PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

Coding and Billing Guide

JANUARY 2026

NEED MORE INFORMATION?

VISIT: pluvicto-hcp.com/psma-positive-mcrpc/novartis-patient-support

CALL: 1-844-638-7222

FAX: 1-844-638-7329

Indication

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibition (ARPI) therapy, and

- are considered appropriate to delay taxane-based chemotherapy, or
- have received prior taxane-based chemotherapy

HIGHLIGHTS OF IMPORTANT SAFETY INFORMATION

Risk From Radiation Exposure

PLUVICTO contributes to a patient's long-term cumulative radiation exposure, which is associated with an increased risk for cancer.

Minimize radiation exposure to patients, medical personnel, and others during and after treatment with PLUVICTO consistent with institutional practices, patient treatment procedures, Nuclear Regulatory Commission patient-release guidance, and instructions to the patient for follow-up radiation protection.

Ensure patients increase oral fluid intake and advise them to void as often as possible to reduce bladder radiation.

Please see additional Important Safety Information on pages 18 and 19.

Please see full Prescribing Information.

Novartis has developed this resource to provide you and your office staff with general coding and reimbursement information for PLUVICTO.

Resource overview:

Please note that the current information is subject to change as new coding and reimbursement information becomes available. Individual payer guidance should be reviewed before submitting a claim.

Disclaimers

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice.

- Laws, regulations, and policies concerning reimbursement are complex and updated frequently
  - While Novartis Pharmaceuticals Corporation has made every effort to be current as of the issue date on this document, the information may not be as current or comprehensive when you view it
  - Similarly, all *Current Procedural Terminology* (CPT®) and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only, and this information does not represent any statement, promise, or guarantee by Novartis about coverage, levels of reimbursement, payment, or charge
- Consult the payer organization(s) for coverage and reimbursement policies and determination processes
- Consult your internal reimbursement specialist with any reimbursement or billing questions specific to your institution
- It is the provider's responsibility to determine and submit accurate information on claims and comply with payer coverage, reimbursement, and claim submission rules
- The existence of billing codes does not guarantee coverage and payment. Novartis Pharmaceuticals Corporation does not guarantee success in obtaining reimbursement or financial assistance. Third-party payment for medical products and services is affected by numerous factors, not all of which can be anticipated or resolved

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Coding for HCP-administered RLTs like PLUVICTO may require separate claims: one for product administration and one for the product itself.[1]

Below is a list of common codes to assist with coding and reimbursement for PLUVICTO. CLICK on each topic below for additional information.

	Code	Notes
HCPCS Code Level I (CPT)[2]*	79101: Radiopharmaceutical therapy, by intravenous administration	Used to report medical procedures and services under public and private health insurance programs
HCPCS Code Level II[3]	A9607	Used to identify drugs, supplies, medical procedures, and other services **Radiopharmaceuticals like PLUVICTO are billed under A-codes, not J-codes**
NDC Numbers[4]	10-digit: 0078-1217-61	Used to identify a specific drug
	11-digit: 00078-1217-61	
POS Codes[5]	11: Office	Used to indicate the setting in which a service was provided
	22: On-Campus Outpatient Hospital	
	49: Independent Clinic	
Revenue Codes[6]	0240: All inclusive ancillary, general	Used for processing product claims. Review individual payer guidance to determine the appropriate codes
	0340: Nuclear medicine, general	
	0342: Nuclear medicine, therapeutic	
	0344: Nuclear medicine, therapeutic radiopharmaceuticals	
	0636: Pharmacy, drugs requiring detailed coding	
JZ Modifier[7]	Zero drug amount discarded/not administered to any patient†	Applied to drugs payable under Medicare Part B that are described as a "single-dose" container or "single-use" package
JW Modifier[7]	Drug amount discarded/not administered to any patient†	

HCP, health care provider; NDC, National Drug Code; POS, Place of Service; RLT, radioligand therapy.
*Separate coding for the administration of therapy may be required under different CPT codes.
†Contact the health plan for questions about utilizing JZ/JW modifiers.

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Appropriate reimbursement for the administration of PLUVICTO depends on accurate coding and documentation. The following information is designed to provide important tips to consider when filing a claim for PLUVICTO.

- ✓ Depending on your plan, reach out to your payer for any questions on utilizing JZ/JW modifiers
- ✓ Verify patient information (eg, name, address, member ID)
- ✓ Use the most appropriate codes to report the patient's diagnosis and care (eg, ICD-10-CM codes, CPT codes)
- ✓ Review the number of units of PLUVICTO administered
- ✓ Ensure medical record information includes appropriate documentation to support diagnosis and associated services. These may include the following:
  - Specific diagnosis for mCRPC
  - Histology to support diagnosis of mCRPC
  - Previous treatment with ARPI
  - Relevant prior imaging documentation (eg, PSMA-positive PET/CT scans)
  - All relevant laboratory tests
- ✓ Recheck place of service (POS) and revenue codes
- ✓ Recheck claim prior to submission to ensure patient and coding information are accurate
- ✓ File claim in a timely manner
- ✓ Complete a PA form if required by payer
- ✓ Make sure to include CPT code 79101 (a separate PA may be required for CPT code 79101 Radiopharmaceutical therapy, by intravenous administration. Consult the payer directly for more information)
- ✓ File an appeal if PA is denied

Individual payer guidance should be reviewed before submission of a claim. Consult with the payer for any other required documentation specific to your patient, as needed.

For any questions and additional support, visit pluvicto-hcp.com/psma-positive-mcrpc/novartis-patient-support or call 1-844-638-7222.

ARPI, androgen receptor pathway inhibition; CT, computed tomography; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; ID, identification; mCRPC, metastatic castration-resistant prostate cancer; PA, prior authorization; PET, positron emission tomography; PSMA, prostate-specific membrane antigen.

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The following key details about PLUVICTO are included to provide context concerning patient access, coding, and reimbursement.[4]

Indication

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibition (ARPI) therapy and

- are considered appropriate to delay taxane-based chemotherapy, or
- have received prior taxane-based chemotherapy

Patient Selection

Select patients with previously treated mCRPC for treatment with PLUVICTO using LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection) or another approved PSMA-11 imaging agent based on PSMA expression in tumors. Additional selection criteria were used in the VISION study.

Dosage and Administration*

The recommended dosage is 7.4 GBq (200 mCi) intravenously every 6 weeks for up to 6 doses, or until disease progression or unacceptable toxicity.

Product Overview

NDC: 0078-1217-61
Single-dose vial: Single-dose vial containing 1000 MBq/mL (27 mCi/mL) of a clear and colorless to slightly yellow solution for intravenous use.

Prefilled syringe: 20-mL prefilled syringe that contains a full dose calibrated for injection on a specific day and time for each individual patient.

Storage and Handling

Store below 30°C (86°F). Do not freeze. Store in the original package to protect from ionizing radiation (lead shielding). Store PLUVICTO in accordance with local and federal laws on radioactive materials. Do not use PLUVICTO after the expiration date and time, which are stated on the label.

*Please refer to the full Prescribing Information for complete information on dosage and administration, including safe handling of radiopharmaceuticals and dose modifications for adverse reactions.

Please see Important Safety Information on pages 18 and 19.
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Diagnosis Codes

Diagnosis codes identify why a patient may need treatment (eg, conditions, diseases, related health problems, abnormal findings) and document the medical necessity for a patient to receive treatment with PLUVICTO.

You should review the payer's guidance to ensure appropriate codes are selected based on the patient's medical record.

When reporting ICD-10-CM codes, it is recommended to ***code to the highest level of specificity to avoid denials.***

Primary Diagnosis Code

ICD-10-CM code[8]	Description[8]
C61	Malignant neoplasm of prostate

Secondary Diagnosis Codes

ICD-10-CM codes[8]	Description[8]
C63	Malignant neoplasm of other and unspecified male genital organs
C69.90	Malignant neoplasm of unspecified site of unspecified eye
C77	Secondary and unspecified malignant neoplasm of lymph nodes
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.3	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified

Please see Important Safety Information on pages 18 and 19.
Please see full Prescribing Information.

Secondary Diagnosis Codes (continued)

ICD-10-CM codes[8]	Description[8]
C78	Secondary malignant neoplasm of respiratory and digestive organs
C78.0	Secondary malignant neoplasm of lung
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum
C78.2	Secondary malignant neoplasm of pleura
C78.3	Secondary malignant neoplasm of other and unspecified respiratory organs
C78.30	Secondary malignant neoplasm of unspecified respiratory organ
C78.39	Secondary malignant neoplasm of other respiratory organs
C78.4	Secondary malignant neoplasm of small intestine
C78.5	Secondary malignant neoplasm of large intestine and rectum
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C78.8	Secondary malignant neoplasm of other and unspecified digestive organs

Please see Important Safety Information on pages 18 and 19.
Please see full Prescribing Information.

Secondary Diagnosis Codes (continued)

ICD-10-CM codes[8]	Description[8]
C78 (continued)	Secondary malignant neoplasm of respiratory and digestive organs
C78.80	Secondary malignant neoplasm of unspecified digestive organ
C78.89	Secondary malignant neoplasm of other digestive organs
C79	Secondary malignant neoplasm of other and unspecified sites
C79.0	Secondary malignant neoplasm of kidney and renal pelvis
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.1	Secondary malignant neoplasm of bladder and other and unspecified urinary organs
C79.10	Secondary malignant neoplasm of unspecified urinary organs
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.2	Secondary malignant neoplasm of skin
C79.3	Secondary malignant neoplasm of brain and cerebral meninges
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.4	Secondary malignant neoplasm of other and unspecified parts of nervous system

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Secondary Diagnosis Codes (continued)

ICD-10-CM codes[8]	Description[8]
C79 (continued)	Secondary malignant neoplasm of other and unspecified sites
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
C79.49	Secondary malignant neoplasm of other parts of nervous system
C79.5	Secondary malignant neoplasm of bone and bone marrow
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.7	Secondary malignant neoplasm of adrenal gland
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.8	Secondary malignant neoplasm of other specified sites
C79.81	Secondary malignant neoplasm of breast
C79.82	Secondary malignant neoplasm of genital organs
C79.89	Secondary malignant neoplasm of other specified sites
C79.9	Secondary malignant neoplasm of unspecified site
Z19.2	Hormone resistant malignancy status

Please see Important Safety Information on pages 18 and 19.
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Healthcare Common Procedure Coding System (HCPCS) Codes

HCPCS Level II codes are used to identify drugs, supplies, medical procedures, and other services. Payers may also require the National Drug Code. HCPs should contact third-party payers for specific information on their coding, coverage, and payment policies.

HCPCS Level II code[3]	Descriptor[3]	Dosage[3]*	Billing units[3]
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 mCi	200 mCi	200 mCi = 200 billing units†

*160 mCi for dose modification for PLUVICTO.
†1 unit is the lowest billable unit.

Modifiers

JZ and JW modifiers should be applied to drugs payable under Medicare Part B that are described as a "single-dose" container or "single-use" package. HCPs and suppliers are required to report the JZ modifier when billing for drugs from single-dose containers when there are no discarded amounts. The JW modifier will still be required to report if any amount of the drug is discarded.

Modifier[7]‡	Description[7]
JZ	Zero drug amount discarded/not administered to any patient
JW	Drug amount discarded/not administered to any patient

‡Contact the health plan for questions about utilizing JZ/JW modifiers.

National Drug Code (NDC)

Some payers require an NDC, which is a 10- to 11-digit code used to identify a specific drug, such as PLUVICTO, in order to process claims.

10-digit NDC[4]	11-digit NDC[4]	Description[4]
0078-1217-61	**00078-1217-61**	Lutetium Lu 177 vipivotide tetraxetan

Current Procedural Terminology (CPT®) Code

CPT codes are the most widely accepted codes for reporting medical procedures and services under public and private health insurance programs. Below is the applicable code that relates to the administration of PLUVICTO.

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

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Place of Service (POS) Codes

POS codes are used to indicate the setting in which a service was provided. CMS maintains a database of POS codes commonly used in the health care industry. Below are POS codes you may use. Review the full listing of the POS codes on the CMS website and consult your payer's guidance to determine the correct code for your institution.

Service[5]	Code[5]	Description[5]
Office	**11**	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the HCP provides health examinations, diagnosis, and treatment on an ambulatory basis.
On Campus–Outpatient Hospital	**22**	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
Independent Clinic*	**49**	Location, not part of a hospital or covered and not described by any other POS code, that is organized and operated to provide preventive, diagnostic, therapeutic, rehabilitative, or palliative services to outpatients only.

Revenue Codes

Specific forms, such as the UB-04 (CMS-1450), require documentation of revenue codes associated with services provided to patients.

Below are commonly used revenue codes for processing claims for products such as PLUVICTO. This is not an all-inclusive list of revenue codes that could be used, and it is recommended to review individual payer guidance to determine the appropriate codes for PLUVICTO.

Code[6]	Description[6]
0240	All inclusive ancillary, general
0340	Nuclear medicine, general
0342	Nuclear medicine, therapeutic
0344	Nuclear medicine, therapeutic radiopharmaceuticals
0636	Pharmacy, drugs requiring detailed coding

*An independent diagnostic testing facility shall not be allowed to bill for any CPT or HCPCS codes that are solely therapeutic.

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Use the following section as an example of how to complete forms (print or electronic) associated with health insurance claims for PLUVICTO.

General information is provided for each form along with annotated thumbnails to visually identify key sections.

Reminder: The sample claim forms in this section are provided for illustrative purposes only and their use is not a guarantee of reimbursement. It is your responsibility to determine the appropriate codes and submit true and correct claims for the products and services rendered. Contact payers directly for specific information on their coding requirements, coverage policies, payment policies, and fee schedules, if needed.

CMS-1500 Claim Form[9]

The CMS-1500 form is a standard Medicare claim form used by HCPs for the administration of PLUVICTO in the HCP office setting.

Key components of this form are described below and illustrated on the sample form on the following page.

Section	
Item 21	Enter the appropriate primary and secondary diagnosis codes (eg, relevant ICD-10-CM codes)
Item 23	Enter the prior authorization number, if applicable
Item 24A	List the date of service in the non-shaded area. In the shaded area, enter the N4 indicator, then the 11-digit NDC, followed by the unit of measurement and quantity. Do not include dashes. The NDC unit of measure code for PLUVICTO is likely ML (for liquids, solutions, or suspensions).[4] Verify with the payer for specific formatting guidelines. Example: N400078121761ML7.4
Item 24B	Enter the appropriate Place of Service (POS) code to indicate the setting where a service was provided
Item 24D	Enter the appropriate HCPCS code, A9607, for PLUVICTO use as required by the payer.[3] The HCPCS code must be accompanied by the JZ or JW modifier.* Include the appropriate CPT code to report the administration procedure, 79101[3]
Item 24E	Enter the diagnosis code reference letter as shown in Item 21 to relate the date of service and the procedures performed to the primary diagnosis. If there is more than one diagnosis required for a procedure code, only reference one letter from Item 21
Item 24G	Include the appropriate number of billing units for PLUVICTO: 200 mCi=200 billing units† and 1 unit for the administration procedure

*Contact the health plan for questions about utilizing JZ/JW modifiers.
†1 unit is the lowest billable unit.

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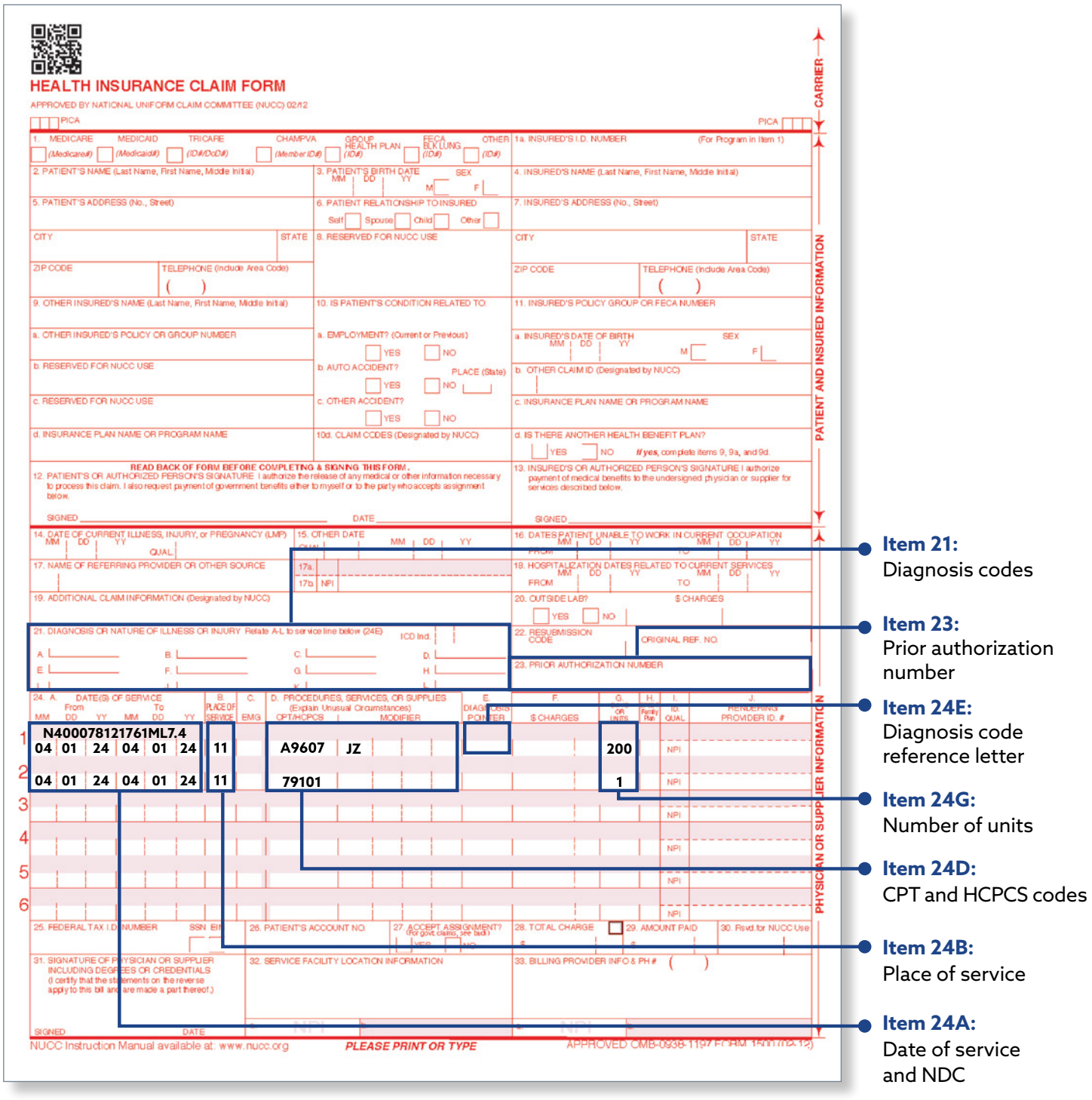
Sample CMS-1500 Claim Form[9]



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)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

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

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

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

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

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

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES 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.

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 QUAL. MM DD YY

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

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

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

A. B. C. D. E. F. G. H. I. J.

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. Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	N400078121761ML7.4														
	04	01	24	04	01	24	11		A9607	JZ			200		NPI
2	04	01	24	04	01	24	11		79101				1		NPI
3															NPI
4															NPI
5															NPI
6															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 Use

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

NPI

33. BILLING PROVIDER INFO & PH # ( )

NPI

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

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

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Item 21:
Diagnosis codes

Item 23:
Prior authorization number

Item 24E:
Diagnosis code reference letter

Item 24G:
Number of units

Item 24D:
CPT and HCPCS codes

Item 24B:
Place of service

Item 24A:
Date of service and NDC

Please see Important Safety Information on pages 18 and 19.
Please see full Prescribing Information.

UB-04 (CMS-1450) Claim Form[10]

The UB-04 form, also known as the CMS-1450 form, is a Medicare claim form used by institutions when PLUVICTO is administered in the inpatient or outpatient setting.

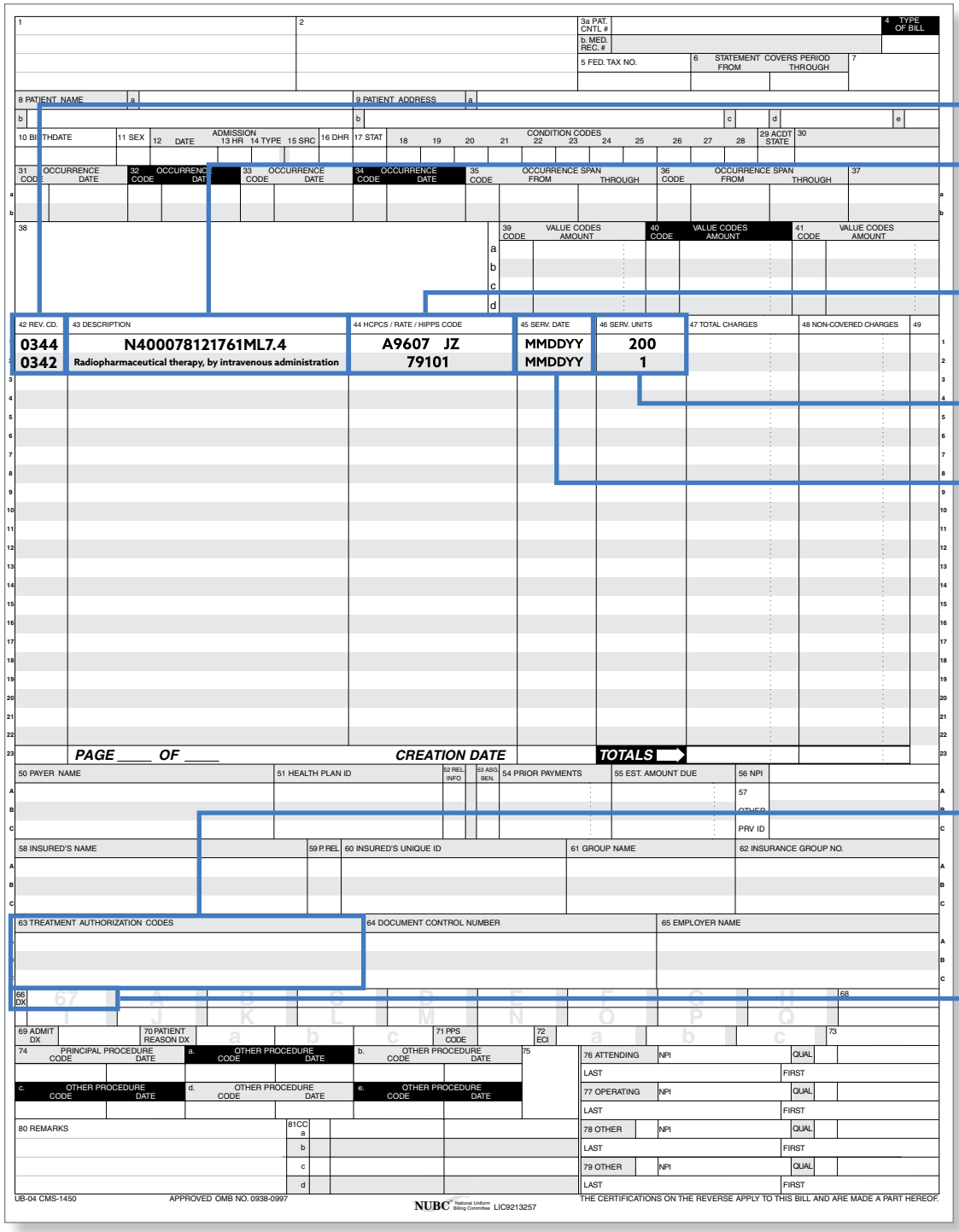
Key components of this form are described below and illustrated on the sample form on the following page.

Section	
Form Locator (FL) 42	Enter the appropriate revenue code corresponding with the HCPCS code in FL 44 (eg, 0344 Nuclear Medicine—Therapeutic Radiopharmaceutical). Then enter the appropriate revenue code corresponding with the CPT code in FL 44 (eg, 0342 Nuclear Medicine—Therapeutic)
FL 43	Enter the revenue code description and NDC. Include the N4 indicator, then the 11-digit NDC, followed by the unit of measurement and quantity. Do not include dashes. The NDC unit of measure code for PLUVICTO is likely ML (for liquids, solutions, or suspensions).[4] Verify with the payer for specific formatting guidelines. Example: N400078121761ML7.4
FL 44	Enter the appropriate HCPCS code, A9607, for PLUVICTO use as required by the payer.[3] The HCPCS code must be accompanied by the JZ or JW modifier.* Include the appropriate CPT code to report the administration procedure, 79101, with a description of Radiopharmaceutical therapy, by intravenous administration[2]
FL 45	Enter the dates of service
FL 46	Include the appropriate number of billing units for PLUVICTO: 200 mCi=200 billing units† and 1 unit for the administration procedure. Some payers may refer to the actual quantity administered via FL 43
FL 63	Enter treatment authorization codes
FL 67	Enter the appropriate primary and secondary diagnosis codes (eg, relevant ICD-10-CM codes)

*Contact the health plan for questions about utilizing JZ/JW modifiers.
†1 unit is the lowest billable unit.

Please see Important Safety Information on pages 18 and 19.
Please see full Prescribing Information.

Sample UB-04 (CMS-1450) Claim Form[10]



42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0344	N400078121761ML7.4	A9607 JZ	MMDDYY	200		
0342	Radiopharmaceutical therapy, by intravenous administration	79101	MMDDYY	1		

PAGE ____ OF ____ CREATION DATE TOTALS

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC® National Uniform Billing Committee LIC9213257 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

FL 42:
Revenue codes

FL 43:
Revenue code description, N4 indicator and NDC

FL 44:
CPT and HCPCS codes

FL 46:
Number of units

FL 45:
Dates of service

FL 63:
Treatment authorization codes

FL 67:
Diagnosis codes

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Prior Authorizations (PAs)

PAs are meant to demonstrate to the payer that the health plan's specific requirements have been met or explain why PLUVICTO is the most appropriate treatment for the patient. It is important to review a payer's guidelines when completing a PA, as these requirements often differ between payers, health plans, prescribed medications, and more.

Checklist for completing a PA

- ✓ Patient's name, date of birth, insurance ID number, insurance group number, and dates of service
- ✓ Patient's diagnosis and corresponding ICD-10-CM code(s)
- ✓ List of previous therapies
- ✓ Make sure to include CPT code 79101 (a separate PA may be required for CPT code 79101: Radiopharmaceutical therapy, by intravenous administration. Consult the payer directly for more information)

It may also be necessary to include the following information at the request of the payer:

- ✓ Physician information, including name and tax ID number
- ✓ Facility information, including name and tax ID number
- ✓ Setting of care
- ✓ Date of service
- ✓ Patient clinical notes detailing relevant diagnosis
- ✓ Supporting documentation for treatment decisions, including laboratory and imaging results
- ✓ Relevant codes, specifically CPT and HCPCS, for services/products to be performed or provided
- ✓ PLUVICTO Prescribing Information

AVOID DELAYS IN TREATMENT. Missing or incomplete information or documentation can lead to a PA being denied. Ensure all requested PA information is included, such as prior treatment history, testing history, and necessary code(s).

For more information on PAs and appeals for PLUVICTO visit pluvicto-hcp.com/psma-positive-mcrpc/novartis-patient-support or call 1-844-638-7222.

Please see Important Safety Information on pages 18 and 19.
Please see full Prescribing Information.

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Appeals

If a patient is denied coverage for PLUVICTO, it is important to first review the denial letter and understand the payer's reason for denial, which is often related to the coverage policy or clinical appropriateness. You can then explain your clinical rationale for prescribing PLUVICTO through a Letter of Appeal. This letter should address each specific reason cited in the denial letter and demonstrate why the health plan's preferred or on-formulary treatment options do not represent the most appropriate treatment for the patient.

It is also important to review the remittance advice (RA), which will indicate where the appeal should be filed, which form to use, and any specific deadlines.

Checklist for completing an appeal

- ✓ Patient's name, date of birth, insurance ID number, insurance group number, and dates of service
- ✓ Patient's diagnosis and corresponding ICD-10-CM code(s)
- ✓ Copies of relevant medical records
- ✓ Clinical support for prescribing PLUVICTO
- ✓ A list of previous therapies, their duration, and explanation for discontinuation
- ✓ A Letter of Medical Necessity and the US Food and Drug Administration approval letter for PLUVICTO

It may also be necessary to include the following information at the request of the payer:

- ✓ Reference number of existing claim decision, if applicable
- ✓ Patient authorization and Notice of Release of Information
- ✓ Denial information, including the denial letter or RA notification
- ✓ Other supporting documentation, such as chart notes, current medications, and laboratory results

For more information on PAs and appeals for PLUVICTO visit pluvicto-hcp.com/psma-positive-mcrpc/novartis-patient-support or call 1-844-638-7222.

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Indication

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibition (ARPI) therapy, and

- are considered appropriate to delay taxane-based chemotherapy, or
- have received prior taxane-based chemotherapy

IMPORTANT SAFETY INFORMATION

Risk From Radiation Exposure

PLUVICTO contributes to a patient's long-term cumulative radiation exposure, which is associated with an increased risk for cancer.

Minimize radiation exposure to patients, medical personnel, and others during and after treatment with PLUVICTO consistent with institutional practices, patient treatment procedures, Nuclear Regulatory Commission patient-release guidance, and instructions to the patient for follow-up radiation protection.

Ensure patients increase oral fluid intake and advise them to void as often as possible to reduce bladder radiation.

To minimize radiation exposure to others, advise patients to limit close contact (less than 3 feet) with household contacts for 2 days or with children and pregnant women for 7 days, to refrain from sexual activity for 7 days, and to sleep in a separate bedroom from household contacts for 3 days, from children for 7 days, or from pregnant women for 15 days.

Myelosuppression

PLUVICTO can cause severe and life-threatening myelosuppression. In the PSMAfore study, grade 3 or 4 decreased hemoglobin (7%), decreased leukocytes (4.4%), decreased neutrophils (3.5%), and decreased platelets (2.7%) occurred in patients treated with PLUVICTO. One death occurred due to bone marrow failure during long-term follow-up in a patient who received PLUVICTO. In the VISION study, 4 myelosuppression-related deaths occurred.

Perform complete blood counts before and during treatment with PLUVICTO. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity of myelosuppression.

Renal Toxicity

PLUVICTO can cause severe renal toxicity. In the PSMAfore study, grade 3 or 4 acute kidney injury (1.3%) occurred in patients treated with PLUVICTO.

Advise patients to remain well hydrated and to urinate frequently before and after administration of PLUVICTO. Perform kidney function laboratory tests, including serum creatinine and calculated creatinine clearance (CrCl), before and during treatment. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity of renal toxicity.

Please see additional Important Safety Information on the following page.
Please see full Prescribing Information.

IMPORTANT SAFETY INFORMATION (continued)

Embryo-Fetal Toxicity

The safety and efficacy of PLUVICTO have not been established in females. Based on its mechanism of action, PLUVICTO can cause fetal harm. No animal studies using lutetium Lu 177 vipivotide tetraxetan have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, radioactive emissions, including those from PLUVICTO, can cause fetal harm. Advise males with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose.

Infertility

The recommended cumulative dose of 44.4 GBq of PLUVICTO results in a radiation-absorbed dose to the testes within the range where PLUVICTO may cause temporary or permanent infertility.

Adverse Reactions and Laboratory Abnormalities

In the pooled safety population for the PSMAfore and VISION studies (N=756), the most common (≥20%) adverse reactions, including laboratory abnormalities, were decreased lymphocytes (83%), decreased hemoglobin (65%), fatigue (49%), dry mouth (46%), decreased platelets (40%), decreased estimated glomerular filtration rate (37%), nausea (35%), decreased neutrophils (31%), decreased calcium (29%), decreased sodium (27%), increased aspartate aminotransferase (26%), increased alkaline phosphatase (24%), arthralgia (22%), decreased appetite (21%), increased potassium (21%), constipation (21%), and back pain (21%).

Please see additional Important Safety Information on the previous page.
Please see full Prescribing Information.

Novartis Patient Support is a comprehensive program that is designed to help your patients start, stay, and save on PLUVICTO.

After enrollment, Novartis Patient Support can assist with:

Benefits investigation

Once you've enrolled your patients in Novartis Patient Support, our team will conduct a benefits investigation to better understand your patients' coverage.

Prior authorization information

We'll help support your practice through the prior authorization and appeals processes to help you navigate access to PLUVICTO treatment.

Financial Support

Co-pay savings* are available for patients with private insurance

We help make PLUVICTO treatment more affordable for your eligible patients through co-pay savings.

Co-pay savings start with enrollment

Eligible patients are considered for co-pay savings when they enroll in Novartis Patient Support. Ensure that patients have completed and signed the Enrollment Form for Novartis Patient Support to activate eligibility assessment.

To complete and submit an Enrollment Form, visit **pluvicto-hcp.com/psma-positive-mcrpc/novartis-patient-support** or call us at **1-844-638-7222**.

Additional financial support may be available for patients without private insurance

To find out if patients are eligible for PLUVICTO treatment through other financial support, call Novartis Patient Support at **1-844-638-7222**, Monday through Friday, 8 AM to 8 PM ET.

*Limitations apply. Valid only for those patients with commercial insurance. Not valid under Medicare or any other federal or state program. Offer subject to a maximum benefit per course of treatment. See complete Terms and Conditions in the Enrollment Forms for details.

References: 1. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS). Accessed September 24, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system **2.** Buy and Bill. Radiopharmaceutical Therapy - 79101 - Code and Cost Information. Accessed December 8, 2025. https://buyandbill.com/radiopharmaceutical-therapy-79101/ **3.** Centers for Medicare & Medicaid Services. CMS HCPCS Application Summaries and Coding Recommendations: Second Quarter, 2022 HCPCS Coding Cycle. Accessed December 4, 2025. https://www.cms.gov/files/document/2022-hcpcs-application-summary-quarter-2-2022-drugs-and-biologicals-updated-07192022.pdf **4.** Pluvicto. Prescribing information. Novartis Pharmaceuticals Corp. **5.** Centers for Medicare & Medicaid Services. Place of service codes for professional claims. Accessed November 18, 2025. https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/downloads/website-pos-database.pdf **6.** Noridian Healthcare Solutions. Revenue codes. Accessed December 4, 2025. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **7.** Centers for Medicare & Medicaid Services. Discarded drugs and biologicals—JW modifier and JZ modifier policy: Frequently asked questions. Accessed November 18, 2025. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **8.** Centers for Medicare and Medicaid Services. ICD-10-CM. Accessed December 4, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes **9.** Centers for Medicare & Medicaid Services. Professional paper claim form (CMS-1500). Accessed November 19, 2025. https://www.cms.gov/medicare/coding-billing/electronic-billing/professional-paper-claim-form **10.** Centers for Medicare & Medicaid Services. Institutional paper claim form (CMS-1450). Accessed November 19, 2025. https://www.cms.gov/medicare/coding-billing/electronic-billing/institutional-paper-claim-form

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