Draft New Policy: Do Not Implement

Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto®)

Does not apply to Commercial or BlueCare Members

DESCRIPTION

Lutetium Lu 177 vipivotide tetraxetan (Pluvicto®) is a radiopharmaceutical and should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals. It is a radioligand therapeutic agent comprised of both a drug that delivers the therapy to cancer cells and a radioactive particle that binds to prostate-specific membrane antigen (PMSA) expressing cells and delivers radiation thereby inducing DNA damage which can lead to cell death.

Lutetium Lu 177 vipivotide tetraxetan is supplied in single use vials of 1,000 MBq/ml (27 mCi/ml). The recommended dosage is 7.4 GBq (200 mCi) administered via intravenous (IV) infusion every six weeks for up to six doses, or until disease progression or unacceptable toxicity. The management of adverse reactions may require temporary dose interruption (extending the dosing interval from every 6 weeks up to every 10 weeks), dose reduction, or permanent discontinuation of treatment. The dose may be reduced by twenty percent to 5.9 GBq (160mCi) once; the dose should not be re-escalated. If an individual has further adverse reactions that would require an additional dose reduction, treatment must be discontinued.

POLICY

- Lutetium Lu 177 vipivotide tetraxetan is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Lutetium Lu 177 vipivotide tetraxetan for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

- Lutetium Lu 177 vipivotide tetraxetan (up to 6 doses) is considered **medically appropriate** if **ALL** of the following are met:
  - Individual has metastatic castration-resistant prostate cancer (mCRPC)
  - The disease is prostate-specific member antigen (PSMA)-positive and **ANY ONE** of the following:
    - One or more PSMA-positive lesions
    - Metastatic disease that is predominately PSMA-positive
  - There are no dominant PSMA-negative metastatic lesions
  - Previously treated with androgen receptor-directed therapy (e.g., abiraterone, enzalutamide) and a taxane-based chemotherapy (e.g., docetaxel, cabazitaxel).
  - **ABSENCE** of **ALL** of the following (see Common Terminology Criteria for Adverse Reactions table below):
    - Recurrent Grade 3 or higher myelosuppression after one (1) dose reduction
    - Grade 3 or higher renal toxicity
    - Recurrent renal toxicity after one (1) dose reduction
    - Recurrent Grade 3 dry mouth after one (1) dose reduction
    - Recurrent Grade 3 or higher gastrointestinal toxicity after one (1) dose reduction
    - Aspartate aminotransferase or alanine aminotransferase greater than five (5) times the upper limit of normal in the absence of liver metastases
    - Any unacceptable toxicity
    - Any serious adverse reaction that requires treatment delay of greater than four (4) weeks

- Any recurrent Grade 3 or 4 or persistent and intolerable Grade 2 adverse reaction after one (1) dose reduction

Common Terminology Criteria for Adverse Events, Version 5.0

Grade	Description
1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
2	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living and refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.
3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living and refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.
4	Life-threatening consequences; urgent intervention indicated.
5	Death related to adverse event.

IMPORTANT REMINDERS

- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

SOURCES

BlueCross BlueShield Association. Evidence Positioning System. (11:2024). *Therapeutic radiopharmaceuticals for prostate cancer* (5.01.43). Retrieved March 19, 2025 from https://www.bcbsaoca.com/eps/. (14 articles and/or guidelines reviewed)

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U.S. Department of Health and Human Services. (2017, November). *Common terminology criteria for adverse events (CTCAE) version 5.0.* Retrieved March 24, 2025 from www.ctep.cancer.gov.

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EFFECTIVE DATE

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