Reference number(s)
5324-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

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 (AR) pathway inhibition and taxane-based chemotherapy.

Compendial Uses

PSMA-positive Prostate Cancer

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Prostate-specific membrane antigen (PSMA) status.

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Coverage Criteria

Prostate Cancer

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) and taxane-based chemotherapy (e.g., docetaxel).
- 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

Authorization of 6 months (up to 6 total doses) may be granted for continued treatment in members requesting reauthorization for an indication listed in in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Pluvicto [package insert]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; October 2022.
2. The NCCN Drugs & Biologics Compendium™ © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org Accessed August 6, 2024.