Pluvicto (lutetium Lu 177 vipivotide tetraxetan)

Humana

Pharmacy Coverage Policy

Effective Date: June 22, 2022
Revision Date: May 24, 2023
Review Date: May 17, 2023
Line of Business: Medicare, Commercial, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected

Pluvicto intravenous solution

Listed Indications

Prostate Cancer

Prostate Cancer

Does the member meet all of the following criteria?	
Criteria #1	The member has metastatic castration-resistant prostate cancer (mCRPC)
Criteria #2	The member has been determined prostate-specific membrane antigen (PSMA)- positive disease by diagnostic imaging* * PSMA-positive mCRPC defined as having at least one tumor lesion and/or metastatic disease that is predominately PSMA-positive and with no dominant PSMA-negative lesions. Imaging with 68GA-PSMA-11 or other approved PSMA imaging agent (e.g., F-18 piflufolastat) for identification of PSMA expression is allowed.
Criteria #3	The member failed to achieve treatment goals or has documented intolerance when previously treated with both of the following: • androgen receptor (AR) pathway inhibition **AND** taxane-based chemotherapy
Criteria #4	Member has not received a prior course of therapy with Pluvicto (i.e., maximum of 6 doses at intervals of at least 6 weeks).
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	Members that have experienced disease progression while on Pluvicto
Approval Duration	
Initial	plan year durations (maximum of 6 doses)

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Background

This is a prior authorization policy about Pluvicto (lutetium Lu 177 vipivotide tetraxetan).

- **Warnings and Precautions:**
  - Risk From Radiation Exposure: Minimize radiation exposure during and after treatment with Pluvicto consistent with institutional good radiation safety practices and patient treatment procedures. Ensure patients increase oral fluid intake and advise patients to void as often as possible to reduce bladder radiation.
  - Myelosuppression: Perform complete blood counts. Withhold, reduce dose, or permanently discontinue Pluvicto and clinically treat based on severity.
  - Renal Toxicity: Advise patients to remain well hydrated and to urinate frequently. Perform kidney function laboratory tests. Withhold, reduce dose, or permanently discontinue Pluvicto based on severity.
  - Embryo-Fetal Toxicity: Can cause fetal harm. Advise male patients with female partners of reproductive potential to use effective contraception.

- Infertility: PLUVICTO may cause temporary or permanent infertility.

Pluvicto (lutetium Lu 177 vipivotide tetraxetan) is a radioligand therapeutic agent whose active moiety lutetium-177 is linked to a moiety that binds to PSMA, a transmembrane protein that is expressed in prostate cancer. When lutetium Lu-177 vipivotide tetraxetan to PSMA-expressing cells, the beta-minus emission from lutetium-177 delivers radiation to PSMA-expressing cells, as well as to surrounding cells, and induces DNA damage which can lead to cell death.

Pluvicto (lutetium Lu 177 vipivotide tetraxetan) is indicated for Prostate-specific membrane antigen (PSMA) – positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy.

Lutetium Lu 177 vipivotide tetraxetan is available as Pluvicto injection containing 1,000 MBq/mL (27 mCi/mL) of lutetium Lu 177 vipivotide tetraxetan in 30 mL single-dose vial.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Pluvicto; lutetium; Lu 177; PSMA; Prostate Cancer; Radiotherapy

References

Clinical Pharmacology [online database]. Tampa, FL: Gold Standard, Inc. URL: http://www.clinicalpharmacology.com. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically.

NCCN Drug and Biologics Compendium. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); Updated periodically.

Pluvicto (lutetium Lu 177 vipivotide tetraxetan) [Prescribing Information]. Novartis. Millburn, NJ. March 2022.

Disclaimer	State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.