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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Antineoplastic Agents	**Original Policy Date:**	February 16, 2018
Subject:	Lutathera	**Page:**	1 of 4

Last Review Date: June 16, 2022

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) in adult patients. 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 somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults (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).

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 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** for patients 18 years of age or older with the diagnosis of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors when the conditions indicated below are met.

Lutathera may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

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

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 adults. 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.

References

1. Lutathera [package insert]. NJ: Advanced Accelerator Applications USA; June 2021.
2. NCCN Drugs & Biologics Compendium® Lutetium lu 177 dotatate 2022. National Comprehensive Cancer Network, Inc. Accessed on April 22, 2022.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.