Updated September 2018

Xofigo® Access Services

Quick Reference Reimbursement Guide
Freestanding Center

Contact Xofigo® Access Services Today for Reimbursement Support

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

Fax: 1-855-963-4463

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

Online Provider Portal:
https://XofigoAccessOnline.com

Please see Important Safety Information on page 2
and click here for full Prescribing Information.

Xofigo® radium Ra 223 dichloride INJECTION

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 ≥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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Healthcare professionals administering Xofigo® in a freestanding center should submit a CMS-1500 form to report the use and administration of Xofigo. Xofigo and its associated services may be reported with the following codes:

Healthcare Common Procedure Coding System (HCPCS) Codes

Effective for dates of service on or after January 1, 2015, in a freestanding center, Xofigo is reported using the product-specific HCPCS A-code, A9606 (Radium ra-223 dichloride, therapeutic, per microcurie).

Product	Code	Description
Xofigo	A9606[1]	Radium ra-223 dichloride, therapeutic, per microcurie

Please note that individual Medicare Administrative Contractors (MACs), private payers, or other payers or claims processors may have different coding requirements for radiopharmaceuticals in the freestanding center. Xofigo® Access Services can research payer-specific coding requirements in performing patient-specific benefit verifications.

Providers should confirm the appropriate coverage, coding, and reimbursement with the applicable payer or claims processor before submitting claims for an item or service. Providers must ensure that all claims submitted to payers are accurate, complete, and adequately supported by documentation in the medical record.

Payers differ on guidelines and criteria required for billing an office visit on the same day as other physician services. It is important to verify appropriate coding with a patient's health insurance plan before submitting the CMS-1500 claim form for reimbursement. Additional information required by the payer may include:

- ☑ Xofigo Prescribing Information
- ☑ FDA approval letter for Xofigo
- ☑ Patient medical history
- ☑ Physician clinical notes on the patient's condition
- ☑ Letter of medical necessity
- ☑ Invoice for Xofigo
- ☑ National Drug Code (NDC) for Xofigo (Medicaid and/or commercial payers)

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.

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Xofigo® radium Ra 223 dichloride INJECTION

Current Procedural Terminology (CPT) Codes

Physicians use CPT codes to report medical services provided in a freestanding center, including the administration of Xofigo®.

Service	Code	Description
Administration of Xofigo	79101[2]	Radiopharmaceutical therapy, by intravenous administration

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Codes[3]

Appropriately coding and classifying the patient's diagnosis and condition is important to support medical necessity for receiving Xofigo.

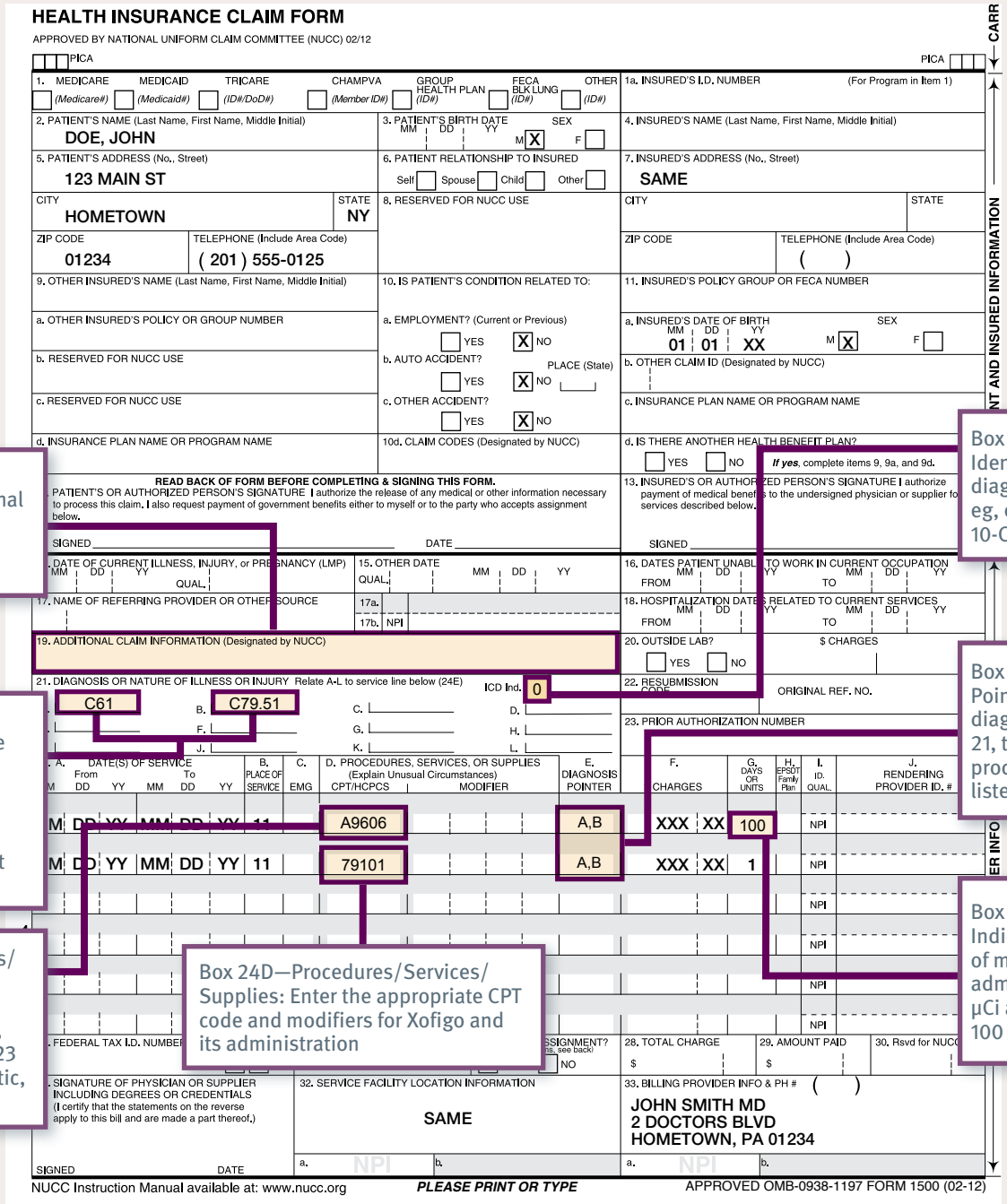
ICD-10-CM Code	Code Description
C61	Malignant neoplasm of prostate
C79.51 or	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow

Evaluation and management (E/M) codes may also be used to describe services provided by the physician when the patient's condition is significant and beyond the intravenous injection of Xofigo. If an E/M service is billed in addition to the intravenous injection of Xofigo, the modifier "-25" is necessary to indicate a significant and separately identifiable E/M service by the same physician on the same day.[2] The provider must document the additional service in the patient's medical record.

Sample CMS-1500 Claim Form (new version 02-12 as of April 2014)

Xofigo® and the associated services provided in a freestanding center setting are billed on the CMS-1500 claim form or its electronic equivalent. A sample CMS-1500 claim form for billing Xofigo is provided below.

As of April 1, 2014, Medicare only accepts claims submitted on the revised CMS-1500 form (version 02-12).



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): DOE, JOHN

3. PATIENT'S BIRTH DATE MM DD YY SEX: M [X] F [ ]

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street): 123 MAIN ST

6. PATIENT RELATIONSHIP TO INSURED: Self [ ] Spouse [ ] Child [ ] Other [ ]

7. INSURED'S ADDRESS (No., Street): SAME

CITY: HOMETOWN STATE: NY

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE: 01234 TELEPHONE (Include Area Code): (201) 555-0125

ZIP CODE TELEPHONE (Include Area Code): ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES [ ] NO [X]

a. INSURED'S DATE OF BIRTH MM DD YY: 01 01 XX SEX: M [X] F [ ]

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES [ ] NO [X] PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES [ ] NO [X]

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES [ ] NO [ ] If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED DATE

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES [ ] NO [ ] $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. C61 B. C79.51 C. D. F. G. H. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
M DD YY	MM DD YY	11		A9606		A,B	XXX XX	100		NPI	
M DD YY	MM DD YY	11		79101		A,B	XXX XX	1		NPI	
										NPI	
										NPI	
										NPI	
										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES [ ] NO [ ] 28. TOTAL CHARGE $ 29. AMOUNT PAID $ 30. Rsvd for NUCC

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION: SAME

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

JOHN SMITH MD
2 DOCTORS BLVD
HOMETOWN, PA 01234

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org **PLEASE PRINT OR TYPE** APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER AND INSURED INFORMATION

Box 19—Additional Information: Additional information may no longer be required with A9606

Box 21—ICD Indicator: Identify the type of ICD diagnosis code used; eg, enter a "0" for ICD-10-CM

Box 21—Diagnosis: Enter the appropriate diagnosis code; eg, ICD-10-CM: C61 Malignant neoplasm of prostate; C79.51 Secondary malignant neoplasm of bone[a]

Box 24E—Diagnosis Pointer: Specify the diagnosis, from Box 21, that relates to the product or procedure listed in Box 24D

Box 24D—Procedures/Services/Supplies: Enter new product-specific HCPCS code, A9606, Radium ra-223 dichloride, therapeutic, per microcurie

Box 24D—Procedures/Services/Supplies: Enter the appropriate CPT code and modifiers for Xofigo and its administration

Box 24G—Units: Indicate number of microcuries administered; eg, if 100 µCi administered, put 100 in Box 24G

[a] Other diagnosis codes may be applicable; code(s) and sequencing order may vary by payer.

Please see Important Safety Information on page 2 and click here for full Prescribing Information.

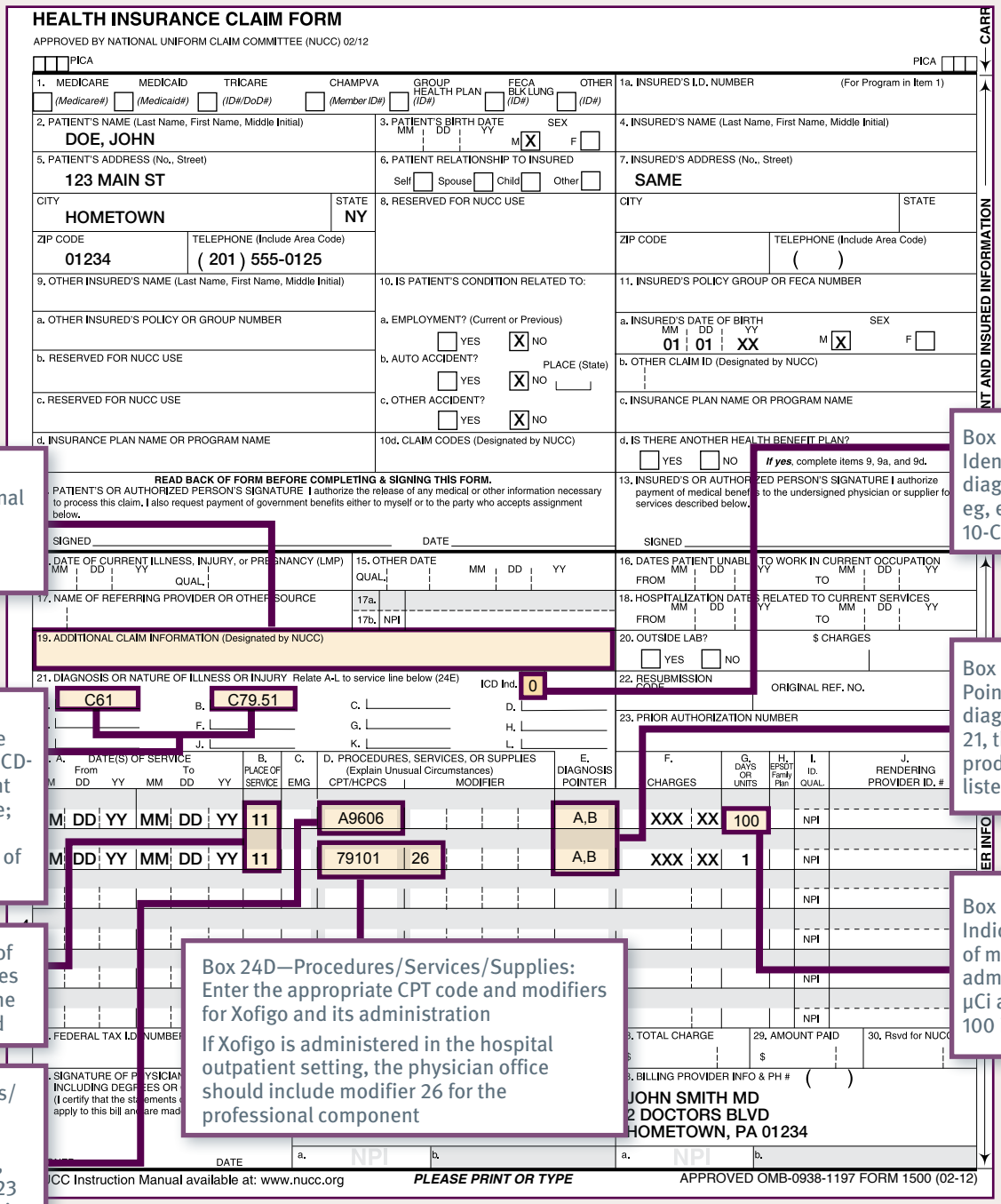
Xofigo® radium Ra 223 dichloride INJECTION

Billing for Xofigo® and Its Administration in Separate Sites of Care

Billing by the Physician for the Administration of Xofigo

According to Medicare guidance, if a physician who is not employed by a hospital administers Xofigo to a patient in that hospital's outpatient department, then the physician may submit a separate claim only for the administration services of Xofigo.

Sample CMS-1500 Claim Form



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10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES X NO

a. INSURED'S DATE OF BIRTH MM DD YY: 01 01 XX SEX: M X F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES X NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES X NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO

If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

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SIGNED DATE

SIGNED

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17b. NPI

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M DD YY	MM DD YY	11		A9606		A,B	XXX XX	100		NPI	
M DD YY	MM DD YY	11		79101	26	A,B	XXX XX	1		NPI	
										NPI	
										NPI	
										NPI	
										NPI	

25. FEDERAL TAX I.D. NUMBER

26. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC

31. SIGNATURE OF PHYSICIAN INCLUDING DEGREES OR (I certify that the statements apply to this bill and are made

DATE

32. BILLING PROVIDER INFO & PH # ( )

JOHN SMITH MD
2 DOCTORS BLVD
HOMETOWN, PA 01234

a. NPI b.

a. NPI b.

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Box 21—Diagnosis: Enter the appropriate diagnosis code; eg, ICD-10-CM: C61 Malignant neoplasm of prostate; C79.51 Secondary malignant neoplasm of bone[a]

Box 24G—Units: Indicate number of microcuries administered; eg, if 100 µCi administered, put 100 in Box 24G

Box 24B—The Place of Service code identifies the location where the service was rendered

Box 24D—Procedures/Services/Supplies: Enter the appropriate CPT code and modifiers for Xofigo and its administration

If Xofigo is administered in the hospital outpatient setting, the physician office should include modifier 26 for the professional component

Box 24D—Procedures/Services/Supplies: Enter new product-specific HCPCS code, A9606, Radium ra-223 dichloride, therapeutic, per microcurie

[a] Other diagnosis codes may be applicable; code(s) and sequencing order may vary by payer.

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For further information, please visit www.xofigo-us.com

References: 1. Centers for Medicare & Medicaid Services. HCPCS release and code sets. Alpha-numeric HCPCS items. 2016. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2016-Alpha-Numeric-HCPCS-File.zip. Accessed November 10, 2016. **2.** 2012 CPT Professional Edition. American Medical Association, 2011. **3.** 2014 International Classification of Diseases, 10th Revision, Clinical Modification Mappings. OptumInsights, Inc., 2013.

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