

# November 25, 2014: Bayer Releases New Reimbursement Information About Xofigo®

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## **Bayer Releases New Reimbursement Information About Xofigo® (radium Ra 223 dichloride)**

CMS has assigned a product-specific HCPCS code for Xofigo, A9606 (Radium ra-223 dichloride, therapeutic, per microcurie),<sup>1</sup> effective January 1, 2015.

1. The new code is mandated by CMS and will facilitate automated billing and reimbursement.\*

2. **Changes in Purchasing, Billing, and Reimbursement:** Currently, providers are purchasing and getting reimbursed for Xofigo's flat-priced, patient-ready dose (PRD). Under the new CMS-mandated microcurie A-code, A9606, providers will have to purchase Xofigo and bill payers based on the number of microcuries administered to each patient, rather than a PRD. Payers will reimburse providers per microcurie billed.

3. **Change in Wholesale Acquisition Cost (WAC):** To accommodate the transition from PRD to per microcurie billing and reimbursement, the WAC for the Xofigo vial, NDC 50419-208-01, will be \$18,439, effective January 1, 2015. This WAC, expressed on a per microcurie basis, is \$113.82. We understand that the standard methodology used by the compendia to suggest an average wholesale price (AWP) is to take the applicable WAC and multiply that amount by 1.2. Following that formula, established by the pricing compendia, a suggested AWP for Xofigo on a per microcurie basis would be \$113.82 x 1.2, or \$136.58.

4. **The Cost of Treating an Average –Weight Xofigo Patient Will Not Change Under New Methodology:** Consistent with the new code, Cardinal Health will begin charging \$113.82 per microcurie instead of \$12,362 for a PRD, effective January 1, 2015. This will result in a higher or lower acquisition cost based on a given patient's weight; **however, the cost for an average-weight (80 kg) Xofigo patient will be equal to the flat-priced PRD, as illustrated below.**

<b>Quick Reference Summary</b> <small>Note: some numbers in chart are rounded to simplify math</small>	<b>For Dates of Services Through 12/31/14</b>	<b>For Dates of Service On or After 1/1/15</b>
HCPCS code(s)	C9399 (Medicare HOPD), A9699	A9606, Radium ra-223 dichloride, therapeutic, per microcurie
Provider acquisition	Flat price per PRD (independent of patient weight or microcuries)	Individualized price per microcurie (dependent on patient weight)

Provider billing unit	One unit	Number of microcuries
Medicare reimbursement (OPPS)	95% AWP	ASP-based payment limit (or APC payment limit)
Medicare reimbursement (physician office/freestanding center)	AWP, invoice, or other methods used by MACs	AWP, invoice, or other methods used by MACs
Commercial reimbursement payer	Per unit	Per microcurie
Total dose (in microcuries) for average-weight Xofigo patient	108 $\mu\text{Ci}$ <sup>1</sup> (ie, 80 kg x 1.35 $\mu\text{Ci/kg}$ )	108 $\mu\text{Ci}$ <sup>a</sup> (ie, 80 kg x 1.35 $\mu\text{Ci/kg}$ )
Xofigo WAC	\$12,362/PRD	\$18,439/162 $\mu\text{Ci}$ vial <sup>b</sup> (NDC 50419-208-01 <sup>c</sup> )
Cost per microcurie (PRD vs NDC vial)	\$113.82 [ $\$12,362 \div 108 \mu\text{Ci}$ ]	\$113.82 ( $\$18,439 \div 162 \mu\text{Ci}$ vial)
<b>Cost per dose for 80 kg patient</b>	<b>\$12,362 per PRD</b>	<b>\$12,362 (per 108 <math>\mu\text{Ci}</math> PRD)</b>

<sup>a</sup>Total dose (in microcuries) for an average-weight patient of 80 kg based on a dosage of 1.35 microcurie (50kBq) per kilogram body weight. A full course of treatment consists of 6 injections given at 4-week intervals.

<sup>b</sup>The Xofigo WAC was adjusted to ensure that costs and reimbursement for an average-weight person do not change when transitioning from a flat-priced WAC per PRD to a WAC per vial. Xofigo is supplied in 6 mL vials and has a concentration of 27 microcuries per mL for a total of 162 microcuries at the reference date. However, it is only available commercially in a PRD based on the patient's weight. The WAC per vial can be used to determine the price per microcurie, and the PRD costs for an average-weight person.

<sup>c</sup>Please note: if a particular payer or electronic claims reporting software requires the NDC to be entered in the 11-digit format, a leading zero must be entered in front of the second segment of numbers, as such: 50419-0208-01.

## Indication

Xofigo<sup>®</sup> is indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease.

## Important Safety Information

**Contraindications:** Xofigo is contraindicated in women who are or may become pregnant. Xofigo can cause fetal harm when administered to a pregnant woman

**Bone Marrow Suppression:** In the randomized trial, 2% of patients in the Xofigo arm experienced bone marrow failure or ongoing pancytopenia, compared to no patients treated with placebo. There were two deaths due to bone marrow failure. For 7 of 13 patients treated with Xofigo bone marrow failure was ongoing at the time of death. Among the 13 patients who experienced bone marrow failure, 54% required blood transfusions. Four percent (4%) of patients in the Xofigo arm and 2% in the placebo arm permanently discontinued therapy due to bone marrow suppression. In the randomized trial, deaths related to vascular hemorrhage in association with myelosuppression were observed in 1% of Xofigo-treated patients compared to 0.3% of patients treated with placebo. The incidence of infection-related deaths (2%), serious infections (10%), and febrile neutropenia (<1%) was similar for patients treated with Xofigo and placebo. Myelosuppression – notably thrombocytopenia, neutropenia, pancytopenia, and leukopenia – has been reported in patients treated with Xofigo.

Monitor patients with evidence of compromised bone marrow reserve closely and provide supportive care measures when clinically indicated. Discontinue Xofigo in patients who experience life-threatening complications despite supportive care for bone marrow failure

**Hematological Evaluation:** Monitor blood counts at baseline and prior to every dose of Xofigo. Prior to first administering Xofigo, the absolute neutrophil count (ANC) should be  $\geq 1.5 \times 10^9/\text{L}$ , the platelet count  $\geq 100 \times 10^9/\text{L}$ , and hemoglobin  $\geq 10 \text{ g/dL}$ . Prior to subsequent administrations, the ANC should be  $\geq 1 \times 10^9/\text{L}$  and the platelet count  $\geq 50 \times 10^9/\text{L}$ . Discontinue Xofigo if hematologic values do not recover within 6 to 8 weeks after the last administration despite receiving supportive care

**Concomitant Use With Chemotherapy:** 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

**Administration and Radiation Protection:** Xofigo should be received, used, and administered only by authorized persons in designated clinical settings. The administration of Xofigo is associated with potential risks to other persons from radiation or contamination from spills of bodily fluids such as urine, feces, or vomit. Therefore, radiation protection precautions must be taken in accordance with national and local regulations

**Adverse Reactions:** The most common adverse reactions ( $\geq 10\%$ ) in the Xofigo arm vs the placebo arm, respectively, were nausea (36% vs 35%), diarrhea (25% vs 15%), vomiting (19% vs 14%), and peripheral edema (13% vs 10%). Grade 3 and 4 adverse events were reported in 57% of Xofigo-treated patients and 63% of placebo-treated patients. The most common hematologic laboratory abnormalities in the Xofigo arm ( $\geq 10\%$ ) vs the placebo arm, respectively, were anemia (93% vs 88%), lymphocytopenia (72% vs 53%), leukopenia (35% vs 10%), thrombocytopenia (31% vs 22%), and neutropenia (18% vs 5%)

Please see full [Prescribing Information](#)

#### **Assistance with Reimbursement**

**A more detailed explanation of the new code and its implications, as well as additional product information can be found in the attachment.** If you have any questions or comments related to the information in this letter, please contact Jorja Sturek at [862-404-5688](tel:862-404-5688).

If a provider has questions or encounters any issues in this transition, providers may contact Xofigo® Access Services at 1-855-6XOFIGO ([1-855-696-3446](tel:1-855-696-3446)), Monday through Friday, 9:00 AM–8:00 PM ET, to speak with a Xofigo Access Services Access Counselor.

**Bayer will also be providing additional opportunities for providers to learn more about these updates, including webinars scheduled in December 2014 and January 2015, and inservices from our Field Reimbursement Team.**

\*The information provided in this resource is for informational purposes only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Customers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. Neither this resource, nor Xofigo® Access Services, is intended as legal advice or as a substitute for a provider's independent professional judgment.

Sincerely,

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Bayer HealthCare

You are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

1. Centers for Medicare and Medicaid Services. HCPCS Release and Code Sets. Alpha-Numeric HCPCS Items. Details for title: 2015. <http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2015-Annual-Alpha-Numeric-HCPCS-File-%C2%A0.zip>.

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