Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Radium Ra-223 dichloride (Xofigo®)

Policy Number: PG0328
Last Review: 12/01/2023

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
X Facility

DESCRIPTION:

Prostate cancer (PC) is the most common cancer in men and the second leading cause of cancer death in men. The annual incidence in the United States is approximately 242,000. Castration-resistant prostate cancer (CRPC) is defined by rising levels of prostate-specific antigen (PSA) in spite of androgen deprivation therapy and castrate levels of serum testosterone. The overall survival (OS) of men with CRPC is approximately 18 months after treatment with the first-line agent, Taxotere (docetaxel). Late-stage PC commonly metastasizes to the bone, particularly the vertebrae, pelvis, ribs, and skull. Metastases can structurally compromise bones and lead to skeletal-related events (SREs) such as fractures, spinal cord compression, and other neurologic symptoms associated with vertebral fractures, pain, hypercalcemia, decreased quality of life, need for orthopedic surgical intervention, need for analgesics including strong opioids, and pancytopenia related to radiotherapy for SREs. Increases in PSA and markers of bone turnover, such as alkaline phosphatase (ALP), correlate with SREs and OS. Available treatments for bony metastases include external beam radiotherapy (EBRT), bisphosphonates, Prolia (denosumab), and beta-emitting radioisotopes. These may relieve pain or delay SREs but have not been shown to prolong OS.

Radium Ra-223 dichloride (Xofigo®) injection (Bayer HealthCare Pharmaceuticals Inc.) is intended for the treatment of patients with castrate-resistant prostate cancer (CRPC) with symptomatic bone metastases, and no visceral metastases. It is an alpha particle-emitting radioactive therapeutic agent that targets bone metastases by selectively binding to areas of bone-repairing activity, causing double-stranded breaks in DNA, but minimizing the effect on adjacent, healthy tissue. Xofigo is administered by slow intravenous injection over 1 minute and patients receive 6 injections of 50 kilobecquerels per kilogram (kBq/kg), given at 4-week intervals. Radiation protection measures are necessary. Treatment is administered on an outpatient basis by a physician, typically a nuclear medicine physician, who is approved and listed on the provider's Radioactive Materials (RAM) License for therapeutic use of radium Ra 223 dichloride with assistance from certified nuclear medicine or radiation oncology staff.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- **Radium Ra-223 dichloride (Xofigo®) (A9606) does not require prior authorization for all product lines when the coverage criteria below is met.**

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Radium Ra-223 dichloride (Xofigo®) (A9606) may be considered medically necessary when All of the following criteria are met:

- The member has metastatic (stage IV) castration-resistant prostate cancer (CRPC)
- The member has symptomatic bone metastases
- The member has no known visceral metastatic disease (e.g., brain, liver, lung, adrenal gland, or peritoneum), or bulky lymph node metastases (>3 to 4cm)
- The member has prostate-specific antigen (PSA) level is 5 ng per milliliter or higher with evidence of progressively increasing PSA values (two consecutive increases over the previous reference value) or objective evidence of progression of osseous metastases on imaging studies at time of initiation of Radium Ra 223 dichloride
- Radium 223 will not be used concomitantly with ANY of the following:
    a. abiraterone (Zytiga, Yonsa)
    b. apalutamide (Erleada)
    c. cytotoxic chemotherapy agents (e.g., docetaxel, cabazitaxel, mitoxantrone) *
    d. darolutamide (Nubeqa)
    e. enzalutamide (Xtandi)
- The dosage does not exceed 1 injection of 55 kBq/kg (1.49 microcurie) every 28 days for 6 total injections
- The member has not received more than 5 doses of radium 223 treatment in their lifetime

*Androgen deprivation therapy (e.g., leuprolide, degarelix), denosumab, or zoledronic acid are not considered cytotoxic chemotherapy; concomitant use is permitted.

The recommended dose and schedule for Radium Ra-223 dichloride (Xofigo®) is 55 kBq/kg (1.49 microcuries/kg) administered by slow intravenous injection over 1 minute every 4 weeks for 6 doses. 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 an authorized person in a designated clinical setting.

The quantity limit for a single-use vial containing 6 mL of solution at a concentration of 1,100 kBq/mL of Radium Ra-223 dichloride (Xofigo®) is 1 vial per 28 days.

Coverage Limitations

Radium Ra-223 dichloride (Xofigo®) therapy is not considered medically necessary for members with the following concomitant conditions:

- Member has imminent or established spinal cord compression
- Used in combination with Zytiga (abiraterone acetate) plus prednisone/prednisolone
- Member has received systemic radiotherapy with radioisotopes within the previous 24 weeks
- Member was treated with chemotherapy or biologic therapy within the previous 4 weeks
- Used in combination with docetaxel or any other systemic therapy except androgen deprivation therapy (ADT)
- Member has received a previous course of Radium Ra 223 dichloride
- Member being treated for a diagnosis other than CRPC
- Members who have experienced disease progression on Radium Ra-223 dichloride (Xofigo®)
- Concomitant Xtandi (enzalutimide) or Zytiga (abiraterone acetate) is not recommended at this time due to lack of evidence supporting safe and effective use
- When the above criteria are not met and for all other indications

CODING/BILLING INFORMATION:
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

HCPCS CODE	
A9606	Radium Ra-223 dichloride, therapeutic, per microcurie
CPT CODE	
79101	Radiopharmaceutical therapy, by intravenous administration [when specified as injection of Xofigo]
ICD-10 CODES	
C61	Malignant neoplasm of prostate
AND at least one of the following:	
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 03/19/2015

Date	Explanation & Changes
03/19/2015	• Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
03/13/2018	• Effective 11/1/17 Radium Ra-223 dichloride (Xofigo®) (A9606) is now covered without prior authorization for Advantage per ODM guidelines • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
12/21/2020	• Medical policy placed on the new Paramount Medical Policy Format
02/22/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
12/01/2023	• Medical Policy reviewed and updated to reflect the most current clinical evidence

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review