CARECONTINUUM™

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: 04/08/2026

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 3.2025 – October 1, 2025), Lutathera may be used for the treatment of somatostatin receptor positive, well-differentiated neuroendocrine tumors (NETs) that are locoregionally advanced and/or metastatic. Lutathera is recommended for gastrointestinal, pancreatic, lung (bronchopulmonary), and thymic NETs in patients with disease progression on octreotide LAR or lanreotide, and it is also recommended as a preferred first-line option when tumors are somatostatin receptor positive, have a Ki-67 ≥10%, and demonstrate clinically significant tumor burden. Somatostatin receptor positivity should be confirmed using somatostatin receptor–based imaging, such as Gallium-68 dotatate imaging. For pheochromocytomas and paragangliomas, Lutathera is recommended for locally unresectable or metastatic disease if tumors are somatostatin receptor positive, and prior treatment with octreotide or lanreotide is not required. Additionally, for functional NETs, including carcinoid tumors, gastrinomas, insulinomas, glucagonomas, and VIPomas, Lutathera is recommended as preferred management for recurrent, locoregionally advanced, or metastatic disease when tumors are somatostatin receptor positive and have progressed on octreotide LAR or lanreotide, either as an alternative first-line therapy or as subsequent therapy following 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.** Patients meets ALL of the following (a, b, and c):
       - **a)** The medication is being used as first-line therapy; AND
       - **b)** Patient has Ki-67 index ≥ 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)** The medication 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)** The medication 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 3.2025 – October 1, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 2, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
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 ≥ 10%, and clinically significant tumor burden", based on guideline update.	04/23/2025
Annual Revision	No criteria changes.	04/08/2026