OncoHealth

Pluvicto (Lutetium Lu 177 Vipivotide Tetraxetan)

Original Effective Date: 11/07/22
Revision Date(s): 11/07/22, 11/01/2023, 5/28/2024, 12/2/2024
Review Date: 12/2/2024
Policy type: Medical Necessity
Line of Business: Commercial

Authorizations are issued for 6 (six) months, unless the ordering physician requests a different timespan or the patients' unique circumstance or condition supports the medical necessity for a different authorization timeframe. Reauthorization requests are reviewed for efficacy, safety and tolerability. Authorizations are for up to 6 doses per lifetime.

Indication Specific Approval Criteria:

Prostate Cancer, Metastatic

- Member is at least 18 years of age; **AND**
- Member's prostate cancer 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**
- Member has not received Radium-223 in prior 6 months; **AND**
- Member has not received prior PSMA-targeted radioligand therapy

Universal Approval Criteria:

Unless otherwise noted, the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- National Comprehensive Cancer Network® (NCCN) - use consistent with NCCN recommendations carrying a Category 1 or 2A level of evidence; **OR**
- United States Food and Drug Administration (FDA) labeling - new drugs or regimens (combinations of drugs) consistent with all components of the product labeling; **OR**
- Indications not included in the official FDA labeling or recommended by NCCN (Category 1 or 2A level of evidence) may be considered if determined to be medically necessary per one or more of the following compendia:
    - Clinical Pharmacology (Strong For); **OR**
    - Wolters Kluwer Lexi-Drugs® (Level A); **OR**

[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.

- Other uses of drugs and biologics may be considered medically necessary if supported as safe and effective according to peer-reviewed articles from one of the following journals:
    - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology;
    - **Meeting abstracts and case reports are excluded from consideration;**
- Non-standard protocols may be approved based on unique clinical circumstances;
- Dose and frequency should be consistent with United States Food and Drug Administration (FDA) labeling, National Comprehensive Cancer Network® (NCCN), or indication specific peer-reviewed literature;
- In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

Billing

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

References

1. Pluvicto [package insert]. Advanced Accelerator Applications USA, Inc. Millburn, NJ. Available at: https://www.novartis.com/us-en/sites/novartis_us/files/pluvicto.pdf
2. Pluvicto. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed December 2, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.
4. Morris MJ, et al. 177Lu-PSMA-617 versus a change of androgen receptor pathway inhibitor therapy for taxane-naive patients with progressive metastatic castration-resistant prostate cancer (PSMAfore): a phase 3, randomised, controlled trial. Lancet. 2024 Sep 28;404(10459):1227-1239. doi: 10.1016/S0140-6736(24)01653-2. Epub 2024 Sep 15. PMID: 39293462.
5. Sartor O, et al. Lutetium-177-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer. N Engl J Med 2021;385(12): 1091-1103.

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Disclaimer

Drug Coverage Policies are developed as needed, reviewed and 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 utilizing this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice nor 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.

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Date	Updates
11/07/22	Policy approved at P&T
11/01/23	Updated Indication Specified Approval Criteria Updated Approval Criteria References updated
5/28/24	Annual Review
12/2/2024	Adhoc Review of medical necessity criteria; update to policy template including universal criteria and disclaimer