

**Pluvicto
(lutetium Lu 177 vipivotide tetraxetan)**

Policy Number: 062

	Commercial and Qualified Health Plans	MassHealth
Authorization required	X	
No Prior Authorization		
Not covered		X

Pluvicto (lutetium Lu 177 vipivotide tetraxetan) 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.

Criteria

1. Criteria for Approval

Authorization of a single treatment given every six weeks for up to six doses may be granted to patients 18 years of age or older for treatment of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer when ALL of the following criteria are met:

- The member has metastatic castration-resistant prostate cancer; *and*
- The member has been treated with androgen receptor (AR) pathway inhibition (e.g., abiraterone) and taxane-based chemotherapy (e.g., docetaxel); *and*
- The member has at least 1 PSMA-positive metastatic lesion and no PSMA-negative lesions on Gallium Ga-68 PSMA-11 OR Pylarify (piflufolostat F18) PSMA PET/CT scan¹

2. Dosing and Administration

- 1,000 MBq/mL (27 mCi/mL) in a single-dose vial for intravenous use. 7.4 GBq (200 mCi) intravenously every 6 weeks for up to 6 doses, or until disease progression, or unacceptable toxicity.
- If a treatment delay due to an adverse reaction persists for > 4 weeks, treatment with Pluvicto must be discontinued.

CPT/HCPC Codes

Authorized CPT/HCPCS Codes	Code Description
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 mCi

Effective

December 2022: Effective Date.

¹ PSMA negative lesions are defined as metastatic disease that lacks PSMA uptake including bone with soft tissue components ≥ 1.0 cm, lymph nodes ≥ 2.5 cm in short axis, solid organ metastases ≥ 1.0 cm in size.



References

National Comprehensive Cancer Network®. NCCN® Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 1.2023 – September 16, 2022.

https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 13, 2022.

Pluvicto [package insert]. Milburn, NJ; Advanced Accelerator Applications USA, Inc; March 2022. Accessed October 2022.

Sartor O, de Bono J, Chi KN, Fizazi K, et al. VISION Investigators. Lutetium-177-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer. *N Engl J Med*. 2021 Sep 16;385(12):1091-1103. doi: 10.1056/NEJMoa2107322.