Xofigo® Access Services

Ordering Xofigo® for Administering Providers

Ordering Xofigo is a simple 3-step process

Step 1 — Contact Xofigo Access Services

- Fax a completed Xofigo Access Services Enrollment Form and a completed, signed Patient Authorization Form 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)
  - —Please provide your patient's anticipated treatment date(s) and time(s) to confirm a treatment date/schedule for your patient
- Xofigo Access Services will fax you a confirmation receipt of your request
- If preferred, call Xofigo Access Services at **1-855-6XOFIGO** (1-855-696-3446) to 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 insurance 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 or log onto the Xofigo Access Services Provider Portal 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 will ship the patient-ready dose to your facility

VA – Department of Veterans Affairs; DoD – Department of Defense.

INDICATION

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

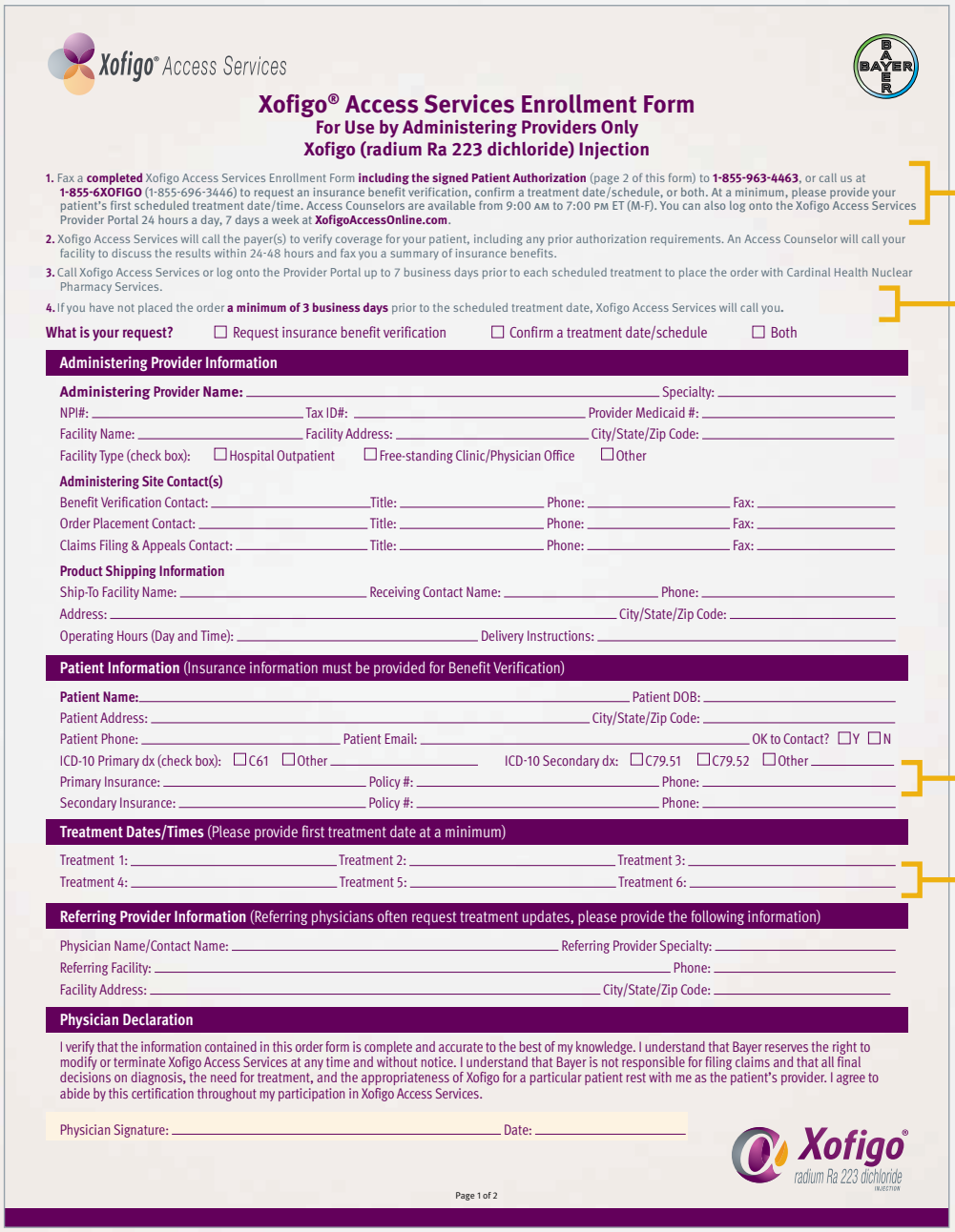
IMPORTANT SAFETY INFORMATION

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

Please see additional Important Safety Information on page 4 and click here for full Prescribing Information.

Xofigo® radium Ra 223 dichloride INJECTION

Xofigo® Access Services Enrollment Form



Xofigo® Access Services

Xofigo® Access Services Enrollment Form

For Use by Administering Providers Only
Xofigo (radium Ra 223 dichloride) Injection

1. Fax a **completed** Xofigo Access Services Enrollment Form **including the signed Patient Authorization** (page 2 of this form) to **1-855-963-4463**, or call us at **1-855-6XOFIGO** (1-855-696-3446) to request an insurance benefit verification, confirm a treatment date/schedule, or both. At a minimum, please provide your patient's first scheduled treatment date/time. Access Counselors are available from 9:00 AM to 7:00 PM ET (M-F). You can also log onto the Xofigo Access Services Provider Portal 24 hours a day, 7 days a week at **XofigoAccessOnline.com**.
2. Xofigo Access Services will call the payer(s) to verify coverage for your patient, including any prior authorization requirements. An Access Counselor will call your facility to discuss the results within 24-48 hours and fax you a summary of insurance benefits.
3. Call Xofigo Access Services or log onto the Provider Portal up to 7 business days prior to each scheduled treatment to place the order with Cardinal Health Nuclear Pharmacy Services.
4. 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.

What is your request? ☐ Request insurance benefit verification ☐ Confirm a treatment date/schedule ☐ Both

Administering Provider Information

Administering Provider Name: _____ Specialty: _____
NPI#: _____ Tax ID#: _____ Provider Medicaid #: _____
Facility Name: _____ Facility Address: _____ City/State/Zip Code: _____
Facility Type (check box): ☐ Hospital Outpatient ☐ Free-standing Clinic/Physician Office ☐ Other

Administering Site Contact(s)

Benefit Verification Contact: _____ Title: _____ Phone: _____ Fax: _____
Order Placement Contact: _____ Title: _____ Phone: _____ Fax: _____
Claims Filing & Appeals Contact: _____ Title: _____ Phone: _____ Fax: _____

Product Shipping Information

Ship-To Facility Name: _____ Receiving Contact Name: _____ Phone: _____
Address: _____ City/State/Zip Code: _____
Operating Hours (Day and Time): _____ Delivery Instructions: _____

Patient Information (Insurance information must be provided for Benefit Verification)

Patient Name: _____ Patient DOB: _____
Patient Address: _____ City/State/Zip Code: _____
Patient Phone: _____ Patient Email: _____ OK to Contact? ☐ Y ☐ N
ICD-10 Primary dx (check box): ☐ C61 ☐ Other _____ ICD-10 Secondary dx: ☐ C79.51 ☐ C79.52 ☐ Other _____
Primary Insurance: _____ Policy #: _____ Phone: _____
Secondary Insurance: _____ Policy #: _____ Phone: _____

Treatment Dates/Times (Please provide first treatment date at a minimum)

Treatment 1: _____ Treatment 2: _____ Treatment 3: _____
Treatment 4: _____ Treatment 5: _____ Treatment 6: _____

Referring Provider Information (Referring physicians often request treatment updates, please provide the following information)

Physician Name/Contact Name: _____ Referring Provider Specialty: _____
Referring Facility: _____ Phone: _____
Facility Address: _____ City/State/Zip Code: _____

Physician Declaration

I verify that the information contained in this order form is complete and accurate to the best of my knowledge. I understand that Bayer reserves the right to modify or terminate Xofigo Access Services at any time and without notice. I understand that Bayer is not responsible for filing claims and that all final decisions on diagnosis, the need for treatment, and the appropriateness of Xofigo for a particular patient rest with me as the patient's provider. I agree to abide by this certification throughout my participation in Xofigo Access Services.

Physician Signature: _____ Date: _____

Xofigo® radium Ra 223 dichloride INJECTION

Page 1 of 2

The Patient Authorization on the following page must be completed and submitted with this form.

Remember to place your order a minimum of 3 business days prior to the scheduled treatment date

To request an insurance benefit verification, please provide your patient's insurance information

To confirm a treatment date/schedule for your patient, please provide your patient's anticipated treatment date(s) and time(s)

For a writeable PDF of this form, please visit **www.xofigo-us.com**

For VA and DoD providers, please note that there is a specific VA/DoD Intake Form on www.xofigo-us.com.

Please see Important Safety Information on pages 1 and 4 and click here for full Prescribing Information.

Xofigo® radium Ra 223 dichloride INJECTION

Patient Authorization for Xofigo® Access Services

Xofigo® Access Services

Patient Authorization for Xofigo® Access Services

I authorize the use and/or disclosure of my private health information, described below, which may include "Protected Health Information" or "PHI" as defined by the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"). In general terms, I understand that Protected Health Information is health information that identifies me or that could reasonably be used to identify me. I understand that this authorization is voluntary.

I authorize my healthcare providers that treat me or provide healthcare services to me, including my physicians and pharmacies, and my health insurer(s) to share or disclose my name, address, and telephone number, along with certain medical records and insurance and financial information with respect to my treatment; my eligibility for insurance or patient assistance; the coordination of my treatment, including scheduling, ordering, and the receipt of my medication; and my participation in the Xofigo Access Services (the "Program") to Bayer and its agents. These agents include a company that is an administrative contractor that administers the Program, the supplier which dispenses Xofigo, and a data analytics company which analyzes and produces reports of aggregated data (collectively "Bayer"). I understand that certain healthcare providers may receive payment or other forms of remuneration from Bayer in connection with the use and disclosure of my PHI as described in this authorization.

I allow the use and disclosure of my PHI for the following purposes: (1) to verify my financial or insurance information; (2) to ensure the accuracy and completeness of the Program enrollment form; (3) to help with my reimbursement questions; (4) to see if I qualify for patient assistance or copayment assistance or to refer me to, or determine my eligibility for, other programs, foundations, or alternate sources of funding or coverage to help me with the costs of obtaining Xofigo; (5) to coordinate my Xofigo treatments; (6) to send me educational materials or other Program information that may be of interest to me; (7) for commercial purposes, including to understand how Xofigo is used across healthcare providers and other market research; (8) to manage supply and availability of Xofigo for my treatments; (9) to follow up with my healthcare providers or myself with regard to any reported adverse event / product technical complaint / incident or other safety related information; and (10) to comply with applicable law.

This authorization expires at the end of my participation in the Program or 3 years (or earlier if required by state law) from the date of my signature, whichever comes first. I can withdraw (ie, take back) this authorization any time, except to the extent my healthcare provider or health plan insurer has taken action in reliance on my authorization. I understand that if I revoke this authorization, it will not have any effect on any actions my healthcare providers or my health plan may have taken before receiving the revocation, and will not affect Bayer's ability to use and disclose any information it has already received. I can withdraw this authorization by mailing a written request to Xofigo Access Services, PO Box 220009, Charlotte, NC 28222-0009, or by faxing a request to 1-855-963-4463.

I also understand that persons or entities that receive my PHI under this authorization may not be required by privacy laws (such as the HIPAA Privacy Rule) to protect the information and may share it with others without my permission, if permitted by laws applicable to them.

My healthcare providers and health plan insurer will not condition my medical treatment or its payment, insurance enrollment, or eligibility for insurance benefits on my signing this form. However, if the information requested about me is not provided, Bayer will be unable to determine my eligibility to participate in an available patient assistance program or copayment assistance program and, thus, I may be unable to participate in these programs. I have read this authorization and/or had its contents read to me. I have had an opportunity to ask questions about the uses and disclosures of PHI described above and all of my questions have been answered to my satisfaction. I authorize the use and disclosure of my information as described in this form. I understand that I am entitled to receive a signed copy of this authorization.

Print Patient's or Patient Representative's Name:_____ Date: ____/____/____

Patient's or Patient Representative's Signature:_____ Date: ____/____/____

If signed by the Patient's Representative, include a description of the Representative's relationship to the Patient and such person's authority to act for the Patient (eg, parent, guardian, etc)

Page 2 of 2

Xofigo® radium Ra 223 dichloride INJECTION

Please see Important Safety Information on pages 1 and 4 and click here for full Prescribing Information.

Xofigo® radium Ra 223 dichloride INJECTION

IMPORTANT SAFETY INFORMATION (continued)

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 ≥1.5 × 10^9/L, the platelet count ≥100 × 10^9/L, and hemoglobin ≥10 g/dL. Prior to subsequent administrations, the ANC should be ≥1 × 10^9/L and the platelet count ≥50 × 10^9/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
- **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 (≥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 (≥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.

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Xofigo® radium Ra 223 dichloride INJECTION