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

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I. Length of Authorization [1]

Coverage will be provided for 6 months (4 doses) and may be renewed 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]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1-3]

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

Prostate Cancer † [1-4]

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

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

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient 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
mCRPC	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. • Select patients with previously treated mCRPC for treatment with Pluvicto using LOCAMETZ or another approved PSMA positron emission tomography (PET) product based on PSMA expression in tumors. ***Note:** Pluvicto is a radiopharmaceutical; handle with appropriate safety measures to minimize radiation exposure. Use waterproof gloves and effective radiation shielding when handling Pluvicto. Radiopharmaceuticals, including Pluvicto, should be used by or under the control of healthcare providers who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals.*

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): 69488-0010-XX

VII. References

1. Pluvicto [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; March 2025. Accessed April 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) lutetium lu 177 vipivotide tetraxetan. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are

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3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 2.2025. National Comprehensive Cancer Network, 2025. 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 April 2025.
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.

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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	National Government Services, Inc. (NGS)
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	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC