Pluvicto Policy

Purpose

To describe the CVS Radiation Oncology External Policy for Pluvicto.

Scope

The scope of this document applies to CVS Health clients who have signed up for the CVS Radiation Oncology program under CVS Health Solutions. This document includes the external policy details for the Pluvicto policy.

Policy

Lutetium Lu 177 vipivotide tetraxetan (Pluvicto)

Continuation of Therapy

See Dosage and Administration information.

Criteria for Initial Approval

CVS Health considers Lutetium Lu 177 vipivotide tetraxetan (Pluvicto) medically necessary for members with the following indications:

a. Prostate Cancer

CVS Health considers lutetium Lu 177 vipivotide tetraxetan (Pluvicto) medically necessary for treatment (up to 6 total doses) of prostate cancer when *all* of the following criteria are met:

a. The member has metastatic castration-resistant prostate cancer; *and*
b. The member has been treated with androgen receptor (AR) pathway inhibition (e.g., abiraterone) and taxane-based chemotherapy (e.g., docetaxel); *and*
c. The disease is prostate-specific membrane antigen (PSMA)-positive; *and*
d. The member has had a bilateral orchiectomy or will be using the requested medication in combination with a GnRH agonist or degarelix.

CVS Health considers lutetium Lu 177 vipivotide tetraxetan (Pluvicto) experimental and investigational for all other indications.

a. Continuation of Therapy

CVS Health considers continuation of lutetium Lu 177 vipivotide tetraxetan (Pluvicto) therapy (up to 6 total doses) medically necessary in members requesting reauthorization for an indication listed in Section I when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Procedure

Dosage and Administration

Lutetium Lu 177 vipivotide tetraxetan is available as Pluvicto for injection as 1,000 MBq/mL (27 mCi/mL) in a single-dose vial for intravenous use.

Prostate cancer:

- The recommended dosage is 7.4 GBq (200 mCi) intravenously every 6 weeks for up to 6 doses, or until disease progression, or unacceptable toxicity.

Source: Advanced Accelerator Applications USA, 2022

References

The Pluvicto policy is based on the following references:

1. Advanced Accelerator Applications USA, Inc. Pluvicto (lutetium Lu 177 vipivotide tetraxetan) injection, for intravenous use. Prescribing Information. Millburn, NJ: Advanced Accelerator Applications USA; revised October 2022.
2. Fallah J, Agrawal S, Gittleman H, et al. FDA Approval Summary: Lutetium Lu 177 vipivotide tetraxetan for patients with metastatic castration-resistant prostate cancer. Clin Cancer Res. 2023;29(9):1651-1657.
3. National Comprehensive Cancer Network (NCCN). Lutetium lu 177 vipivotide tetraxetan. NCCN Drugs & Biologics Compendium. Plymouth Meeting, PA: NCCN; August 2023.
4. U.S. Food and Drug Adminstration (FDA). FDA approves Pluvicto for metastatic castration-resistant prostate cancer. Drugs. Silver Spring, MD: FDA; March 23, 2022.