PLUVICTO AT A GLANCE

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

First Radioligand Therapy for Patients With PSMA-Positive mCRPC Previously Treated With Only 1 ARPI

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.

PLUVICTO PRODUCT SPECIFICATION GUIDE

NDC[1]	0078-1217-61
Price (WAC)	$51,168.13 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 6 doses, or until disease progression, or unacceptable toxicity†

ARPI, androgen receptor pathway inhibitor; CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code; WAC, wholesale acquisition cost.

*Effective January 7, 2026.

† 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 transitional pass-through status that CMS granted PLUVICTO expired on September 30, 2025**.

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 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.

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 full Prescribing Information.

References: 1. Pluvicto. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated September 23, 2025. Accessed October 28, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **3.** American Medical Association. CPT® (Current Procedural Terminology). Accessed October 28, 2025. https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080