

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Somatostatin Analogs – Lutathera Utilization Management Medical Policy

- Lutathera® (lutetium Lu 177 dotatate intravenous infusion – Advanced Accelerator Applications USA)

REVIEW DATE: 04/23/2025

OVERVIEW

Lutathera, a radiolabeled somatostatin analog, is indicated in adult and pediatric patients ≥ 12 years of age for the treatment of somatostatin receptor-positive **gastroenteropancreatic neuroendocrine tumors** (NETs), including foregut, midgut, and hindgut neuroendocrine tumors.¹ The recommended dose of Lutathera is 7.4 gigabecquerel (GBq) [200 millicuries {mCi}] administered intravenously over 30 to 40 minutes, once every 8 weeks for a total of four doses.

Guidelines

According to the National Comprehensive Cancer Network (NCCN) guidelines for **neuroendocrine and adrenal tumors** (version 1.2025 – March 27, 2025), Lutathera may be considered for bronchopulmonary NETs and thymus NETs if somatostatin receptor-positive and disease progression on an octreotide acetate injection product (e.g., Bynfezia Pen™, Sandostatin® [generics], Sandostatin® LAR Depot) or Somatuline® Depot (lanreotide injection). Somatostatin receptor-positive tumors are detected by somatostatin receptor-positive imaging (e.g., Gallium-68 dotatate imaging [positron emission tomography {PET}/computed tomography {CT} or PET/magnetic resonance imaging {MRI}] or somatostatin receptor-positive scintigraphy). Lutathera is recommended for tumors that are locoregional advanced disease and/or distant metastases. Lutathera is recommended as first line if the tumor is somatostatin receptor-positive, Ki-67 $\geq 10\%$, and a clinically significant tumor burden as a preferred regimen for neuroendocrine tumors of the pancreas, gastrointestinal tract, lung, and thymus. For pheochromocytomas or paragangliomas the same recommendations are made with the exception of using Lutathera in locally unresectable disease without prior use of an octreotide acetate injection product or Somatuline Depot. For carcinoid tumors, gastrinoma, insulinoma, glucagonoma, VIPomas, Lutathera is recommended as preferred management of recurrent, locoregional advanced disease and/or distant metastases if the tumor is somatostatin receptor positive and prior progression on octreotide LAR or lanreotide as an alternative-first-line therapy or as subsequent therapy if disease progression.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Lutathera. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Lutathera as well as the monitoring required for adverse events and long-term efficacy, approval requires Lutathera to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lutathera is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Neuroendocrine Tumors (NETs) of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas.

Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

A) Patient is ≥ 12 years of age; AND

B) Patient has locally advanced or metastatic disease; AND

C) Patient has somatostatin receptor-positive tumor as detected by somatostatin receptor-based imaging; AND

Note: Examples of somatostatin receptor-based imaging include Gallium-68 dotatate imaging (positron emission tomography [PET]/computed tomography or PET/magnetic resonance imaging) or somatostatin receptor scintigraphy.

D) Patient meets ONE of the following (i or ii):

i. Patient has progressed on an octreotide acetate injection product (e.g., Bynfezia Pen, Sandostatin [generic], Sandostatin LAR Depot) or Somatuline Depot (lanreotide injection); OR

ii. Patient meets ALL of the following (a, b, and c):

a) Medication is being used as first-line therapy; AND

b) Patient has Ki-67 index $\geq 10\%$; AND

c) Patient has a clinically significant tumor burden; AND

Note: Examples of clinically significant tumor burden include inoperable tumor, large tumor size, location of tumor, or presence of symptoms.

E) Lutathera is prescribed by or in consultation with an oncologist, radiologist, or endocrinologist.

Dosing. Approve up to 7.4 GBq [200 mCi] administered intravenously no more frequently than once every 8 weeks for a maximum of 4 doses.

Other Uses with Supportive Evidence

2. Pheochromocytoma and Paraganglioma.

Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND

B) Patient has locally unresectable disease or distant metastases; AND

C) Patient has somatostatin receptor-positive tumor as detected by somatostatin receptor-based imaging; AND

Note: Examples of somatostatin receptor-based imaging include Gallium-68 dotatate imaging (positron emission tomography [PET]/computed tomography or PET/magnetic resonance imaging) or somatostatin receptor scintigraphy.

D) Lutathera is prescribed by or in consultation with an oncologist or radiologist.

Dosing. Approve up to 7.4 GBq [200 mCi] administered intravenously no more frequently than once every 8 weeks for a maximum of 4 doses.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lutathera is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lutathera® intravenous infusion [prescribing information]. Millburn, NJ: Advanced Accelerator Applications USA; November 2024.
2. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2025 – March 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 10, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/16/2023
Early Annual Revision	Neuroendocrine Tumors (NETs) of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas: The age requirement was changed from ≥ 18 to ≥ 12 years of age. There were no other changes to the criteria.	05/15/2024
Annual Revision	Neuroendocrine Tumors (NETs) of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas: the following criteria were added as an option of approval: medication is used as first line, patient has Ki-67 index $\geq 10\%$, and clinically significant tumor burden”, based on guideline update.	04/23/2025