Radium-223 (Xofigo®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 10/4/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of radium-223. Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendation), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1]

The active moiety of radium-223 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. The high linear energy transfer of alpha particles (80 keV/micrometer) leads to a high frequency of double-strand DNA breaks in adjacent cells including tumor cells, osteoblasts and osteoclasts, resulting in an anti-tumor effect on bone metastases. The alpha particle range from radium-223 dichloride is less than 100 micrometers (less than 10 cell diameters) which limits damage to the surrounding normal tissue.

FDA Indications[1]

Radium-223 is FDA indicated for the following:

- Treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease.

Coverage Determinations[1,2]

Radium-223 will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met:

Castration-Resistant Prostate Cancer

- The member has a diagnosis of progressive castrate-resistant prostate cancer **AND**
- The member has metastatic disease with:
  - Symptomatic bone metastases **AND**
  - No known visceral metastases **AND**
- Radium-223 will be used as monotherapy

Recommended dosage: 55 kBq/kg IV every 4 weeks for 6 injections

All indications:

- Radium-223 will be determined through clinical review for up to a 6-month duration.

Coverage Limitations

Treatment with radium-223 is not considered medically necessary for members with the following concomitant conditions:

- The member has experienced disease progression on radium-223.
- The member will use radium-223 in combination with abiraterone acetate/prednisone or enzalutamide.
- The member is receiving concomitant chemotherapy
- The member has known visceral metastases
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- There are no contraindications listed in the US manufacturer's labeling.
- Warnings/Precautions:
  - Bone Marrow Suppression
  - Increased Fractures and Mortality in Combination with Abiraterone plus Prednisone/Prednisolone
  - Embryo-Fetal Toxicity

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- Description: inj., radium-223, 1 kBq
  - HCPCS: A9606

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

1. Xofigo® [package insert]. Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ. Available at: http://labeling.bayerhealthcare.com/html/products/pi/Xofigo_PI.pdf
2. Radium-223. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
3. Hoskin P, Sartor O, O'Sullivan JM, et al. Efficacy and safety of radium-223 dichloride in patients with castration-resistant prostate cancer and symptomatic bone metastases, with or without previous docetaxel use: a prespecified subgroup analysis from the randomised, double-blind, phase 3 ALSYMPCA trial. Lancet Oncol. 2014;15:1397–1406. DOI: 10.1016/S1470-2045(14)70474-7.
4. 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):213-223. DOI: 10.1056/NEJMoa1213755.
5. Sartor O, Coleman R, Nilsson S, et al. Effect of radium-223 dichloride on symptomatic skeletal events in patients with castration-resistant prostate cancer and bone metastases: results from a phase 3, double-blind, randomised trial. Lancet Oncol. 2014 Jun;15:738–746. DOI: 10.1016/S1470-2045(14)70183-4.