# 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:** 08/16/2023

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## OVERVIEW

Lutathera, a radiolabeled somatostatin analog, is indicated in adults 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 1.2023 – August 2, 2023), 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. 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.

## 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 the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 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 has progressed on an octreotide acetate injection product (e.g., Bynfezia Pen, Sandostatin [generic], Sandostatin LAR Depot) or Somatuline Depot (lanreotide injection); AND
   - **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 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; March 2023
2. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2023 – August 2, 2023). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 9, 2023.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | No criteria changes. | 08/10/2022 |
| Annual Revision | No criteria changes. | 08/16/2023 |