# Clinical Policy: Lutetium Lu 177 vipivotide tetraxetan (Pluvicto)

Reference Number: PA.CP.PHAR.582
Effective Date: 09/2023
Last Review Date: 08/2023

**Description**
Lutetium Lu 177 vipivotide tetraxetan (Pluvicto ™) is a radioligand therapeutic agent.

**FDA Approved Indication(s)**
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.

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Pluvicto is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Metastatic Castration-resistant Prostate Cancer** (must meet all)**:**

1. Diagnosis of metastatic CRPC;
2. Documentation of disease progression despite bilateral orchiectomy or other androgen deprivation therapy (ADT) (see *Appendix D*);
3. Documentation of PSMA-positive disease confirmed on a GA-PSMA-11 or piflufolastat F-18 positive emission tomography (PET) or computed tomography (CT) scan;
4. Prescribed by or in consultation with an oncologist or urologist;
5. Age ≥ 18 years;
6. Member will use a gondatropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy;
7. Failure of both of the following, unless contraindicated or clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. A taxane-based regimen (e.g. docetaxel, cabazitaxel);*
      **Prior authorization may be required for docetaxel and cabazitaxel*
   b. Abiraterone (Zytiga®), unless member has previously failed Yonsa® (abiraterone) or Xtandi® (enzalutamide);*
      **Prior authorization may be required for Zytiga, Yonsa, and Xtandi*
8. Pluvicto is not prescribed concurrently with cytotoxic chemotherapy, immunotherapy, radioligand therapy, or investigational therapy;

9. Request meets one of the following (a or b):
   a. Dose does not exceed 7.4 GBq (200 mCi) every 6 weeks for up to 6 doses;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months (up to a total of 6 doses)**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

## II. Continued Therapy

**A. Diagnosis** (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Member has not received ≥ 6 doses (infusions) of Pluvicto;
4. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 7.4 GBq (200 mCi) every 6 weeks for up to 6 doses;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months (up to a total of 6 doses)**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

ADT: androgen deprivation therapy
AR: androgen receptor
BSoC: best standard of care
CRPC: castration- resistant prostate cancer
CT: computed tomography
FDA: Food and Drug Administration
GnRH: gondatropin-releasing hormone
LHRH: luteinizing hormone-releasing hormone
NCCN: National Comprehensive Cancer Network
PET: positive emission tomography

PSMA: prostate- specific membrane antigen

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| abiraterone (Zytiga®) | 1,000 mg PO QD (given in combination with prednisone) | 1,000 mg/day; 2,000 mg/day if taking a strong CYP3A4 inducer |
| docetaxel | Androgen-deprivation therapy with docetaxel 75 mg/m$^2$ for 6 cycles | Varies |
| Jevtana® (cabazitaxel) | 20 mg/m$^2$ IV every 3 weeks | 25 mg/m$^2$ once every 3 weeks |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*
None reported

*Appendix D: General Information*
- Castration-resistant prostate cancer is prostate cancer that progresses clinically, radiographically, or biochemically despite castrate levels of serum testosterone (< 50 ng/dL).
- Per the NCCN, androgen deprivation therapy (ADT) should be continued in patients with metastatic CRPC while additional therapies, including secondary hormone therapies, chemotherapies, immunotherapies, radiopharmaceuticals, and/or targeted therapies are applied.
- Examples of ADT include:
  - Bilateral orchiectomy (surgical castration)
  - Luteinizing hormone-releasing hormone (LHRH) agonist given with or without an anti-androgen:
    - LHRH agonists: Zoladex® (goserelin), leuprolide (Lupron Depot®, Eligard®), and Trelstar® (triptorelin)
    - Anti-androgens: bicalutamide (Casodex®), flutamide (Eulexin®), nilutamide (Nilandron®), Xtandi® (enzalutamide), Erleada® (apalutamide), Nubeqa® (darolutamide)
  - LHRH antagonist: Firmagon® (degarelix), Orgovyx® (relugolix)

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Metastatic CRPC | 7.4 GBq (200 mCi) IV every 6 weeks for up to 6 doses | See dosing regimen |

## VI. Product Availability

Injection, single-dose vial: 1,000 MBq/mL (27 mCi/mL)

## VII. References

1. Pluvicto Prescribing Information. Millburn, NJ: Novartis AG.; October 2022. Available at https://www.novartis.com/us-en/sites/novartis_us/files/pluvicto.pdf. Accessed January 6, 2023.
2. National Comprehensive Cancer Network. Prostate Cancer Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed January 11, 2023.
3. ClinicalTrials.gov. Study of 177Lu-PSMA-617 in Metastatic Castrate-Resistant Prostate Cancer (VISION). Available at https://clinicaltrials.gov/ct2/show/NCT03511664. Accessed April 15, 2022.
4. IPD Analytics. NOC Code Guide: Pluvicto (lutetium Lu 177 vipivotide tetraxetan) injection, for intravenous use by Advanced Accelerator Applications USA, Inc. Published April 2022.
5. IPD Analytics. New Drug Review: Pluvicto (lutetium Lu 177 vipivotide tetraxetan). Published April 6, 2022.
6. Virgo KS, Rumble B, de Wit R, et al. Initial Management of Non-Castrate Advanced, Recurrent or Metastatic Prostate Cancer. American Society of Clinical Oncology (ASCO). Published ahead of print January 26, 2021, DOI: 10.1200/JCO.20.03256. Available at: https://www.asco.org/practice-patients/guidelines/genitourinary-cancer#/9521. Accessed January 11, 2023.
7. Basch E, Loblaw DA, Oliver TK, et al. Systemic Therapy in Men with Metastatic Castration-Resistant Prostate Cancer (CRPC). American Society of Clinical Oncology (ASCO). Published online before print September 8, 2014. Available at: https://ascopubs.org/doi/full/10.1200/JCO.2013.54.8404. Accessed January 11, 2023.
8. Garje R, Rumble B, Parikh RA. Systemic Therapy Update on 177Lutetium-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer: ASCO Rapid Recommendation. Journal of Clinical Oncology 2022. 40(31): 3664-3666. Available at: https://www.asco.org/practice-patients/guidelines/genitourinary-cancer#/9496.
9. Sartor O, de Bono J, Chi KN, et al. Lutetium-177-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer. N Engl J Med. 2021 Sep 16; 385(12): 1091-1103.

## Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| A9607 | Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 mCi |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 08/2023 | |