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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Antineoplastic Agents	**Original Policy Date:**	April 29, 2022
Subject:	Pluvicto	**Page:**	1 of 4

Last Review Date: June 16, 2022

Pluvicto

Description

Pluvicto (lutetium Lu 177 vipivotide tetraxetan)

Background
Pluvicto (lutetium Lu 177 vipivotide tetraxetan) is a radioligand therapeutic agent. The active moiety is the radionuclide lutetium-177 which is linked to a moiety that binds to prostate-specific membrane antigen (PSMA), a transmembrane protein that is expressed in prostate cancer. Upon binding to these PSMA-expressing cells, the beta-minus emission from lutetium-177 delivers radiation to PSMA-expressing cells, as well as to surrounding cells, and induces DNA damage which can lead to cell death (1).

Regulatory Status
FDA-approved indication: Pluvicto is a radioligand therapeutic agent 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 (1).

Select patients with previous treated mCRPC for treatment with Pluvicto using Locametz or another approved PSMA-11 imaging agent based on PSMA expression in tumors (1).

Pluvicto contains warnings regarding risk from radiation exposure, myelosuppression, renal toxicity, and infertility (1).

Pluvicto can cause fetal harm. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Pluvicto and for 14 weeks after the last dose (1).

The safety and effectiveness of Pluvicto in pediatric patients have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Pluvicto may be considered **medically necessary** for patients 18 years of age or older with metastatic castration resistant prostate cancer (mCRPC) and if the conditions indicated below are met.

Pluvicto may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Metastatic castration-resistant prostate cancer (mCRPC)

AND ALL of the following:

1. Prostate-specific membrane antigen (PSMA)-positive as confirmed using Locametz or another approved PSMA-11 imaging agent
2. Patient has previously been treated with androgen-receptor (AR) pathway inhibition and taxane-based chemotherapy
3. Prescriber agrees to monitor complete blood counts (CBC) and kidney function tests
4. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Pluvicto and for 14 weeks after the last dose

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 6 single dose vials

Duration 3 months (only one PA approval per lifetime)

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Pluvicto is a radiopharmaceutical used in the treatment of PSMA-positive metastatic castration-resistant prostate cancer (mCRPC). Patients should be selected using Locametz or another approved PSMA-11 imagine agent based on PSMA expression in tumors. Pluvicto can cause myelosuppression and renal toxicity. The safety and effectiveness of Pluvicto in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Pluvicto while maintaining optimal therapeutic outcomes.

References

1. Pluvicto [package insert]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; March 2022.
2. NCCN Clinical Practice Guidelines in Oncology® Prostate Cancer (Version 3.2022). National Comprehensive Cancer Network, Inc. January 2022. Accessed on May 5, 2022.

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Policy History

Date	Action
April 2022	Addition to PA
June 2022	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.