

5.21.107

Section:	Prescription Drugs	Effective Date:	July 1, 2026
Subsection:	Antineoplastic Agents	Original Policy Date:	February 16, 2018
Subject:	Lutathera	Page:	1 of 4

Last Review Date: June 11, 2026

Lutathera

Description

Lutathera (lutetium Lu 177 dotatate)

Background

Lutathera (lutetium Lu 177 dotatate) is a somatostatin analog that acts as radiation therapy for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Lutathera is a “radiolabeled” compound that binds with specific receptors on the tumor cells. Once bound to the tumor, the Lutathera chemical compound gets internalized (brought into) the cancerous cells. After being internalized into the tumor cells, the radiation emitted from Lutathera creates free radicals, which injures and destroys the targeted cancer cells (1).

Regulatory Status

FDA-approved indication: Lutathera is a radiolabeled somatostatin analog indicated for the treatment of adult and pediatric patients 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors (1).

Lutathera is a radioactive moiety, and specific precautions should be taken in the handling of Lutathera. Antiemetics and intravenous amino acid should be administered before the administration of Lutathera (1). NCCN recommends that somatostatin analogs (SSAs) (octreotide or lanreotide) be administered 4-24 hours after each Lutathera dose (2). Additionally, long-acting octreotide should be administered every 4 weeks after completion of Lutathera therapy for up to 18 months or until disease progression (1).

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Myelosuppression, secondary myelodysplastic syndrome (MDS) and leukemia, renal toxicity, hepatotoxicity, neuroendocrine hormonal crisis, embryo-fetal toxicity, and a risk of infertility are possible adverse effects from this treatment. Providers should monitor their patients accordingly (1).

Patients with baseline renal impairment may be at greater risk of toxicity. Lutathera has not been studied in patients with severe renal impairment (creatinine clearance < 30 mL/min). Also, the safety of Lutathera in patients with severe hepatic impairment has not been studied (1).

Safety and effectiveness in pediatric patients less than 12 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lutathera may be considered **medically necessary** if the conditions indicated below are met.

Lutathera may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

Gastroenteropancreatic Neuroendocrine Tumor (GEP - NETs)

AND ALL of the following:

1. Prescriber agrees to use a somatostatin analog (SSA) (octreotide or lanreotide) after each Lutathera dose and after completion of therapy

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2. Documented confirmation that the tumor(s) are somatostatin receptor-positive by an OctreoScan® test
3. Prescriber agrees to monitor for toxicities and adjust dose or discontinue therapy as indicated
4. **NO** severe hepatic impairment (Child-Pugh Class C)
5. Creatinine clearance > 30 mL/min

Prior – Approval *Renewal* Requirements

None

[Policy Guidelines](#)

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 4 single dose vials per lifetime.

Prior – Approval *Renewal* Limits

None

[Rationale](#)

Summary

Lutathera is a radiolabeled somatostatin analog indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adult and pediatric patients 12 years and older. Radiation emitted from Lutathera creates free radicals, which injures and destroys the targeted cancer cells. Myelosuppression, secondary myelodysplastic syndrome (MDS) and leukemia, renal toxicity, hepatotoxicity, neuroendocrine hormonal crisis, embryo-fetal toxicity, and a risk of infertility are possible adverse effects from this treatment. Providers should monitor their patients accordingly (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Lutathera while maintaining optimal therapeutic outcomes.

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References

- 1. Lutathera [package insert]. Millburn, NJ: Advanced Accelerator Applications USA; November 2024.
- 2. NCCN Drugs & Biologics Compendium® Lutetium lu 177 dotatate 2026. National Comprehensive Cancer Network, Inc. Accessed on April 27, 2026.

Policy History

Date	Action
February 2018	Addition to PA
March 2018	Annual review
June 2018	Annual review
June 2019	Annual review and reference update
September 2019	Revised requirement to use a SSA after each Lutathera dose and after completion of therapy to be in line with NCCN guidelines
December 2019	Annual review
June 2020	Annual review
June 2021	Annual review and reference update
June 2022	Annual review and reference update
June 2023	Annual review and reference update
May 2024	Per PI update, reduced age requirement to 12 and older from 18 and older
June 2024	Annual review and reference update
June 2025	Annual review and reference update
June 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.