Pluvicto® (lutetium Lu 177 vipivotide tetraxetan) (Intravenous)

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I. Length of Authorization [1]

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), 4 doses.
- Renewal: Prior authorization validity may be renewed for 45 days to provide for 2 additional doses. The total number of doses authorized cannot exceed 6 doses.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 200 billable units (7.4 GBq = 200 mCi) every 6 weeks for a total of 6 doses

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**
- Member has been screened for prostate-specific membrane antigen (PSMA) expression in tumors via an FDA-approved PSMA positron emission tomography (PET) product (e.g., F-18 piflufolastat PSMA, F-18 flotufolastat PSMA, Ga-68 PSMA-11, etc.); **AND**

Universal Criteria [1-3]

- Member will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy; **AND**

Prostate Cancer † ‡ [1-4,7]

- Member has metastatic castration-resistant prostate cancer (mCRPC); **AND**
  - Member has at least one PSMA-positive lesion and/or predominately PSMA-positive disease; **AND**
  - Member has no dominant PSMA-negative metastatic lesions; **AND**
  - Member has been previously treated with an androgen receptor-directed therapy (e.g., enzalutamide, abiraterone, darolutamide, apalutamide, etc.); **AND**
    - Member has received prior taxane-based chemotherapy; **OR**
    - Member is considered appropriate to delay taxane-based chemotherapy; **OR**
- Member has metastatic androgen pathway modulation-naïve or -sensitive prostate cancer (mAPMN/S); **AND**

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- Member has PSMA-positive disease; **AND**
- Used in combination with androgen receptor pathway inhibitor (ARPI) therapy

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelosuppression (e.g., anemia, thrombocytopenia, leukopenia, neutropenia), severe renal toxicity, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or at least a partial response

V. Dosage/Administration [1]

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

VI. Billing Code/Availability Information

HCPCS code:

- A9607 – Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie; 1 billable unit = 1 millicurie

NDC:

- Pluvicto 1,000 MBq/mL (27 mCi/mL) of lutetium Lu 177 vipivotide tetraxetan 30 mL single-dose vial containing 7.4 GBq (200 mCi): 00078-1217-XX

VII. References

1. Pluvicto [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; July 2026. Accessed August 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) lutetium lu 177 vipivotide tetraxetan. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most

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recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2026.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 6.2026. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2026.
4. Sartor O, de Bono J, Chi KN, et al; VISION Investigators. Lutetium-177-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer. N Engl J Med. 2021 Sep 16;385(12):1091-1103. Doi: 10.1056/NEJMoa2107322. Epub 2021 Jun 23.
5. Morris MJ, Castellano D, Herrmann K, et al; PSMAfore Investigators. 177Lu-PSMA-617 versus a change of androgen receptor pathway inhibitor therapy for taxane-naive patients with progressive metastatic castration-resistant prostate cancer (PSMAfore): a phase 3, randomised, controlled trial. Lancet. 2024 Sep 28;404(10459):1227-1239. doi: 10.1016/S0140-6736(24)01653-2. Epub 2024 Sep 15. Erratum in: Lancet. 2025 Dec 21;404(10471):2542. doi: 10.1016/S0140-6736(24)02716-8. PMID: 39293462.
6. Sartor O, Castellano Gauna DE, Herrmann K, et al. LBA_{13} Phase III trial of [177Lu]Lu-PSMA-617 in taxane-naive patients with metastatic castration-resistant prostate cancer (PSMAfore). Annals of Oncology, Volume 34, S1324 - S1325.
7. Tagawa ST, Sartor O, Piulats JM, et al. [177Lu]Lu-PSMA-617 in patients with PSMA-positive metastatic androgen pathway modulator-naive/sensitive prostate cancer (PSMAddition): a phase 3 randomised, controlled trial. The Lancet 2026 Aug 06; 0140-6736, doi.org/10.1016/S0140-6736(26)01092-5.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	Wellpoint Federal
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	Wellpoint Federal
15	KY, OH	CGS Administrators, LLC

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