

Xofigo Radioactive Therapeutic Agent

Policy Number	XOF02262014RP	Approved By	UnitedHealthcare Medicare Reimbursement Policy Committee	Current Approval Date	02/26/2014
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IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies use Current Procedural Terminology (CPT®*), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy. This information is intended to serve only as a general resource regarding UnitedHealthcare's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee's benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the

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provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. CPT codes and descriptions are copyright 2010 American Medical Association (or such other date of publication of CPT). All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to Government use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Current Dental Terminology (CDT), including procedure codes, nomenclature, descriptors, and other data contained therein, is copyright by the American Dental Association, 2002, 2004. All rights reserved. CDT is a registered trademark of the American Dental Association. Applicable FARS/DFARS apply.

Summary

Overview

Xofigo® (radium Ra 223 dichloride) injection is an alpha particle-emitting radioactive therapeutic agent indicated for the treatment of patients with castration-resistant prostate cancer (CRPC), 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. Safety and efficacy beyond 6 injections with Xofigo have not been studied.

Safety and efficacy of concomitant chemotherapy with Xofigo have not been established. Outside of a clinical trial, concomitant use of Xofigo in patients on chemotherapy is not recommended due to the potential for additive myelosuppression. If chemotherapy, other systemic radioisotopes, or hemibody external radiotherapy are administered during the treatment period, Xofigo should be discontinued. Xofigo is contraindicated in women who are or may become pregnant. Xofigo can cause fetal harm when administered to a pregnant woman. Xofigo® was approved by the FDA on May 15, 2013.

Reimbursement Guidelines

For dates of service immediate post-FDA approval (beginning May 15, 2013), hospital outpatient departments should bill Medicare for Radium Ra-223, using HCPCS code C9399 Unclassified drugs or biological for Xofigo® as it is a new FDA approved therapeutic radiopharmaceutical without a more specific HCPCS code. The appropriate unit of measure for an unlisted code is one unit. When using HCPCS code C9399, include NDC #50419-0208-01 for Xofigo®, on the claim form so that the payer can identify the therapeutic radiopharmaceutical.

As noted in Transmittal 2718 Change Request 8338 published on June 7, 2013 CMS will pay for therapeutic radiopharmaceuticals at 95 percent of the published average wholesale price (AWP) until average sale price (ASP) data is available and updated by CMS in their quarterly OPPS files.

CPT/HCPCS Codes

Code	Description
C9399	Unclassified drugs or biological
A9699	Radiopharmaceutical, therapeutic, not otherwise classified
79101	Radiopharmaceutical therapy by IV administration

References Included (but not limited to):

CMS LCD(s)

Numerous LCDs

CMS Transmittals

Transmittal 2718, Change Request 8338, Dated 06/07/2013 (July 2013 Update of the Hospital Outpatient Prospective Payment System (OPPS))

UnitedHealthcare Medicare Advantage Coverage Summaries

Chemotherapy, and Associated Drugs and Treatments

Others

National Government Services Medicare Monthly Review, December 2013, Xofigo, Page 5, National

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Government Services Website

Palmetto GBA Jurisdiction 11, Part A: How Should I Submit Medicare Claims For Radium Ra-223?, Palmetto Website

Xofigo Package Insert, Bayer Healthcare Pharmaceuticals Website

Xofigo Reimbursement Informatin and Support, Xofigo Website

History

Date	Revisions
09/08/2014	Liability references removed
02/26/2014	New Policy