necessary for the treatment of prostate cancer when **ALL** of the following criteria are met:

1. Patients have castration resistant prostate cancer;
2. Patients have symptomatic bone metastases;
3. Patients have no known visceral metastatic disease.

FDA prescribing information states Xofigo is to be given at 4 week intervals for a total of 6 injections. The use of non-FDA-approved dosing of Xofigo is considered experimental and investigational.

SWHP considers the use of Xofigo experimental and investigational for breast cancer, breast cancer bone metastasis, and osteosarcoma, and for use in combination with docetaxel or any other chemotherapy because its effectiveness for indications other than the one listed above has not been established.

SWHP considers the use of Xofigo not medically necessary for members who have experienced disease progression while on Xofigo.

OVERVIEW:

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 simulates calcium and forms complexes with the bone mineral hydroxyapatite areas of increased bone turnover, as often seen in bone metastases. It thus delivers 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 standard medical or surgical treatments. This is referred to as metastatic castration-resistant prostate cancer, or mCRPC.

Patients receiving this therapy should also have symptomatic bone metastases but no known visceral metastatic disease.

MANDATES: none

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CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	
ICD10 codes:	
HCPCS:	A9606

CMS: HCPCS code A9606 is covered by CMS MAC Novitas

POLICY HISTORY:

Status	Date	Action
New	2/12/2015	New policy
Reviewed	2/04/2016	No changes
Reviewed	3/28/2017	Updated criteria
Reviewed	2/27/2018	Removed PA requirement
Reviewed	2/25/2019	PA requirement added

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. C. Parker, et al.; Alpha Emitter Radium-223 and Survival in Metastatic Prostate Cancer; N Engl J Med 2013; 369:213-223July 18, 2013DOI: 10.1056/NEJMoa1213755
2. Food & Drug Administration; Radium-223Labeling; https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/203971lbl.pdf