OncoHealth

# Pluvicto (Lutetium Lu 177 Vipivotide Tetraxetan)

**Effective Date:** 3/1/2022
**Revision Date(s):** n/a
**Review Date:** 11/16/2022
**Policy type:** Medical Necessity

Authorizations are for up to 6 doses per lifetime.

## Initial Approval Criteria

Coverage is provided for the following conditions:

### Universal Criteria Applied to All Requests

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.

### Indication Specific Criteria

#### Prostate Cancer

- Member has metastatic prostate cancer; AND
- Member is castration resistant; AND
- Member has prostate-specific membrane antigen-positive disease; AND
- Used as a single agent[1]; AND
- Member has been treated with:
    - Androgen receptor pathway inhibitors[2] AND;
    - Taxane based chemotherapy

## Billing

| Drug Name | HCPCS Code | Description |
|---|---|---|
| Pluvicto | A9607 | Inj., Lutetium Lu 177 Vipivotide Tetraxetan, 200 mCi |

## References


1. Pluvicto. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 10/14/22


[1] Members may continue androgen deprivation therapy (ADT) to maintain castrate levels of serum testosterone (<50 ng/dL).
[2] Examples include abiraterone, enzalutamide, darolutamide, or apalutamide. Abiraterone given as part of neoadjuvant/concomitant/adjuvant ADT with EBRT is not considered prior novel hormonal therapy.

2. Pluvicto [package insert]. Advanced Accelerator Applications USA, Inc. Millburn, NJ. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215833s000lbl.pdf
3. Sartor O, et al. Lutetium-177-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer. N Engl J Med 2021;385(12): 1091-1103.

# Disclaimer

*Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.*

*Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.*