Lutetium
Lutathera (lutetium lu 177 dotatate) A9513, Pluvicto (Lutetium Lu 177 Vipivotide Tetraxetan) A9607
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ **Lutathera (lutetium Lu 177 dotatate)**

- ☐ Patient has diagnosis of one of the following:
  - ☐ Locally advanced, inoperable or metastatic well-differentiated somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut and hindgut neuroendocrine tumors in adults;
  - ☐ Locally advanced or distant metastatic bronchopulmonary or thymus neuroendocrine tumors when:
    - ☐ Patient is 18 years or older; AND
    - ☐ Tumor has progressed while receiving greater than or equal to 4 months of somatostatin analog therapy (such as octreotide LAR or lanreotide) with evidence of tumor progression on imaging; AND

☐ Patient has target lesions overexpressing somatostatin receptors confirmed by an appropriate somatostatin receptor-based imaging study (such as 68Ga-dotatate PET/CT or somatostatin receptor scintigraphy); AND

☐ Patient has an ECOG performance status of 0 to 2; AND

☐ Patient has not received prior treatment with a radiolabeled somatostatin analog.

☐ Locally unresectable or metastatic pheochromocytoma or paraganglioma when:

☐ Patient is 18 years or older; AND

☐ Patient has target lesions overexpressing somatostatin receptors confirmed by an appropriate somatostatin receptor-based imaging study (such as 68Ga-dotatate PET/CT or somatostatin receptor scintigraphy); AND

☐ Patient has an ECOG performance status of 0 to 2; AND

☐ Patient has not received prior treatment with a radiolabeled somatostatin analog.

☐ Pluvicto (lutetium Lu 177 vipivotide tetraxetan)

☐ Patient is 18 years or older; AND

☐ Patient has a diagnosis of prostate-specific membrane antigen (PSMA)-positive metastatic, castration-resistant prostate cancer (mCRPC); AND

☐ Patient has been treated with androgen receptor (AR) pathway inhibition; AND

☐ Patient has been treated with a taxane-based chemotherapy; AND

☐ Patient has been treated with a GnRH analog or bilateral orchiectomy; AND

☐ Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Lutetium Drug PA

Drug Name(s):

LUTATHERA	**LUTETIUM LU 177 DOTATATE**
PLUVICTO	**LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

Oncologist or related provider

Coverage Duration:

Approval will be approved for 12 months

FDA Indications:

Lutathera

- Neuroendocrine tumor, Somatostatin receptor-positive gastroenteropancreatic

Pluvicto

- Metastatic castration-resistant prostate cancer, Prostate-specific membrane antigen (PSMA) positive after treatment with androgen receptor pathway inhibition and taxane-based chemotherapy

Off-Label Uses:

N/A

Age Restrictions:

Safety and effectiveness have not been established in pediatric patients

Other Clinical Consideration:

N/A:

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/39991C/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/5A0E32/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932413&contentSetId=100&title=Lutetium+Lu+177+Dotatate&servicesTitle=Lutetium+Lu+177+Dotatate&brandName=Lutathera&UserMdxSearchTerm=Lutathera&=null#

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