Utilization Review Policy 287

POLICY: Oncology (Injectable) – Pluvicto Utilization Management Medical Policy

- Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan intravenous infusion – Advanced Accelerator Applications/Novartis)

EFFECTIVE DATE: 07/01/2022
LAST REVIEW DATE: 04/09/2025

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Pluvicto, radioligand therapeutic agent, is indicated for the treatment of prostate-specific membrane antigen (PSMA)-positive **metastatic castration-resistant prostate cancer** (mCRPC) in adults who have been treated with androgen receptor pathway inhibition and are considered appropriate to delay taxane-based chemotherapy or have received prior taxane-based chemotherapy.[1]

Dosing Information

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.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer (version 2.2025 – April 16, 2025) lists Pluvicto as "Useful in Certain Circumstances" (category 1) for patients who have received prior docetaxel and prior novel hormone therapy.[2] Pluvicto is also recommended under "Useful in Certain Circumstances" for PSMA-positive metastases after progression on prior novel hormone therapy and no prior docetaxel (category 2A). In a footnote, NCCN notes that Pluvicto is a treatment option for patients with at least one PSMA-positive lesion and/or metastatic disease that is predominantly PSMA-positive and with no dominant PSMA-negative metastatic lesions. It is recommended in patients who have been previously treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Pluvicto. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Pluvicto as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Pluvicto to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Pluvicto is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Prostate Cancer - Metastatic Castration Resistant (mCRPC).** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **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 (i and ii):
     - **i.** Patient has tried at least one androgen receptor pathway inhibitor; AND
       Note: Examples of androgen receptor pathway inhibitors include: abiraterone, Yonsa (abiraterone acetate tablets), Xtandi (enzalutamide tablets or capsules), Erleada (apalutamide tablets), or Nubeqa (darolutamide tablet).
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has tried at least one taxane-based chemotherapy regimen; OR
       - **b)** It is considered appropriate to delay taxane-based chemotherapy; AND
         Note: Examples of taxane-based chemotherapy regimens include: docetaxel or Jevtana (cabazitaxel intravenous infusion).
   - **D)** Patient meets ONE of the following (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), Orgovyx (relugolix tablet).
     - **ii.** Patient has had a bilateral orchiectomy; AND
   - **E)** The medication is prescribed by or in consultation with an oncologist.

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Pluvicto is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Pluvicto™ intravenous infusion [prescribing information]. Millburn, NJ: Advanced Accelerator Applications USA/Novartis; March 2025.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – April 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 22, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	04/12/2023
Annual Revision	No criteria changes	04/24/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	**Prostate Cancer – Metastatic Castration Resistant (mCRPC):** Added criterion "It is considered appropriate to delay taxane-based chemotherapy", based on prescribing information.	04/09/2025
Update	4/22/2025: In the Overview, updated guidelines section.	--