PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

PLUVICTO At A Glance

First and Only Radioligand Therapy for Patients With Previously Treated PSMA+ mCRPC

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.

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.

PLUVICTO® Product Specification Guide	
NDC[1]	69488-010-61
Price (WAC)	$45,517.50 per dose (200 mCi)
HCPCS code[2]	A9607 Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 mCi
CPT® code[3]	79101 Radiopharmaceutical therapy, by intravenous administration
Nomenclature[1]	Radioligand therapeutic agent
Dosage and administration[1]	Recommended dosage is 7.4 GBq (200 mCi) intravenously every 6 weeks for up to 6 doses, or until disease progression, or unacceptable toxicity[a]

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; mCRPC, metastatic castration-resistant prostate cancer; NDC, National Drug Code; PSMA+, prostate-specific membrane antigen positive; WAC, wholesale acquisition cost.

[a] Please see full Prescribing Information for complete information on dosing and administration, including safe handling of radiopharmaceuticals, premedication and concomitant medications, and dose modifications for adverse reactions.

Additionally, **the Centers for Medicare & Medicaid Services (CMS) has granted PLUVICTO 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.

It is the health care professional's responsibility to determine and submit accurate information on claims and comply with payer coverage, reimbursement, and claim submission rules. These codes are provided for informational purposes only. 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.

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

PLUVICTO® Product Specification Guide (continued)

Storage and handling[1]	• Shelf life is 120 hours (5 days) from the date and time of calibration • 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

IMPORTANT SAFETY INFORMATION (continued)

Risk From Radiation Exposure (continued)

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.

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, 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.

Please see full Prescribing Information.

References: 1. Pluvicto. Prescribing information. Advanced Accelerator Applications. **2.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated May 24, 2023. Accessed June 16, 2023. https://www.cms.gov/medicare/coding/hcpcsreleasecodesets/hcpcs-quarterly-update **3.** American Medical Association. CPT® (Current Procedural Terminology). Accessed June 16, 2023. https://www.ama-assn.org/practice-management/cpt-current-procedural-terminology

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