Medical Policy:

Xofigo for castration-resistant prostate cancer (radium ra 223 dichloride) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.199	January 2, 2025	January 12, 2017

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Xofigo® (radium Ra 223 dichloride injection) — an alpha particle-emitting radioactive therapeutic agent that is administered intravenously at four-week intervals for six months.

Length of Authorization

Coverage will be provided for 6 months (6 injections only) and may NOT be renewed.

Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

• 178 billable units every 28 days

Guideline

1. Prostate Cancer †

Members are eligible for coverage of Xofigo when the following criteria are met; **all**:

A. Patient is at least 18 years of age; **AND**

B. Patient has castration-resistant disease; **AND**

C. Patient has symptomatic bone metastases; **AND**

D. Patient does not have any known visceral metastatic disease; **AND**

E. Must be used as a single agent

Limitations/Exclusions

Preauthorization is required

Xofigo is not considered medically necessary when:

1. More than six injections are administered
2. Concurrent chemotherapy with Xofigo is considered experimental, investigational

Applicable Procedure Codes

Code	Description
A9606	Radium ra-223 dichloride, therapeutic, per microcurie
79101	Radiopharmaceutical therapy, by intravenous administration

Applicable NDCs

Code	Description
50419-0208-01	Radium ra 223 dichloride 30 uci/1mL

ICD-10 Diagnoses

Code	Description
C61	Malignant neoplasm of prostate
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2025	Annual Review: Updated length of authorization and dosing limits
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Initial Criteria: Removed: “Skeletal bone metastases A. No evidence of visceral metastases or bulky regional lymph nodes > 3 cm on imaging performed within the last 30 days B. Member has received and exhausted all medical or surgical-ablative hormonal treatments. The member may be kept on ablative treatment to maintain a castrate level in accordance with NCCN® guidelines

		C. Medically or surgically castration-resistant prostate cancer, as defined by: a. Serum testosterone level < 50 ng/dl and either: i. Sequential rise of prostate specific antigen (PSA) ii. Worsening of existing bone metastases or development of new bone metastases on a bone scan performed within the past 60 days despite androgen-deprivation treatment" Replaced with "Patient is at least 18 years of age; **AND** Patient has castration-resistant disease; **AND** Patient has symptomatic bone metastases; **AND** Patient does not have any known visceral metastatic disease; **AND** Must be used as a single agent"
EmblemHealth & ConnectiCare	3/14/2023	Annual Review: No revisions
EmblemHealth & ConnectiCare	1/18/2023	Transfer to New Template, added NDC code
EmblemHealth & ConnectiCare	12/30/2020	Annual review: no policy changes.
EmblemHealth & ConnectiCare	10/08/2019	Changed MP # from MG.MM.RA.07 to MG.MM.PH.199
EmblemHealth & ConnectiCare	1/12/2017	Added coverage allowance for positive lymph nodes

References

1. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 2. 2017: http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 2019.
2. Xofigo (radium Ra 223 dichloride) package insert. Bayer HealthCare Pharmaceuticals, Inc., Wayne, NJ. May 2017
3. http://labeling.bayerhealthcare.com/html/products/pi/Xofigo_PI.pdf. Accessed December, 2019.
Specialty-matched clinical peer review.