Reference number(s)
5330-A

Specialty Guideline Management
Pluvicto

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Pluvicto	lutetium Lu 177 vipivotide tetraxetan

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Pluvicto is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibitor (ARPI) therapy, and

- are considered appropriate to delay taxane-based chemotherapy, or
- have received prior taxane-based chemotherapy

Compendial Uses[2]

PSMA-positive Prostate Cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Documentation

The following documentation must be available, upon request, for all submissions:

Prostate-specific membrane antigen (PSMA) status.

Coverage Criteria

Prostate Cancer[1,2]

Authorization of 6 months (up to 6 total doses) may be granted for treatment of prostate cancer when all of the following criteria are met:

- The member has metastatic castration-resistant prostate cancer.
- The member has been treated with androgen receptor (AR) pathway inhibition (e.g., abiraterone).
- The member has been treated with taxane-based chemotherapy (e.g., docetaxel) or it is appropriate to delay taxane-based chemotherapy.
- The disease is prostate-specific membrane antigen (PSMA)-positive.
- The member has had a bilateral orchiectomy or will be using the requested medication in combination with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix).

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 6 months (up to 6 total doses) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity on the current regimen AND
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Pluvicto.

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- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Prostate cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Pluvicto are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Pluvicto [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2025.
2. The NCCN Drugs & Biologics Compendium™ © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org Accessed August 11, 2025.

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