

# Lutathera (lutetium Lu 177 dotatate)

Override(s)	Approval Duration
Lutathera (lutetium Lu 177 dotatate)	1 year

Medications
Lutathera (lutetium Lu 177 dotatate) 10 Mci/MI (370 Mbq/MI) Intravenous Solution

## **APPROVAL CRITERIA**

Requests for Lutathera (lutetium Lu 177 dotatate) may be approved if the following criteria are met:

- I. Individual has a diagnosis of locally advanced, inoperable, recurrent, symptomatic, or metastatic well-differentiated somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut and hindgut neuroendocrine tumors (Label, NCCN 1, 2A);

### **OR**

- II. Individual has neuroendocrine tumors of the lung or thymus (NCCN 2A); **AND**
- III. Disease is somatostatin receptor positive; **AND**
- IV. Individual has experienced disease progression while receiving octreotide LAR or lanreotide therapy;

### **OR**

- V. Individual has a diagnosis of locally unresectable or metastatic pheochromocytoma **or** paraganglioma (NCCN 2A); **AND**
- VI. Individual has target lesions overexpressing somatostatin receptors; **AND**
- VII. Individual has not received prior treatment with a radiolabeled somatostatin analog.

Requests for Lutathera (lutetium Lu 177 dotatate) may **not** be approved for the following:

- I. 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. Lutathera® (lutetium Lu 177 dotatate) [product information]. Giacosa (TO), Italy. April 2024.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on December 21, 2024.
  - a. Neuroendocrine and Adrenal Tumors. V3.2024. Revised January 6, 2025.

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

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