XOFIGO® RADIOACTIVE THERAPEUTIC AGENT

Guideline Number: MPG356.04
Approval Date: February 13, 2019

PAGES

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POLICY 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 given at 4 week intervals for 6 injections. Safety and efficacy beyond 6 injections with Xofigo have not been studied.

According to Bayer Healthcare (2017), safety and efficacy of simultaneous chemotherapy with Xofigo have not been established. Outside of a clinical trial, simultaneous 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 same 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.

Guidelines
CMS has assigned a product-specific HCPCS code for Xofigo, A9606 (Radium ra-223 dichloride, therapeutic, per microcurie), effective January 1, 2015. Providers must purchase Xofigo and bill payers based on the number of microcuries administered to each patient; CMS will reimburse per microcurie billed. The recommended dose and schedule for Xofigo® is 55 kBq/kg (1.49 microcuries/kg) administered by slow intravenous injection over 1 minute every 4 weeks for 6 doses.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>79101</td>
<td>Radiopharmaceutical therapy, by intravenous administration</td>
</tr>
</tbody>
</table>

CPT® is a registered trademark of the American Medical Association

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>A9606</td>
<td>Radium RA-223 dichloride, therapeutic, per microcurie</td>
</tr>
</tbody>
</table>
**ICD-10 Diagnosis Code** | **Description**
---|---
C61 | Malignant neoplasm of prostate

**AND at least one of the following:**

<table>
<thead>
<tr>
<th>ICD-10 Diagnosis Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C79.51</td>
<td>Secondary malignant neoplasm of bone</td>
</tr>
<tr>
<td>C79.52</td>
<td>Secondary malignant neoplasm of bone marrow</td>
</tr>
</tbody>
</table>

**PURPOSE**

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the **REFERENCES** section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

**REFERENCES**

**CMS Local Coverage Determinations (LCDs)**

<table>
<thead>
<tr>
<th>LCD</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
</tr>
</thead>
<tbody>
<tr>
<td>L37205 (Chemotherapy Drugs and their Adjuncts) WPS</td>
<td>AK, AL, AR, AZ, CT, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, OH, OR, RI, SC, SD, TN, UT, VA, VI, VT, WA, WI, WV, WY</td>
<td>IA, IN, KS, MI, MO, NE</td>
</tr>
</tbody>
</table>

**CMS Articles**

<table>
<thead>
<tr>
<th>Article</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
</tr>
</thead>
<tbody>
<tr>
<td>A54559 (Xofigo Billing Instructions) Palmetto</td>
<td>AL, GA, NC, SC, TN, VA, WV</td>
<td>AL, GA, NC, SC, TN, VA, WV</td>
</tr>
</tbody>
</table>

**CMS Benefit Policy Manual**

- Chapter 15; § 50 Drugs and Biologicals

**CMS Claims Processing Manual**

- Chapter 12; § 30.5 Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions
- Chapter 14; § 10 General Ambulatory Surgical Center
- Chapter 17; § 90.2 Drugs, Biologicals, and Radiopharmaceuticals

**UnitedHealthcare Commercial Policies**

- Therapeutic Radiopharmaceuticals

**Others**

- CMS HCPCS Codes for which ASP Reporting is in Units of Measure Other Than an NDC, Updated May 10, 2018, CMS Website
- CMS Medicare Hospital Outpatient PPS Addendum A and B Updates, CMS Website
- CMS Medicare Hospital Outpatient PPS Addendum B Update:HCPCS code A9606, January 2019
- Coverage, Coding, & Billing for Xofigo® (radium Ra 223 dichloride) Injection Effective January 1, 2015, Xofigo Website
- Xofigo Package Insert, Bayer Healthcare Pharmaceuticals Website

**GUIDELINE HISTORY/REVISION INFORMATION**

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>02/13/2019</td>
<td>• Annual review for MAPG Committee presentation and approval</td>
</tr>
</tbody>
</table>
TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines 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 or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.