## Procedure:

Lutetium Lu 177 vipivotide tetraxetan (Pluvicto®) for treatment of Metastatic Castrate-Resistant Prostate Cancer.

## Clinical indication:

Lutetium Lu 177 vipivotide tetraxetan (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 pathway inhibitor (ARPI) therapy and are considered appropriate to delay taxane-based chemotherapy or have received prior taxane-based chemotherapy.

## Eligibility Criteria:

Patients selected to receive Lutetium Lu 177 vipivotide tetraxetan (Pluvicto®) should meet the following criteria:

1. Have metastatic castration-resistant prostate cancer *(disease progression defined as serial rise (x 3) of PSA or radiographic progression despite testosterone < 50 ng/dL)*, **AND**
2. Prostate-specific membrane antigen (PSMA)-positive disease demonstrated by positive PSMA based PET scan *(patients with ≥1 PSMA-positive lesion and/ or metastatic disease that is predominately PSMA-positive and with no dominant PSMA negative metastatic lesions)*, **AND**
3. Previous treatment with androgen receptor pathway inhibition (abiraterone, enzalutamide, etc.), **AND**
4. Previous taxane-based therapy, **OR**
    a. Considered appropriate to delay taxane-based chemotherapy (with clinical documentation) **AND**
    b. Not a candidate for PARP inhibitor

## Clinical Requirements:

1. ECOG PS 0-2; **AND**
2. Life expectancy of at least 6 months; **AND**
3. Adequate organ and bone marrow function

*Other therapies to consider in the post androgen receptor pathway inhibitors (ARPI's) and docetaxel setting include:

- Olaparib – patients with BRCA mutation
- Cabazitaxel

## 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.
- 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.

## Billing:

| Drug Name | HCPCS Code | Description |
|---|---|---|
| Pluvicto® | A9607 | Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie |

**References:**

1. Pluvicto [Package Insert]. Novartis AG. March 2025. Available at: https://www.novartis.com/us-en/sites/novartis_us/files/pluvicto.pdf
2. Pluvicto. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 7/25/2025
3. Sartor O, de Bono J, Chi KN, et al. Lutetium-177-PSMA-617 for metastatic castration-resistant prostate cancer. N Engl J Med 2021;385:1091-1103. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2107322
4. Morris M, Castellano D, Herrmann K, et al. $^{177}$Lu-PSMA-617 versus a change of androgen receptor pathway inhibitor therapy for taxane-naive patients with progressive metastatic castration-resistant prostate cancer (PSMAfore): a phase 3, randomised, controlled trial. Lancet 2024;404:1227-1239. Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)01653-2/abstract

**Revision History:**
V1.0 No Preceding Documents (Prepared by Rama Al Ghannam, PharmD, BCOP)

| Version # | Effective Date | Revision History |
|---|---|---|
| V1.0 | 8/1/2025 | Reviewed by Jeffrey Langsam, DO |
| V1.1 | 11/15/2025 | Reviewed by Jeffrey Langsam, DO and Richy Agajanian, MD |