

Your single source of support for

- Confirming patient scheduling
- Reimbursement support
- Patient assistance

Phone: 1-855-6XOFIGO (1-855-696-3446)

Online: <https://XofigoAccessOnline.com/>

As a committed partner to providers and patients, Bayer offers fully integrated and comprehensive reimbursement support, patient assistance, and product acquisition services to facilitate treatment access. Xofigo[®] Access Services offers a dedicated team of Access Counselors available by phone to support patient access to Xofigo.

Online access is available 24 hours a day, 7 days a week via the Xofigo Access Services Provider Portal.

Please see Important Safety Information on pages 2 and 3
and click here for full [Prescribing Information](#).

INDICATION

Xofigo[®] 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

Warnings and Precautions:

- **Bone Marrow Suppression:** In the phase 3 ALSYMPCA 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 $\geq 1.5 \times 10^9/L$, the platelet count $\geq 100 \times 10^9/L$, and hemoglobin ≥ 10 g/dL. Prior to subsequent administrations, the ANC should be $\geq 1 \times 10^9/L$ and the platelet count $\geq 50 \times 10^9/L$. Discontinue Xofigo if hematologic values do not recover within 6 to 8 weeks after the last administration despite receiving supportive care

Please click here for full [Prescribing Information](#).



IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued):

- **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
- **Increased Fractures and Mortality in Combination With Abiraterone Plus Prednisone/Prednisolone:** Xofigo is not recommended for use in combination with abiraterone acetate plus prednisone/prednisolone outside of clinical trials. At the primary analysis of the phase 3 ERA-223 study that evaluated concurrent initiation of Xofigo in combination with abiraterone acetate plus prednisone/prednisolone in 806 asymptomatic or mildly symptomatic mCRPC patients, an increased incidence of fractures (28.6% vs 11.4%) and deaths (38.5% vs 35.5%) have been observed in patients who received Xofigo in combination with abiraterone acetate plus prednisone/prednisolone compared to patients who received placebo in combination with abiraterone acetate plus prednisone/prednisolone. Safety and efficacy with the combination of Xofigo and agents other than gonadotropin-releasing hormone analogues have not been established

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 click here for full [Prescribing Information](#).



Xofigo® Access Services Support



Provider Portal

- 24/7 access
- Efficient, secure patient access management
- Streamlined service
- Electronic signature

Visit www.XofigoAccessOnline.com to access the Provider Portal today!



Product Order and Patient Scheduling Confirmation

- Product order request processing
- Appointment and treatment schedule confirmation
- Seamless transfer for administering provider to Cardinal Health Nuclear Pharmacy Services radiopharmacist
- Questions regarding returns, damaged product, patient cancellations, or rescheduling



Reimbursement Support

- Insurance benefit verifications
- Prior authorization support (physician office must submit PA)
- Claims appeal research and information
- Claims tracking
- Billing and coding information
- Payer policy information



Xofigo Patient Assistance Program*

Brought to you by the Bayer US Patient Assistance Foundation

- Assistance for qualified uninsured and underinsured patients



Introducing \$0 Copay/Coinsurance Assistance

- Copay/coinsurance assistance for privately insured Xofigo patients[†]
- Eligible patients pay nothing for Xofigo prescriptions

* The Xofigo Patient Assistance Program is a charitable program that is offered through the Bayer US Patient Assistance Foundation.

[†] Some restrictions apply. For full terms and conditions, please call Xofigo Access Services at 1-855-6XOFIGO (1-855-696-3446). Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. As a condition precedent of the copayment support provided under this program, eg, copay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payers of any benefits they receive and the value of this program, as required by contract or otherwise. Void where prohibited by law, taxed, or restricted. Patients enrolled in Bayer's Patient Assistance Program are not eligible. Bayer may determine eligibility, monitor participation, equitably distribute product and modify or discontinue any aspect of this program at any time.

Please see Important Safety Information on pages 2 and 3 and click here for full [Prescribing Information](#).



Xofigo® (radium Ra 223 dichloride) injection will be ordered and distributed through a single point of contact distribution model. Ordering Xofigo is a simple 3-step process.

Step 1



Contact Xofigo® Access Services

- Fax a completed Xofigo® Access Services Enrollment Form, including the signed patient authorization, to **1-855-963-4463**
 - To request an insurance benefit verification, please provide the patient's insurance information (alternatively, you may conduct your own insurance benefit verification)
 - To confirm a treatment date/schedule for your patient, please provide your patient's anticipated treatment date(s) and time(s)
- Xofigo Access Services will fax you a confirmation receipt of your request
- If preferred, you can call Xofigo Access Services at **1-855-6XOFIGO** (1-855-696-3446) to verbally initiate your request or log onto the Provider Portal at <https://XofigoAccessOnline.com> to submit your request online

Step 2



Receive Confirmation From Xofigo Access Services

- A completed insurance benefit verification, if requested, with a written summary of the patient's benefits, within 24-48 hours
- A letter to confirm the treatment date and time of your patient's next dose

Step 3



Order Xofigo

- Call Xofigo Access Services up to 7 business days prior to each patient's scheduled treatment date to order Xofigo with Cardinal Health Nuclear Pharmacy Services
- If you have not placed the order **a minimum of 3 business days** prior to the scheduled treatment date, Xofigo Access Services will call you to process the order
- If you are a provider with the VA or DoD, please identify yourself as such when you call
- Cardinal Health Nuclear Pharmacy Services central radiopharmacy will ship the patient-ready dose to your facility

Please have the following information available when you call Xofigo® Access Services:



Patient name



Patient weight (kg)



Planned date and time of administration



Facility shipment address



Dosage

Please see Important Safety Information on pages 2 and 3 and click here for full [Prescribing Information](#).



Your First Step: Contact Xofigo® Access Services

For Administering Providers

Confirm treatment dates, order Xofigo, or request the following:

- Insurance benefit verifications
- Prior authorization support (physician office must submit PA)
- Patient assistance
- Other reimbursement support
- Licensing information

For Referring Providers

Inquire about licensed Xofigo sites, or request the following:

- Insurance benefit verifications
- Prior authorization support
- Patient assistance
- Other reimbursement support

For Patients

Initiate insurance benefit verifications

- Request insurance plan and alternate coverage research
- Inquire about patient assistance

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Contact Xofigo® Access Services Today



Phone: 1-855-6XOFIGO (1-855-696-3446)



Fax: 1-855-963-4463



Hours: 9:00 AM – 7:00 PM ET
Monday through Friday



Secure Online Provider Portal:
<https://XofigoAccessOnline.com/>

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.

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