

Medical Policy:

Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.358	February 27, 2025	June 27, 2022

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

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Definitions

Pluvicto, radioligand therapeutic agent, is indicated for the treatment of adults with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy.

Length of Authorization

Approve for 1 year

Dosing Limits [Medical Benefit]

Approve 7.4 GBq (200 mCi) intravenously every 6 weeks for up to a maximum of 6 doses (total).

Guideline

1. **Prostate Cancer - Metastatic Castration Resistant (mCRPC).**
 - A. Patient is ≥ 18 years of age; **AND**
 - B. Patient has prostate-specific membrane antigen (PSMA)-positive disease; **AND**
 - C. Patient meets both of the following criteria (i **and** ii):

- i. Patient has tried at least one androgen receptor pathway inhibitor; **AND**
Note: Examples of androgen receptor pathway inhibitor include: abiraterone, Yonsa (abiraterone acetate tablets), Xtandi (enzalutamine tablets or capsules), Erleada (apalutamide tablets), or Nubeqa (darolutamide tablet).
- ii. Patient has tried at least one taxane-based chemotherapy regimen; **AND**
Note: Examples of taxane-based chemotherapy regimen include: docetaxel or Jevtana (cabazitaxel intravenous infusion).
- D. Patient meets one of the following criteria (i **or** ii):
 - i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog; **OR**
Note: Examples of GnRH analog include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), or Orgovyx (relugolix tablet).
 - ii. Patient has had a bilateral orchiectomy; **AND**
- E. The medication is prescribed by or in consultation with an oncologist.

Dosing/Administration:

The recommended dose of Pluvicto is 7.4 GBq (200 mCi) intravenously every 6 weeks for up to 6 doses, or until disease progression or unacceptable toxicity.

Applicable Procedure Codes

Code	Description
A9607	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie

Applicable NDCs

Code	Description
69488-0010-61	Pluvicto (lutetium Lu 177 vipivotide tetraxetan) 27MCl/mL Solution (single dose vial)

ICD-10 Diagnoses

Code	Description
C61	Malignant neoplasm of prostate

Revision History

Company(ies)	DATE	REVISION
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EmblemHealth & ConnectiCare	2/27/2025	<p>Annual Review: removed A9699, added A9607. No criteria changes.</p> <p>Removed:</p> <table border="1"> <tr> <td>C63</td> <td>Malignant neoplasm of other and unspecified male genital organs</td> </tr> <tr> <td>C69.90</td> <td>Malignant neoplasm of unspecified site of unspecified eye</td> </tr> <tr> <td>C77</td> <td>Secondary and unspecified malignant neoplasm of lymph nodes</td> </tr> <tr> <td>C77.0</td> <td>Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck</td> </tr> <tr> <td>C77.1</td> <td>Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes</td> </tr> <tr> <td>C77.2</td> <td>Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes</td> </tr> <tr> <td>C77.3</td> <td>Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes</td> </tr> <tr> <td>C77.4</td> <td>Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes</td> </tr> <tr> <td>C77.5</td> <td>Secondary and unspecified malignant neoplasm of 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		C79.10	Secondary malignant neoplasm of unspecified urinary organs
		C79.11	Secondary malignant neoplasm of bladder
		C79.19	Secondary malignant neoplasm of other urinary organs
		C79.2	Secondary malignant neoplasm of skin
		C79.3	Secondary malignant neoplasm of brain and cerebral meninges
		C79.31	Secondary malignant neoplasm of brain
		C79.32	Secondary malignant neoplasm of cerebral meninges
		C79.4	Secondary malignant neoplasm of other and unspecified parts of nervous system
		C79.40	Secondary malignant neoplasm of unspecified part of nervous system
		C79.49	Secondary malignant neoplasm of other parts of nervous system
		C79.5	Secondary malignant neoplasm of bone and bone marros
		C79.51	Secondary malignant neoplasm of bone
		C79.52	Secondary malignant neoplasm of bone marros
		C79.7	Secondary malignant neoplasm of adrenal gland
		C79.70	Secondary malignant neoplasm of unspecified adrenal gland
		C79.71	Secondary malignant neoplasm of right adrenal gland
		C79.72	Secondary malignant neoplasm of left adrenal gland
		C79.8	Secondary malignant neoplasm of other specified sites
		C79.81	Secondary malignant neoplasm of breast
		C79.82	Secondary malignant neoplasm of genital organs
		C79.89	Secondary malignant neoplasm of other specified sites
		C79.9	Secondary malignant neoplasm of unspecified site
		Z19.2	Hormone resistant malignancy status
EmblemHealth & ConnectiCare	1/17/2024	Annual Review: No Criteria Changes	
EmblemHealth & ConnectiCare	5/22/2023	Annual Review: no criteria changes	
EmblemHealth & ConnectiCare	6/27/2022	New Policy	

References

1. Pluvicto™ intravenous infusion [prescribing information]. Millburn, NJ: Advanced Accelerator Applications USA/Novartis; June 2022.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 3.2022 – January 10, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 31, 2022.