

**POLICY:** Somatostatin Analogs – Lutathera® (lutetium Lu 177 dotatate – Advanced Accelerator Applications USA, Inc.)

**EFFECTIVE DATE:** 1/1/2021

**LAST REVISION DATE:** 08/11/2021

**COVERAGE CRITERIA FOR:** All Aspirus Medicare Plans

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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.<sup>1</sup> 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 2.2021 – June 18, 2021), 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 the following criteria:

### **FDA-Approved Indications**

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**1. Neuroendocrine Tumors (NETs) of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):

- A) Patient is  $\geq 18$  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**

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**2. Pheochromocytoma and Paraganglioma.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):

- A) Patient is  $\geq 18$  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; June 2021.
- 2. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 2.2021 – June 18, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed August 5, 2021.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
Annual Revision	<p><b>Neuroendocrine Tumors (NETs) of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas:</b> The examples of somatostatin receptor-based imaging were moved to a Note (previously listed as examples within the criteria). Positron emission tomography [PET]/ magnetic resonance imaging [MRI] was added as an example to somatostatin receptor-based imaging.</p> <p><b>Pheochromocytoma and Paraganglioma:</b> The examples of somatostatin receptor-based imaging were moved to a Note (previously listed as examples within the criteria). Positron emission tomography [PET]/ magnetic resonance imaging [MRI] was added as an example to somatostatin receptor-based imaging.</p>	08/05/2020
Annual Revision	No criteria changes.	08/11/2021