Xofigo® Access Services

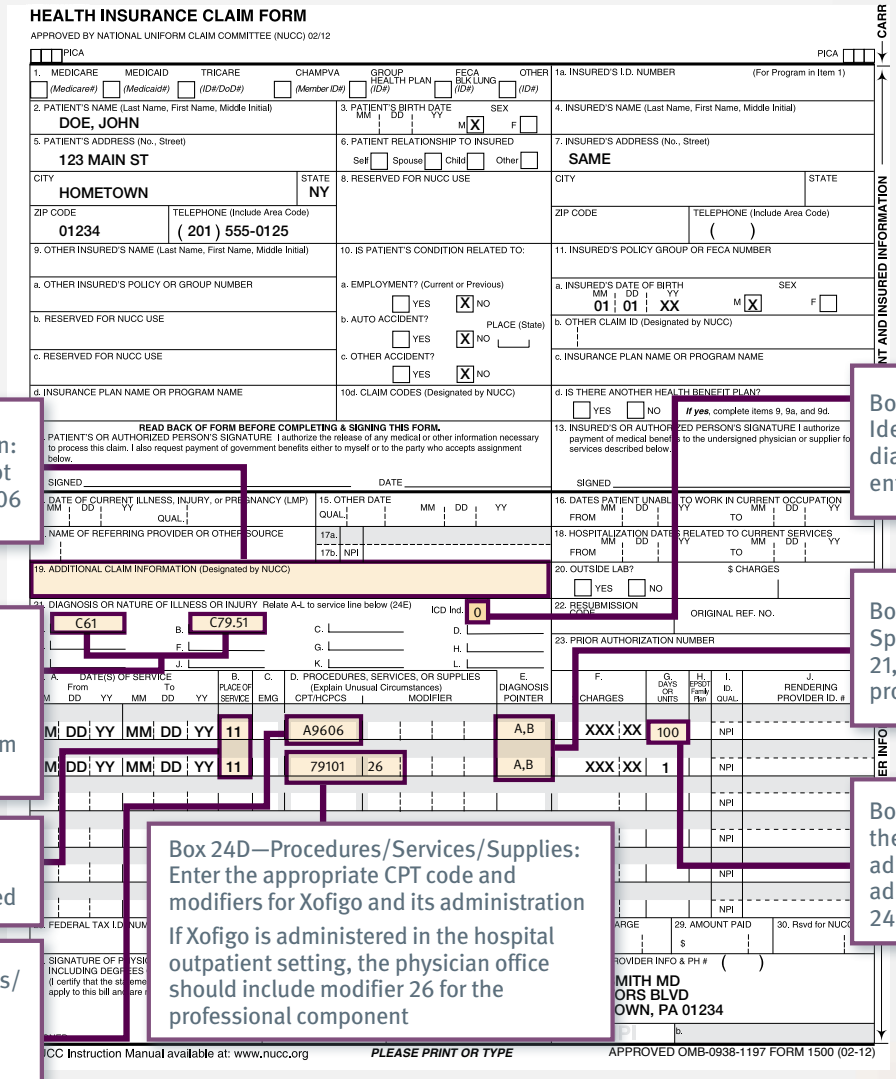
Billing for Xofigo® (radium Ra 223 dichloride) Injection and Administration in Separate Sites of Care

Providers are solely responsible for confirming appropriate coverage, coding and reimbursement and ensuring that all claims are accurate, complete and adequately supported by documentation in the medical record. Information provided in this resource is for informational purposes only and does not guarantee that codes are appropriate or that reimbursement will result. This resource is not intended as legal advice or as a substitute for a provider's independent professional judgment.

Billing by the Physician for the Administration of Xofigo

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

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



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.

SIGNED DATE

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

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

15. OTHER DATE MM DD YY QUAL.

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. E. F. G. H. I. 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. #
MM DD YY	MM DD YY	11		A9606		A,B	XXX XX	100		NPI	
MM DD YY	MM DD YY	11		79101	26	A,B	XXX XX	1		NPI	
										NPI	
										NPI	
										NPI	
										NPI	

25. FEDERAL TAX I.D. NUM

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back)

28. TOTAL CHARGE

29. AMOUNT PAID $

30. Rsvd for NUCC

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

32. SERVICE FACILITY LOCATION INFO

33. BILLING PROVIDER INFO & PH # ( )

MITH MD
ORS BLVD
OWN, PA 01234

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

Box 19—Additional Information: Additional information may not be required by payers for A9606

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

Box 24D—Procedures/Services/Supplies: Enter the 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

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

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

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

Box 24G—Units: Indicate the 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.

INDICATION

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

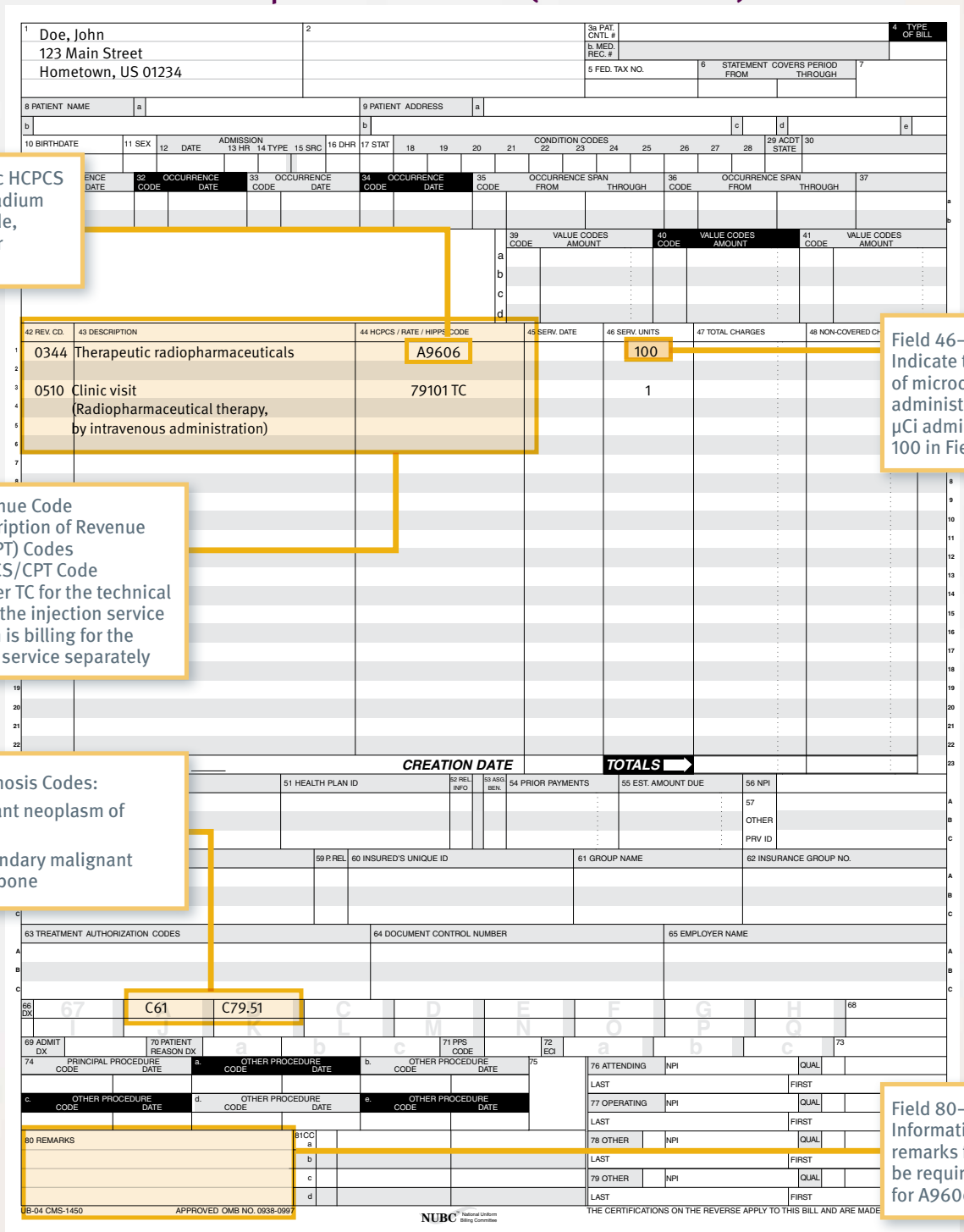
Please see Important Safety Information on page 3 and click here for full Prescribing Information.

Xofigo® radium Ra 223 dichloride INJECTION

Billing by the Hospital Outpatient Department for the product Xofigo®

According to Medicare guidance, the hospital outpatient department may submit a separate claim for the product Xofigo purchased on behalf of the non-hospital physician and the technical component of its administration.

Sample UB-04 Claim Form (Medicare Patient)



Product-specific HCPCS code, A9606, radium ra-223 dichloride, therapeutic, per microcurie

Field 46—Service Units: Indicate the number of microcuries administered; eg, if 100 µCi administered, put 100 in Field 46

Field 42—Revenue Code
Field 43—Description of Revenue (and HCPCS/CPT) Codes
Field 44—HCPCS/CPT Code
Include modifier TC for the technical component[a] of the injection service if the physician is billing for the administration service separately

Field 67—Diagnosis Codes:
- C61—Malignant neoplasm of prostate
- C79.51—Secondary malignant neoplasm of bone

Field 80—Remarks: Information in the remarks field may not be required by payers for A9606

[a] The technical component includes non-physician work, including administrative, personnel, equipment, and facility costs and related malpractice expenses.

Please see Important Safety Information on page 3 and click here for full Prescribing Information.

Please see disclaimer on page 1.

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.

PP-600-US-3648 09/18

Xofigo® radium Ra 223 dichloride INJECTION