Mass General Brigham
Health Plan

Medical Policy
Pluvicto (lutetium Lu 177 vipivotide tetraxetan)

Policy Number: 062

	Commercial and Qualified Health Plans	Mass General Brigham ACO	Medicare Advantage	OneCare	Senior Care Options (SCO)
Authorization required	X		X	X	X
No Prior Authorization					
Not payable		X			

Overview

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 dominant PSMA-negative lesions on Gallium Ga-68 PSMA-11 OR Pylarify (piflufolastat F18) PSMA PET/CT scan[1]

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.

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare had:**

- **Medicare Benefit Policy Manual Chapter 15 - Covered Medical and Other Health Services**

[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.

MassHealth Variation
Mass General Brigham Health Plan uses guidance from MassHealth for medical necessity determinations for its Mass General Brigham ACO members. When there is no guidance from MassHealth for a requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **As of Mass General Brigham Health Plan's most recent policy review, MassHealth does not consider lutetium Lu 177 vipivotide tetraxetan payable.**

OneCare and SCO Variation
Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its OneCare and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. When there is no guidance from CMS or from MassHealth, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

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

Summary of Evidence
The pivotal VISION trial (Sartor et al., 2021) was an open-label, phase 3 trial to evaluate the efficacy of lutetium-177–PSMA-617 in patients with metastatic castration-resistant prostate cancer (mCRPC). Treatment with Pluvicto resulted in significant improvements in overall survival and prolonged progression-free survival compared to standard care, establishing the therapy as a viable option for heavily pretreated patients with advanced prostate cancer. Based primarily on evidence from this trial, NCCN (2025) and Mass General Brigham Health Plan consider Lu-177-PSMA-617 to be a medically necessary treatment option for patients with progression on taxane-based therapy and a novel hormone therapy who have PSMA-positive metastatic disease.

Related Policies
- PSMA-11 Imaging for Patients with Prostate Cancer Medical Policy

Effective
January 2026: Ad hoc review. Updated prior authorization table and added variation for OneCare and SCO members. Fixed code disclaimer.
March 2025: Annual review. Added Summary of Evidence, code disclaimer language, MassHealth variation, and related policies. Code list updated. References updated.
March 2024: Annual review. Added "dominant" to criterion 1 bullet 3. Medicare variation added. Updated references.
December 2022: Effective Date.

References
National Comprehensive Cancer Network®. NCCN® Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 1.2025 – December 4, 2024. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed January 7, 2025.

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

Sartor O, de Bono J, Chi KN, 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.