Xofigo® Access Services | Sample Letter of Appeal

[Date]

[Contact at health insurance company]
[Title]
[Name of health insurance company]
[Address]
[City, State, ZIP Code]

Insured: [First and last name]
Patient: [First and last name]
Policy Number: [Number]
Group Number: [Number]
Patient Date of Birth: [MM/DD/YYYY]

Dear [Name of Contact]:

I am requesting an expedited appeal for medically necessary services prescribed to [name of patient] for therapy with Xofigo® (radium Ra 223 dichloride) injection on [date(s) of service]. [Name of health insurance company] denied a claim in the amount of [enter dollar amount of charges] on [date(s) of service] due to [summarize insurer's stated reason for claim denial].

Xofigo is indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease. Because [name of patient] has been diagnosed with [patient's diagnosis] as of [date of diagnosis], and [provide a brief discussion of patient's relevant medical history, condition/symptoms and therapy to date, including other treatments attempted and results], I believe Xofigo is medically necessary and a clinically appropriate treatment for [name of patient].

Thank you in advance for your review and consideration of this appeal. If you have any questions or require additional information regarding this case, please contact me at [physician's telephone number].

Sincerely,
[Physician's Name]
[Physician's Practice Name]

Attachments: [original claim form, copy of denial or explanation of benefits (if applicable), copy of patient's insurance card, Xofigo Prescribing Information, FDA approval letter, etc.]

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

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.

Please see additional Important Safety Information on pages 2 and 3 and click here for full Prescribing Information.

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In the event the payer made an error in processing the claim, the provider office should contact the payer to discuss the processing issue in order to allow the patient access to Xofigo®. When appealing a denied claim, payers may request additional documentation (if not submitted with the original claim), including:

- ☑ Letter of appeal
- ☑ Copy of the original claim
- ☑ Copy of denial notification from payer
- ☑ Copy of invoice
- ☑ Patient medical history, including clinical notes
- ☑ Copy of physician's order
- ☑ Xofigo® Prescribing Information
- ☑ FDA approval letter

IMPORTANT SAFETY INFORMATION (continued)

- **Bone Marrow Suppression** (continued)**:** 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

Please see additional Important Safety Information on pages 1 and 3 and click here for full Prescribing Information.

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IMPORTANT SAFETY INFORMATION (continued)

- **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
- **Embryo-Fetal Toxicity:** The safety and efficacy of Xofigo have not been established in females. Xofigo can cause fetal harm when administered to a pregnant female. Advise pregnant females and females of reproductive potential of the potential risk to a fetus. Advise male patients to use condoms and their female partners of reproductive potential to use effective contraception during and for 6 months after completing treatment with Xofigo

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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