PLUVICTO AT A GLANCE

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

The first and only PSMA-targeted therapy approved for patients with mAPMN/S & mAPMR prostate cancer (also known as mHSPC and mCRPC)

Indications

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is indicated in combination with androgen receptor pathway inhibitor (ARPI) therapy for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer.

PLUVICTO is indicated for the treatment of adult patients with PSMA-positive metastatic androgen pathway modulation-resistant (mAPMR) prostate cancer who have been treated with 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.

PLUVICTO PRODUCT SPECIFICATION GUIDE

NDC[1]	0078-1217-61
Price (WAC)[2]	$52,703.17 per dose (200 mCi)*
HCPCS code[3]	A9607 lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 mCi
CPT® code[4]	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†

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; mAPMN/S, metastatic androgen pathway modulation-naïve or -sensitive; mAPMR, metastatic androgen pathway modulation-resistant; mCi, millicurie; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; NDC, National Drug Code; PSMA, prostate-specific membrane antigen; WAC, wholesale acquisition cost.

*Effective July 1, 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)

- 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 others 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 room from others 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 clinical trials (PSMAddition, PSMAfore, VISION) grade 3 or 4 decreased hemoglobin (ranged from 4.3-15%), decreased leukocytes (4.4-7%), decreased neutrophils (3.5-4.5%), and decreased platelets (1.1-9%) occurred in patients treated with PLUVICTO. 5 myelosuppression-related deaths have occurred, including one due to bone marrow failure during long-term follow-up.
- 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 clinical trials grade 3 or 4 acute kidney injury (ranged from 1.3-3.4%) 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 PSMAddition, PSMAfore and VISION studies (N=1320), the most common (≥20%) adverse reactions, including laboratory abnormalities, were decreased lymphocytes (86%), decreased hemoglobin (68%), fatigue (51%), dry mouth (46%), decreased neutrophils (35%), nausea (35%), decreased platelets (33%), decreased estimated glomerular filtration rate (28%), increased aspartate aminotransferase (25%), decreased sodium (22%), increased magnesium (22%), increased potassium (21%), decreased calcium (21%), and increased alkaline phosphatase (20%).

Please see full Prescribing Information.

References: 1. Pluvicto. Prescribing information. Novartis Pharmaceuticals Corp. **2.** RED BOOK Online. Merative Micromedex® [database online]; 2026. Accessed July 10, 2026. https://www.micromedexsolutions.com **3.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Accessed May 6, 2026. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **4.** American Medical Association. Current Procedural Terminology (CPT®) code set. Accessed May 6, 2026. https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080