Pluvicto (Lutetium Lu 177 vipivotide tetraxetan)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications

Pluvicto (Lutetium Lu 177 vipivotide tetraxetan) Intravenous Solution

APPROVAL CRITERIA

Requests for Pluvicto (Lutetium Lu 177 vipivotide tetraxetan) may be approved if the following criteria are met:

- I. Individual is 18 years or older; AND
- II. Individual has a diagnosis of prostate-specific membrane antigen (PSMA)-positive metastatic, castration-resistant prostate cancer (mCRPC); **AND**
- III. Individual has been treated with androgen receptor (AR) pathway inhibition; AND
- IV. Individual has been treated with a taxane-based chemotherapy; AND
- V. Individual has been treated with a GnRH analog or bilateral orchiectomy.

Requests for Pluvicto (lutetium Lu 177 vipivotide tetraxetan) may not be approved for the following:

- I. Individual has severe renal impairment (CrCl 29ml/min or less) or end-stage renal disease; **OR**
- II. Individual has already received 6 doses of Pluvicto (lutetium Lu 177 vipivotide tetraxetan); **OR**
- III. May not be approved when the above criteria are not met and for all other indications.

Key References:

- 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2025. URL: http://www.clinicalpharmacology.com. Updated periodically.
- 2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 3. Lexi-Comp ONLINE[™] with AHFS[™], Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
- 4. Pluvicto® (lutetium Lu 177 vipivotide tetraxetan) [product information]. Millburn, NJ. March 2022.
- 5. NCCN Clinical Practice Guidelines in Oncology[™]. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <u>http://www.nccn.org/index.asp. Accessed on December 21</u>, 2024.
 - a. Prostate Cancer. V1.2025. Revised December 4, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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