

Lutathera (lutetium Lu 177 dotatate)

PAM – 027

Iowa Medicaid Program	Prior Authorization	Effective Date	01/01/2021
Revision Number	6	Last Reviewed	01/16/2026
Reviewed By	Medicaid Medical Director	Next Review	01/15/2027
Approved By	Medicaid Clinical Advisory Committee	Approved Date	12/23/2020

Overview

Medication: ¹	lutetium Lu 177 dotatate
Brand Name:	Lutathera®
Pharmacologic Category:	Antineoplastics; radiolabeled somatostatin analog
FDA-Approved Indication(s):	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
How Supplied:	30 mL single-dose vial containing 7.4 GBq (200 mCi) \pm 10% of lutetium Lu 177 dotatate at the time of injection
Dosage and Administration:	<ul style="list-style-type: none"> • 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses • Discontinue long-acting somatostatin analogs (e.g., long-acting octreotide) for at least 4 weeks prior to initiating Lutathera® • Administer short-acting octreotide as needed (discontinue at least 24 hours prior to initiating Lutathera®)
Benefit Category:	Medical

Descriptive Narrative

Neuroendocrine tumors (NETs) are a heterogeneous group of malignancies arising in the diffuse neuroendocrine system. They are characterized by a relatively slow rate of growth and the production of a variety of peptide hormones and biogenic amines. Although NETs may develop in almost any organ, they arise predominately within the gastrointestinal (GI) tract and the pancreas. The term carcinoid is still widely used to describe NETs originating in the GI tract.

Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) have distinct clinical features based on their site of origin. Metastatic mid-gut carcinoids often secrete serotonin and other vasoactive substances, producing the

typical carcinoid syndrome with symptoms of flushing, diarrhea, and right-sided valvular heart disease.

Lutathera® is a targeted form of systemic radiotherapy (radioactive drug) peptide receptor radionuclide therapy that binds to cell surface somatostatin receptors which may be present in certain tumors. After binding to the receptor, the drug enters the cell, allowing radiation to cause damage to the tumor cells. Most GEP-NETs express high-affinity receptors for somatostatin. Somatostatin-based imaging can also provide information on tumor burden and location. Lutathera® is a treatment option in adult and pediatric patients 12 years and older with GEP-NETs who progress despite first-line therapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. The guidelines are developed and updated by 63 individual panels, comprising over 1,900 clinicians and oncology researchers from the 33 NCCN Member Institutions. The categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines Panel.

The library of NCCN Guidelines® currently apply to more than 97 percent of people living with cancer or anyone at risk for a diagnosis of cancer in the United States. The guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management and are intended to assist all individuals who impact decision-making in cancer care, including physicians, nurses, pharmacists, payers, patients and their families, and others.

The NCCN Guidelines provide recommendations based on the best evidence available at the time they are derived. Because new data are published continuously, it is essential that the NCCN Guidelines also be continuously updated and revised* to reflect new data and clinical information that may add to or alter current clinical practice standards.^{2,3}

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):⁴

- Neuroendocrine and Adrenal Tumors (v.3.2025 – October 1, 2025)

* To view the most recent and complete version of the guidelines, go online to [NCCN.org](https://www.NCCN.org). NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

NCCN Guidelines® Recommendation(s) – Neuroendocrine and Adrenal Tumors

PRRT – peptide receptor radionuclide therapy	SSTR – somatostatin receptor
(1) Neuroendocrine Tumors of the Gastrointestinal Tract (Well-Differentiated Grade 1/2) ^a	
A. Locoregional Advanced Disease and/or Distant Metastases	
i. PRRT with lutetium Lu 177 dotataate (if SSTR-positive and progression on octreotide LAR/lanreotide): Category 2A, Preferred Regimen (Category 1 for progressive mid-gut tumors)	
ii. First-line PRRT with lutetium Lu 177 dotataate (if SSTR-positive, Ki-67 ≥ 10 %, and clinically significant tumor burden): Category 2A, Preferred Regimen	
(2) Distant Metastatic Neuroendocrine Tumors of Lung and Thymus ^a	
A. Distant Metastases (clinically significant tumor burden and low grade [typical carcinoid] or evidence of disease progression or intermediate grade [atypical carcinoid] or symptomatic)	
i. PRRT with lutetium Lu 177 dotataate (if SSTR-positive and progression on octreotide LAR or lanreotide): Category 2A, Useful in Certain Circumstances	
(3) Pancreatic Neuroendocrine Tumors (Well-Differentiated Grade 1/2) ^a	
A. Locoregional Advanced Disease and/or Distant Metastases	
i. First-line PRRT with lutetium Lu 177 dotataate (if SSTR-positive, Ki-67 ≥ 10%, and clinically significant tumor burden): Category 2A, Preferred Regimen	
ii. PRRT with lutetium Lu 177 dotataate (if SSTR-positive and progression on octreotide LAR or lanreotide): Category 2A, Preferred Regimen	
(4) Well-Differentiated, Grade 3 Neuroendocrine Tumors	
A. Locally Advanced/Metastatic Disease with Favorable Biology ^b (unresectable with clinically significant tumor burden or evidence of disease progression)	
i. Clinical trial preferred	
ii. PRRT with lutetium Lu 177 dotataate ^c (if SSTR-positive): Category 2A	
(5) Pheochromocytoma/Paraganglioma	
A. Locally Unresectable	
i. Clinical trial	
ii. PRRT with lutetium Lu 177 dotataate (if SSTR-positive) ^{d, e} : Category 2A	
B. Distant Metastases	
i. Clinical trial	
ii. PRRT with lutetium Lu 177 dotataate (if SSTR-positive) ^{d, e} : Category 2A	

^a If clinically significant disease progression, treatment with octreotide LAR or lanreotide should be discontinued for non-functional tumors and continued in patients with functional tumors.

^b Favorable biology (e.g., relatively low Ki-67 [$<55\%$], slow growing, positive SSTR-based PET imaging)

^c Consider trial of SSA before PRRT. Preliminary data suggest reduced efficacy if high Ki-67 and/or FDG-PET avid.

^d SSTR PET tracers include: 68Ga-DOTATATE, 64Cu-DOTATATE, and 68Ga-DOTATOC.

^e Data are limited on the use of PRRT with lutetium Lu 177 dotataate in this setting.

Principles of Peptide Receptor Radionuclide Therapy (PRRT) with Lutetium Lu 177 Dotataate

- Lutetium Lu 177 dotataate is a radiolabeled SSA used as PRRT.
- It is approved by the FDA for the treatment of adult and pediatric patients ≥ 12 years of age with SSTR-positive GEP NETs, including foregut, midgut, and hindgut NETs.
- Currently there are no randomized data, but there are reports of treatment efficacy and favorable outcomes when PRRT is used for PCCs, PGLs, and lung/thymic NETs. If feasible, participation in clinical trials of PRRT is strongly recommended for patients with such rare groups of NET.
- PRRT may reduce symptoms for symptomatic insulinoma and other functional NETs.
- Key eligibility: well-differentiated NET; SSTR expression of NET as detected by SSTR-PET/CT or SSTR-PET/MR; Adequate bone marrow, renal, and hepatic function

GEP gastroenteropancreatic
NET neuroendocrine tumor
PanNET pancreatic neuroendocrine tumor
PCC pheochromocytoma

PGL paraganglioma
PRRT peptide receptor radionuclide therapy
SSA somatostatin analog
SSTR somatostatin receptor

Scanning Techniques	
PET/CT	Procedure that combines a positron emission tomography (PET) scan and a computed tomography (CT) scan. The PET and CT scans are done at the same time with the same machine. The combined scans give more detailed pictures of areas inside the body than either scan gives by itself. ⁵
PET/MR	Procedure that combines a positron emission tomography (PET) scan and a magnetic resonance imaging (MRI) in one scanner, allowing for simultaneous acquisition of MR and PET images. The MR's capacity to produce high-resolution images, combined with the PET's ability to display cell metabolism and molecular events results in outstanding images that denote organ position, function, and metabolism all in one image. The simultaneous image acquisition technique greatly reduces radiation exposure for the subject and reduces image acquisition time and effort. ⁶

Principles of Pathology for the Diagnosis of Neuroendocrine Neoplasms				
2022 WHO Classification and Grading Criteria for Neuroendocrine Neoplasms of the Gastrointestinal and Pancreatobiliary Tract ⁷				
Terminology	Differentiation	Grade	Mitotic Rate (mitoses/2 mm ²)	Ki-67 Index (percent)
NET, G1	Well-differentiated	Low	< 2	< 3
NET, G2	Well-differentiated	Intermediate	2 to 20	3 to 20
NET, G3	Well-differentiated	High	> 20	> 20
SCNEC	Poorly differentiated	High ▲	> 20	> 20 (often >70)
LCNEC	Poorly differentiated	High ▲	> 20	> 20 (often >70)
MINEN	Well or poorly differentiated ♦	Variable ♦	Variable ♦	Variable ♦

Mitotic rates are the number of mitoses/2 mm² (i.e., 10 high-power fields at 40x magnification and an ocular field diameter of 0.5 mm).

- To assess the mitotic rate, count in 50 fields of 0.2 mm² (over a total area of 10 mm²).
- To assess the Ki-67 proliferation index, count at least 500 cells in the regions of highest labeling (using scanning magnification).
- The final grade is determined by the value (mitotic rate or Ki-67 proliferation index) that places the tumor in the category with the higher grade.

The **Ki-67 proliferation index** is a way to measure how fast cancer cells in a tumor are dividing (Ki-67 is a protein that is found only in cells that are dividing).

- A Ki-67 proliferation index over 30% is typically considered high.
- The Ki-67 proliferation index may be used to help predict how well some cancers, such as breast cancer, will respond to certain treatments, such as chemotherapy.
- Also called Ki-67 score.

▲ Poorly differentiated NECs are not formally graded; are considered high grade by definition

♦ In most MINENs, both the neuroendocrine and non-neuroendocrine components are poorly differentiated. Additionally, the mitotic rate and Ki-67 proliferation index of the neuroendocrine component usually fall into the same range as an NEC. However, in some MINENs, either (or both) components could be well-differentiated so they should be graded separately, if possible.

NCCN Categories of Evidence and Consensus	
(all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale ⁸

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and to determine appropriate treatment and prognosis.

Grade	ECOG Performance Status	[Synonyms: WHO/Zubrod score]
0	Fully active, able to carry on all pre-disease performance without restriction.	
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.	
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.	
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.	
5	Dead.	

Criteria

Prior authorization is required.

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

Lutathera® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut NETs which is locally advanced, inoperable, or metastatic well-differentiated; **AND**
2. Member has experienced disease progression despite receiving somatostatin analog therapy (octreotide or lanreotide); **AND**
3. Member is 12 years of age or older; **AND**
4. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2; **AND**
5. Prescribed by, or in consultation with, an oncologist; **AND**
6. Dose does not exceed 7.4 GBq (200 mCi) every 8 weeks (\pm 1 week), up to a total of 4 doses.

Pheochromocytoma≠ or Paraganglioma ≠

Lutathera® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of pheochromocytoma or paraganglioma and disease is somatostatin receptor-positive, locally advanced, unresectable, or metastatic; **AND**
2. Member is 12 years of age or older; **AND**
3. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2; **AND**
4. Prescribed by, or in consultation with, an oncologist; **AND**
5. Dose does not exceed 7.4 GBq (200 mCi) every 8 weeks (\pm 1 week), up to a total of 4 doses.

*Off-label indication supported by NCCN guidelines (level of evidence 2A).

Lung or Thymus Neuroendocrine Tumors ≠

Lutathera® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of lung or thymus neuroendocrine tumor and disease is locally unresectable or metastatic; **AND**
2. Member has experienced has experienced disease progression despite receiving somatostatin analog therapy (octreotide or lanreotide); **AND**
3. Member is 12 years of age or older; **AND**
4. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2; **AND**
5. Prescribed by, or in consultation with, an oncologist; **AND**
6. Dose does not exceed 7.4 GBq (200 mCi) every 8 weeks (\pm 1 week), up to a total of 4 doses.

*Off-label indication supported by NCCN guidelines (level of evidence 2A).

Continuation Therapy (all above indications)

Lutathera® is considered medically necessary for continuation of therapy when

ALL of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, an oncologist; **AND**
4. Member has not received \geq 4 doses of Lutathera®; **AND**
5. Dose does not exceed 7.4 GBq (200 mCi) every 8 weeks (\pm 1 week), up to a total of 4 doses.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	4 doses (32 weeks)	Only authorized for up to a total of 4 doses. If member did not receive all 4 doses on the initial authorization, may approve remaining doses if criteria are met.
Quantity Limits	7.4 GBq (200 mCi) per dose	7.4 GBq (200 mCi) per dose

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
A9513	Lutetium Lu 177, dotatate, therapeutic, 1 mCi

ICD-10	Description
C7A.00	Malignant carcinoid tumor of unspecified site
C7A.010	Malignant carcinoid tumor of the duodenum
C7A.011	Malignant carcinoid tumor of the jejunum
C7A.012	Malignant carcinoid tumor of the ileum
C7A.019	Malignant carcinoid tumor of the small intestine, unspecified portion
C7A.020	Malignant carcinoid tumor of the appendix
C7A.021	Malignant carcinoid tumor of the cecum
C7A.022	Malignant carcinoid tumor of the ascending colon
C7A.023	Malignant carcinoid tumor of the transverse colon
C7A.024	Malignant carcinoid tumor of the descending colon
C7A.025	Malignant carcinoid tumor of the sigmoid colon
C7A.026	Malignant carcinoid tumor of the rectum
C7A.029	Malignant carcinoid tumor of the large intestine, unspecified portion
C7A.092	Malignant carcinoid tumor of the stomach
C7A.094	Malignant carcinoid tumor of the foregut NOS
C7A.095	Malignant carcinoid tumor of the midgut NOS
C7A.096	Malignant carcinoid tumor of the hindgut NOS
C7A.098	Malignant carcinoid tumors of other sites
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7B.00	Secondary carcinoid tumors, unspecified site
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.02	Secondary carcinoid tumors of liver
C7B.04	Secondary carcinoid tumors of peritoneum
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
69488-0003-01 (30 mL single-dose vial containing 7.4 GBq (200 mCi) \pm 10%)	Advanced Accelerator Applications USA, Inc. (69488)	1 mCi	1	EA	200

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

¹ Lutathera® prescribing information (10/2024). Advanced Accelerator Applications USA, Inc.: Millburn, NJ. Available online: www.lutathera-hcp.com. Accessed October 27, 2025.

² National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

³ National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

⁴ NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are continuously updated and revised to reflect new data and clinical information that may add to or alter current clinical practice standards. To view the most

recent and complete version, go online to [NCCN.org](https://www.nccn.org). NCCN Guidelines® referenced at the time of this revision (note version number and effective date):

- Neuroendocrine and Adrenal Tumors (v.3.2025 – October 1, 2025)

⁵ NCI Dictionary of Cancer Terms. National Cancer Institute, a division of the National Institutes of Health (NIH). Online at www.cancer.gov/publications/dictionaries/cancer-terms.

⁶ Human Imaging Modalities. Biomedical Research Imaging Center: UNC School of Medicine. Online at www.med.unc.edu/bric/human-imaging/human-imaging-modalities/pet-mr/.

⁷ WHO Classification of Tumors: Endocrine tumours, 5th ed, International Agency for Research on Cancer 2022. Vol 10. tumourclassification.iarc.who.int.

⁸ Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
	Signature		
Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
	Signature		
Change Date	Changed By	Description of Change	Version
01/16/2026	CAC	Annual review. Added table to Guidelines section, “2022 WHO Classification and Grading Criteria for Neuroendocrine Neoplasms of the Gastrointestinal and Pancreatobiliary Tract.” Updated NCCN Guidelines.	6
	Signature		
	William (Bill) Jagiello, DO		

Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
01/17/2025	CAC	Annual review. Changed criteria requirement to 12 years and older to align with FDA approval on 4/23/2024 which expanded the eligible population (previously only approved for ages 18 years and older). Updated age range change in Overview table and Descriptive Narrative as well. Updated NCCN references.	5

Signature

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Change Date	Changed By	Description of Change	Version
01/19/2024	CAC	Annual review. Updated NCCN Guidelines.	4

Signature

William (Bill) Jagiello, DO



Change Date	Changed By	Description of Change	Version
01/20/2023	CAC	Added details of NCCN Guidelines recommendation. Added information on scans used in diagnosis (e.g., PET/CT). Added continuation criteria (only applicable if Member did not receive all 4 doses on initial authorization). Removed "Not Covered If" section as these were all accounted for in initial criteria.	3

Signature

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Change Date	Changed By	Description of Change	Version
01/21/2022	CAC	Annual review. Formatting changes.	2

Signature

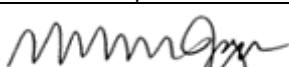
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Change Date	Changed By	Description of Change	Version
01/15/2021	CAC	Criteria implementation.	1

Signature

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CAC = Medicaid Clinical Advisory Committee
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