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

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) 27MCI/mL Solution (single dose vial)

ICD-10 Diagnoses

Code	Description
C61	Malignant neoplasm of prostate

Revision History

Company(ies)	DATE	REVISION

<table>
<tr>
<td>EmblemHealth &
ConnectiCare</td>
<td>2/27/2025</td>
<td>Annual Review: removed A9699, added A9607. No criteria changes.
Removed:
<table>
<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 unspeficied 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 intrapelvic lymph nodes</td></tr>
<tr><td>C77.8</td><td>Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions</td></tr>
<tr><td>C77.9</td><td>Secondary and unspecified malignant neoplasm of lymph node, unspecified</td></tr>
<tr><td>C78</td><td>Secondary malignant neoplasm of respiratory and digestive organs</td></tr>
<tr><td>C78.0</td><td>Secondary malignant neoplasm of lung</td></tr>
<tr><td>C78.00</td><td>Secondary malignant neoplasm of unspecified lung</td></tr>
<tr><td>C78.01</td><td>Secondary malignant neoplasm of right lung</td></tr>
<tr><td>C78.02</td><td>Secondary malignant neoplasm of left lung</td></tr>
<tr><td>C78.1</td><td>Secondary malignant neoplasm of mediastinum</td></tr>
<tr><td>C78.2</td><td>Secondary malignant neoplasm of pleura</td></tr>
<tr><td>C78.3</td><td>Secondary malignant neoplasm of other and unspecified respiratory organs</td></tr>
<tr><td>C78.30</td><td>Secondary malignant neoplasm of unspecified respiratory organ</td></tr>
<tr><td>C78.39</td><td>Secondary malignant neoplasm of other respiratory organs</td></tr>
<tr><td>C78.4</td><td>Secondary malignant neoplasm of small intestine</td></tr>
<tr><td>C78.5</td><td>Secondary malignant neoplasm of large intestine and rectum</td></tr>
<tr><td>C78.6</td><td>Secondary malignant neoplasm of retroperitoneum and peritoneum</td></tr>
<tr><td>C78.7</td><td>Secondary malignant neoplasm of liver and intrahepatic bile duct</td></tr>
<tr><td>C78.8</td><td>Secondary malignant neoplasm of other and unspecified digestive organs</td></tr>
<tr><td>C78.80</td><td>Secondary malignant neoplasm of unspecified digestive organ</td></tr>
<tr><td>C78.89</td><td>Secondary malignant neoplasm of other digestive organs</td></tr>
<tr><td>C79</td><td>Secondary malignant neoplasm of other and unspecified sites</td></tr>
<tr><td>C79.0</td><td>Secondary malignant neoplasm of kidney and renal pelvis</td></tr>
<tr><td>C79.00</td><td>Secondary malignant neoplasm of unspecified kidney and renal pelvis</td></tr>
<tr><td>C79.01</td><td>Secondary malignant neoplasm of right kidney and renal pelvis</td></tr>
<tr><td>C79.02</td><td>Secondary malignant neoplasm of left kidney and renal pelvis</td></tr>
<tr><td>C79.1</td><td>Secondary malignant neoplasm of bladder and other</td></tr>
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			unspecified urinary organs
		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.