

Clinical Policy: Lutetium Lu 177 vipivotide tetraxetan (Pluvicto)

Reference Number: PA.CP.PHAR.582

Effective Date: 09/2023

Last Review Date: 04/2025

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-68-PSMA-11 or F-18 piflutolastat, or F-18 flutolastat positive emission tomography (PET) or computed tomography (CT) scan;
4. Prescribed by or in consultation with an oncologist or urologist;
5. Age \geq 18 years;
6. Member will use a gonadotropin-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) or are appropriate to delay;*
**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. Metastatic Castration-resistant Prostate Cancer (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.PHARM.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.PHARM.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: gonadotropin-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 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 17, 2025.
2. National Comprehensive Cancer Network. Prostate Cancer Version 1.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 10, 2025.
3. ClinicalTrials.gov. Study of 177Lu-PSMA-617 in Metastatic Castrate-Resistant Prostate Cancer (VISION). Available at <https://clinicaltrials.gov/ct2/show/NCT03511664>. Accessed February 10, 2025.
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 April 3, 2023, DOI: 10.1200/JCO.20.03256. Available at: <https://www.asco.org/guidelines/GUIDELINEASCO9521>. Accessed February 10, 2025.
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 February 10, 2025.
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/guidelines/GUIDELINEASCO9496>.
9. Garje R, Rumble B, Parikh RA. Systemic Therapy Update on 177Lutetium-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer: ASCO Guideline Rapid Recommendation Update. Journal of Clinical Oncology. November 6, 2023. Available at: <https://ascopubs.org/doi/10.1200/JCO.23.02128>. Accessed February 10, 2025.
10. Garje R, Rumble RB, Parikh RA. Systemic Therapy Update on 177Lutetium-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer Guideline Expert Panel. Systemic Therapy Update on ¹⁷⁷Lutetium-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer: ASCO Guideline Rapid Recommendation Update. J Clin Oncol. 2024 Nov; 42(31): 3751-3752.
11. 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.

CLINICAL POLICY

Lutetium Lu 177 vipivotide tetraxetan



HCPCS Codes	Description
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie

Reviews, Revisions, and Approvals	Date
Policy created	08/2023
2Q 2024 annual review: added F-18 flutufolastat as an additional option to confirm PSMA-positive disease; references reviewed and updated.	04/2024
2Q 2025 annual review: no significant changes; references reviewed and updated.	04/2025