AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Pluvicto® (lutetium Lu 177 vipivotide tetraxetan) **IV (A9699) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Quantity Limits:

A. **Length of Authorization:**
- Coverage will be provided for six months (4 doses) and may be renewed to provide for 2 additional doses (3-months)
- The total number of doses authorized cannot exceed 6 doses

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B. Max Units (per dose and over time) [HCPCS Unit]:

- 200 mCi (7.4 GBq = 200 mCi) every 6 weeks for a total of 6 doses
- Pluvicto 1,000 MBq/mL (27 mCi/mL) of lutetium Lu 177 vipivotide tetraxetan: 30 mL single- dose vial containing 7.4 GBq (200 mCi)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 4 doses

- ❑ Member is at least 18 years of age
- ❑ Requesting provider is an oncologist
- ❑ Member has a diagnosis of metastatic castration-resistant prostate cancer (mCRPC)
- ❑ Member's disease is confirmed to be prostate-specific membrane antigen (PSMA)-positive **[defined as Ga-68 gozetotide uptake greater than that of liver parenchyma in one or more metastatic lesions of any size in any organ system]**
- ❑ Member will receive concurrent treatment with a gonadotropin releasing hormone (GnRH)-analog, **OR** has had a bilateral orchiectomy
- ❑ Member has been previously treated with an androgen receptor pathway inhibitor (e.g., enzalutamide, abiraterone) **AND** taxane-based chemotherapy (e.g., docetaxel)
- ❑ Provider will follow the recommended dosage per weight and timeline indication detailed in the table below:

Indication	Dose
mCRPC	• The recommended Pluvicto dosage is 7.4 GBq (200 mCi) intravenously every 6 weeks (up to 10 weeks for toxicities) for up to 6 doses, or until disease progression, or unacceptable toxicity

Reauthorization: Additional 2 doses. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Confirmation of disease response with initial treatment as defined by stabilization of disease or at least a partial response has been documented and submitted by provider
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., bone marrow suppression, nephrotoxicity)
- ❑ Member has **NOT** received more than 6 total doses

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Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy - PropriumRx**

For urgent reviews: Practitioner should call AvMed's Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 7/21/2022
REVISED/UPDATED: 8/7/2022