PLUVICTO™
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

Coding and Reimbursement

OCTOBER 2022

NEED MORE INFORMATION?

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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 (AR) pathway inhibition and taxane-based chemotherapy.

HIGHLIGHTS OF IMPORTANT SAFETY INFORMATION

Risk From Radiation Exposure

PLUVICTO contributes to a patient's overall long-term cumulative radiation exposure, which is associated with an increased risk for cancer. Ensure patients increase oral fluid intake and advise patients to void as often as possible to reduce bladder radiation. Minimize radiation exposure during and after treatment with PLUVICTO consistent with institutional good radiation safety practices and patient treatment procedures.

Please see Important Safety Information on pages 17 and 18.
Please see full Prescribing Information.

Introduction

Advanced Accelerator Applications (AAA) has developed this resource to provide you and your office staff general coding and reimbursement information for PLUVICTO™ (lutetium Lu 177 vipivotide tetraxetan).

This resource contains information about:

General Best Practices ..... *page 3*
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Completing Prior Authorizations and Appeals ..... *page 15*
Support With AAA PatientCONNECT™ ..... *page 19*

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

Disclaimers

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

- Laws, regulations, and policies concerning reimbursement are complex and updated frequently
  - While AAA 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 AAA about coverage, levels of reimbursement, payment, or charge
- Consult the payer organization(s) for coverage and reimbursement policies and determination processes
- Consult with your internal reimbursement specialist for 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. AAA 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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General Best Practices

Appropriate reimbursement for the administration of PLUVICTO™ (lutetium Lu 177 vipivotide tetraxetan) depends on accurate coding and documentation. The following information is designed to provide important tips to consider when filing a claim for PLUVICTO.

- ✓ 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
  - ☐ 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 is accurate
- ✓ File claim in a timely manner
- ✓ Complete a PA form if required by payer
- ✓ 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 www.aaapatientconnect.com or call 1-844-638-7222.

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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Product Details

The following key details about PLUVICTO™ (lutetium Lu 177 vipivotide tetraxetan) are included to provide context concerning patient access, coding, and reimbursement.[1]

Indication

PLUVICTO is a 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 (AR) pathway inhibition and 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.

How Supplied

NDC: 69488-010-61
Dosage form and strength: 1000 MBq/mL (27 mCi/mL) in a single-dose vial.

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.

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Coding and Billing

Coding and billing are essential to the patient access journey. This guide provides information on coding and classifying your patient's diagnosis and treatment, which may be required for reimbursement.

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™ (lutetium Lu 177 vipivotide tetraxetan). You should review the payer's guidance to ensure appropriate codes are selected based on the patient's medical record.

Primary Diagnosis Code

ICD-10-CM code[2]	Description[2]
C61	Malignant neoplasm of prostate

Secondary Diagnosis Codes

ICD-10-CM codes[2]	Description[2]
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

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Coding and Billing (continued)

Diagnosis Codes (continued)

Secondary Diagnosis Codes (continued)

ICD-10-CM codes[2]	Description[2]
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified
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

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Coding and Billing (continued)

Diagnosis Codes (continued)

Secondary Diagnosis Codes (continued)

ICD-10-CM codes[2]	Description[2]
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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Coding and Billing (continued)

Diagnosis Codes (continued)

Secondary Diagnosis Codes (continued)

ICD-10-CM codes[2]	Description[2]
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 17 and 18.
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Coding and Billing (continued)

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. Health care professionals (HCPs) should contact third-party payers for specific information on their coding, coverage, and payment policies.

Effective October 1, 2022:

Code[3]	Description[3]	Lowest billable unit[3]
A9607	Lutetium lu 177 vipivotide tetraxetan, therapeutic	1 millicurie

Prior to October 1, 2022, a not otherwise classified (NOC) HCPCS code was required in the absence of a product-specific code. A9699 (Radiopharmaceutical, therapeutic; not otherwise classified) was used for commercial insurers and C9399 (Unclassified drugs or biologicals) was used for Medicare.

Additionally, **the Centers for Medicare & Medicaid Services (CMS) has granted PLUVICTO™ (lutetium Lu 177 vipivotide tetraxetan) transitional pass-through status effective October 1, 2022**. Transitional pass-through status is a temporary payment policy granted by CMS under the Hospital Outpatient Prospective Payment System as indicated by status indicator "G". This only applies when PLUVICTO is administered to Medicare patients in the hospital outpatient setting.

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 number[1]	11-digit NDC number[1]	Description[1]
69488-010-61	69488-0010-61	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[4]	Code[4]	Description[4]
Administration of PLUVICTO	79101	Radiopharmaceutical therapy, by intravenous administration

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Coding and Billing (continued)

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™ (lutetium Lu 177 vipivotide tetraxetan). 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]
240	All inclusive ancillary, general
340	Nuclear medicine, general
342	Nuclear medicine, therapeutic
344	Nuclear medicine, therapeutic radiopharmaceuticals
636	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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Sample Claim Forms

Use the following section as an example of how to complete forms (print or electronic) associated with health insurance claims for PLUVICTO™ (lutetium Lu 177 vipivotide tetraxetan). 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

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	
Box 19*	Enter the drug name, route of administration, and dose administered (do not use any punctuation in the box)
Box 21	Enter the appropriate diagnosis codes (eg, relevant ICD-10-CM codes)
Box 24B	Enter the appropriate code to indicate the setting where a service was provided
Box 24D	Enter the appropriate CPT code(s) and HCPCS code
Box 24G	Enter the appropriate number of units for PLUVICTO

*Some payers may require associated costs. Please consult your specific payer.

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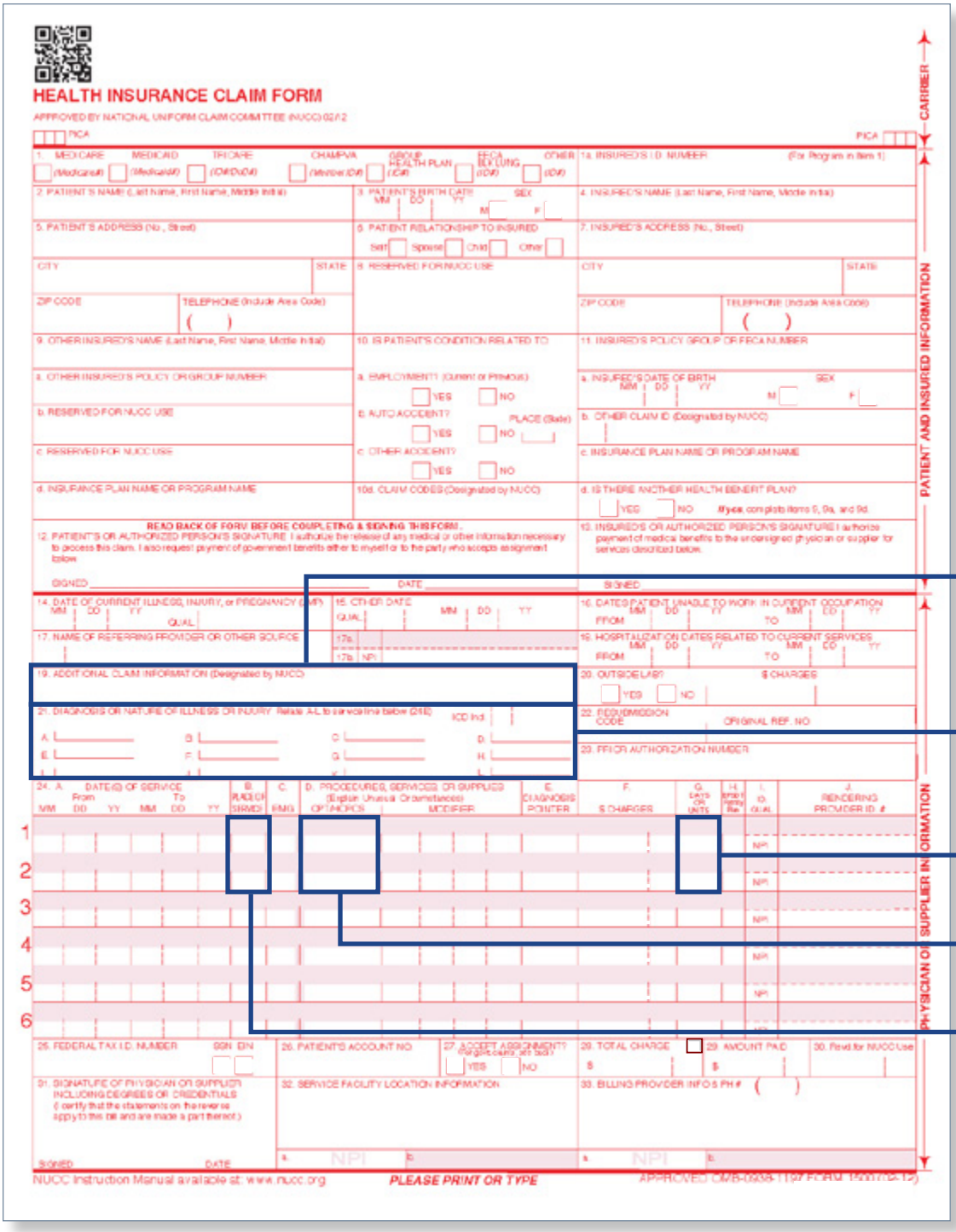
Sample Claim Forms (continued)

Sample CMS-1500 Claim Form



BOX 19:
Drug name, route of administration, and dose administered

BOX 21:
Diagnosis codes

BOX 24G:
Number of units

BOX 24D:
CPT and HCPCS codes

BOX 24B:
Place of service

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Sample Claim Forms (continued)

UB-04 (CMS-1450) Claim Form

The UB-04 form, also known as the CMS-1450 form, is a Medicare claim form used by institutions when PLUVICTO™ (lutetium Lu 177 vipivotide tetraxetan) 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	
Box 42	Enter the appropriate revenue codes corresponding to the HCPCS code in Box 44
Box 43	Enter the description corresponding to the revenue codes in Box 42
Box 44	Enter the appropriate CPT code(s) and HCPCS code
Box 45	Enter the dates of service
Box 46	Enter the appropriate number of units for PLUVICTO
Box 67	Enter the appropriate diagnosis codes (eg, relevant ICD-10-CM codes)
Box 80*	Enter drug-identifying information as required by the payer (eg, drug name, NDC 11-digit format, dosage, method of administration)

*Some payers may require associated costs. Please consult your specific payer.

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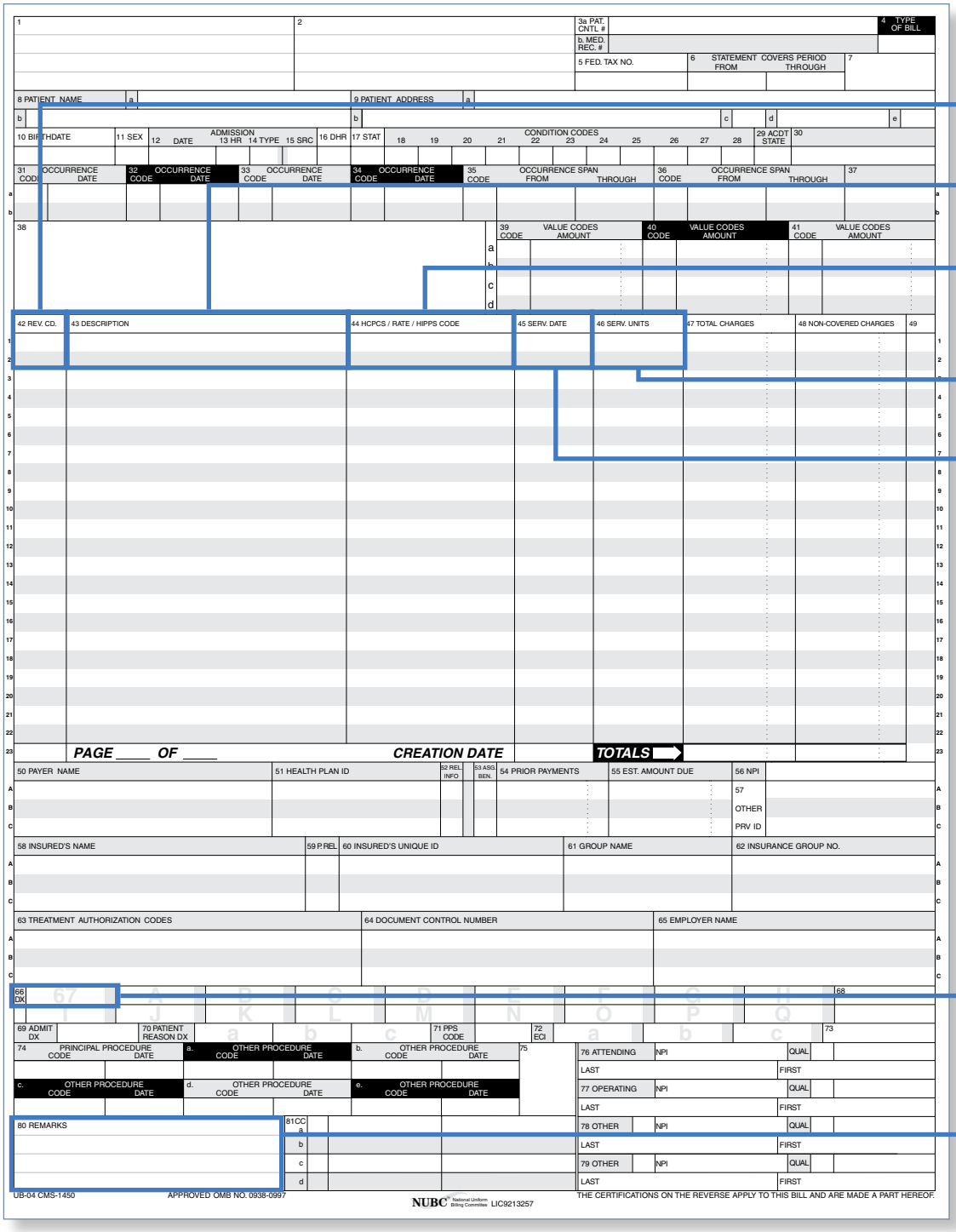
Sample Claim Forms (continued)

Sample UB-04 (CMS-1450) Claim Form



BOX 42:
Revenue codes

BOX 43:
Revenue code descriptions

BOX 44:
CPT and HCPCS codes

BOX 46:
Number of units

BOX 45:
Dates of service

BOX 67:
Diagnosis codes

BOX 80:
Drug-identifying information

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Completing Prior Authorizations and Appeals

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™ (lutetium Lu 177 vipivotide tetraxetan) 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

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 FURTHER 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 www.aaapatientconnect.com or call 1-844-638-7222.

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Completing Prior Authorizations and Appeals (continued)

Appeals

If a patient is denied coverage for PLUVICTO™ (lutetium Lu 177 vipivotide tetraxetan), 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 Explanation of Benefits, 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 Explanation of Benefits notification
- ✓ Other supporting documentation, such as chart notes, current medications, and laboratory results

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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 household contacts 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 VISION study, grade 3 or 4 decreased hemoglobin (15%), decreased platelets (9%), decreased leukocytes (7%), and decreased neutrophils (4.5%) occurred in patients treated with PLUVICTO. Grade ≥3 pancytopenia occurred in 1.1% of patients (including 2 fatal events). Two deaths (0.4%) due to intracranial hemorrhage and subdural hematoma in association with thrombocytopenia were observed. One death due to sepsis and concurrent neutropenia was observed.

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

Renal Toxicity

PLUVICTO can cause severe renal toxicity. In the VISION study, grade 3 or 4 acute kidney injury (3%) and increased creatinine (0.9%) 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.

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IMPORTANT SAFETY INFORMATION (continued)

Embryo-Fetal Toxicity

The safety and efficacy of PLUVICTO™ (lutetium Lu 177 vipivotide tetraxetan) 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, all radiopharmaceuticals, including PLUVICTO, have the potential to cause fetal harm. Advise male patients 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

The most common adverse reactions (≥20%) occurring at a higher incidence in patients who received PLUVICTO plus best standard of care (BSoC) were fatigue, dry mouth, nausea, anemia, decreased appetite, and constipation. Clinically relevant adverse reactions in <5% of patients included dry eye, vertigo, and pancytopenia (including bicytopenia).

Laboratory Abnormalities

The most common laboratory abnormalities that worsened from baseline in ≥30% of patients who received PLUVICTO plus BSoC were decreased lymphocytes, decreased hemoglobin, decreased leukocytes, decreased platelets, decreased calcium, and decreased sodium.

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Support With AAA PatientCONNECT™

AAA PatientCONNECT™ is a patient-centric support program committed to delivering assistance to eligible patients undergoing radioligand therapy.

After enrollment, AAA PatientCONNECT™ can assist with:

- Benefits verification
- Prior authorization information
- Financial assistance options
- Product ordering
- Reimbursement information

Speak with a AAA PatientCONNECT™ Patient Navigator today.

PHONE: 1-844-638-7222 *VISIT:* www.aaapatientconnect.com

References: 1. PLUVICTO [prescribing information]. Millburn, NJ: Advanced Accelerator Applications. **2.** Centers for Medicare & Medicaid Services. [2022] ICD-10-CM tabular list of diseases and injuries. https://www.cms.gov/medicare/icd-10/2022-icd-10-cm. Accessed [August 31, 2022]. **3.** Centers for Medicare & Medicaid Services. Second quarter, [2022] HCPCS coding cycle. https://www.cms.gov/files/document/2022-hcpcs-application-summary-quarter-2-2022-drugs-and-biologicals.pdf. Accessed [August 31, 2022]. **4.** American Medical Association. *CPT Professional Edition.* Chicago, IL; [2021]. **5.** Centers for Medicare & Medicaid Services. Place of service code set. https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set. Accessed [August 31, 2022]. **6.** Noridian Healthcare Solutions. Revenue codes. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes. Accessed [August 31, 2022].

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