CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Pluvicto Utilization Management Medical Policy
- Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan intravenous infusion – Advanced Accelerator Applications/Novartis)

REVIEW DATE: 04/15/2026; selected revision 09/16/2026

OVERVIEW

Pluvicto, a radioligand therapeutic agent, is indicated for the following uses:[1]

- **Metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer:** Pluvicto in combination with androgen receptor pathway inhibitor (ARPI) therapy for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive disease.
- **Metastatic androgen pathway modulation-resistant (mAPMR) prostate cancer:** Treatment of prostate-specific membrane antigen (PSMA)-positive mAPMR prostate cancer in adults who have been treated with ARPI therapy and are considered appropriate to delay taxane-based chemotherapy or have received prior taxane-based chemotherapy.

Dosing Information

The recommended dose of Pluvicto is 7.4 GBq (200 mCi) intravenously every 6 weeks for 6 doses, or until disease progression or unacceptable toxicity.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer (version 7.2026 – August 27, 2026) recommends Pluvicto for use with androgen deprivation therapy with an ARPI for metastatic castration-sensitive prostate cancer (mCSPC) if PSMA-positive under "Useful in Certain Circumstances" (category 2A).[2] In a footnote NCCN notes that this is an option for patients with mCSPC by CT, MRI, or bone scan who have at least one PSMA-positive metastatic lesion. It is also noted that some Panel members advocate waiting for more mature follow-up data before using this regimen in the mCSPC setting due to the lack of overall survival benefit, moderate acute toxicity, and uncertain late toxicity. Pluvicto is also recommended as "Useful in Certain Circumstances – Disease State-Specific Therapy (category 2A) for patients who have been treated withprior ARPI and before docetaxel therapy. Pluvicto is also recommended for PSMA-positive metastases after progression on prior ARPI therapy and prior docetaxel (category 1). 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 or are considered appropriate to delay 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. 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

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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 Androgen Pathway Modulation-Naïve or Sensitive (mAPMN/S).** 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)** The medication is used in combination with androgen receptor pathway inhibitor; AND
     Note: Examples include abiraterone, Yonsa (abiraterone acetate tablets), Xtandi (enzalutamide tablets or capsules), Erleada (apalutamide tablets), or Nubeqa (darolutamide tablets).
   - **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).

2. **Prostate Cancer – Metastatic Androgen Pathway Modulation-Resistant (mAPMR).** 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 tablets).
     - **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

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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; July 2026.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 7.2026 – August 27, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 11, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/24/2024
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.	--
Annual Revision	No criteria changes.	04/15/2026
Selected Revision	**Prostate Cancer – Metastatic Androgen Pathway Modulation-Naïve or Sensitive (mAPMN/S):** Added new approval condition and criteria. **Prostate Cancer – Metastatic Androgen Pathway Modulation-Resistant (mAPMR):** The indication name was changed to as listed. Previously it was "Prostate Cancer – Metastatic Castration-Resistant (mCRPC)".	09/16/2026

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