Medical Policy:
Lutathera® (lutetium Lu 177 dotatate)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.45	February 2, 2024	

Definitions

Lutathera (lutetium Lu 177 dotatate) 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. Lutathera binds to somatostatin receptors on cells, including malignant somatostatin receptor-positive tumor cells and is internalized upon binding. The beta emission from Lu 177 induces cellular damage by formation of free radicals in somatostatin receptor-positive cells and in neighboring cells. Lutathera is a radiopharmaceutical, so it must be handled with appropriate safety measures to minimize radiation exposure. It should be under the control of physicians who are qualified by specific training and experience. The physician's training and experience must have been approved by a governmental agency authorized to license the use of radiopharmaceuticals.

The recommended dose of Lutathera is 7.4 gigabecquerel (GBq) administered intravenously (IV) every 8 weeks for a total of 4 doses. During treatment, long-acting octreotide 30 mg should be administered intramuscularly (IM) between 4 to 24 hours after each dose of Lutathera. Following completion of the 4-dose treatment of Lutathera, long-acting octreotide 30 mg should be administered IM every 4 weeks until disease progression or for up to 18 months.

Length of Authorization
Coverage will be provided for 1 year (4 doses only) and may NOT be renewed.

Dosing Limits
Max Units (per dose and over time) [HCPCS Unit]:
200 billable units (7.4 GBq = 200 mCi) every 8 weeks for a total of 4 doses

Guideline
Lutathera is considered medically necessary when all of the following criteria are met:

1. **Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)**

A. The patient has a diagnosis of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs); **AND**
B. The patient's disease is unresectable, locally advanced, or metastatic; **AND**
C. The patient has had disease progression despite somatostatin analog therapy or molecularly targeted therapy (e.g. everolimus); **AND**
D. Somatostatin receptor-positive GEP-NETs on all target lesions has been confirmed via Octreoscan; **AND**
E. The tumor is well differentiated with a Ki-67 index ≤ 20%; **AND**
F. The patient has a Karnofsky performance-status score of ≥ 60; **AND**
G. The patient is at least 18 years of age; **AND**
H. The patient is not currently pregnant or breastfeeding; **AND**
I. If the patient is a sexually-active female of reproductive potential has had pregnancy status verified through a pregnancy test; **AND**
J. The patient has a creatinine clearance ≥ 30 mL/min by Cockcroft-gault; **AND**
K. The patient's total bilirubin ≤ 3 times upper limit normal; **AND**
L. Lutathera is prescribed by or in consultation with an oncologist or physician who specialized in the treatment of GEP-NETs; **AND**
M. Lutathera will be administered by physicians qualified by specific training and approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals; **AND**
N. Long-acting somatostatin analogs will be discontinued at least 4 weeks prior to initiating Lutathera; **AND**
O. Short-acting octreotide will be discontinued at least 24 hours prior to initiating Lutathera; **AND**
P. Long-acting octreotide 30 mg will be administered IM 4 to 24 hours after each Lutathera dose; **AND**
Q. Long-acting octreotide 30 mg will be administered IM every 4 weeks following completion of Lutathera treatment until disease progression or for up to 18 months;

Limitations/Exclusions
1. Approval will be granted for 4 doses of Lutathera
2. Coverage cannot be renewed; a maximum of 4 doses will apply

Applicable Procedure Codes

Code	Description
A9513	Letetium lu 177, dotatate, therapeutic, 1 millicurie, 1 billable unit = 1 millicurie

Applicable NDCs

Code	Description

69488-0003-01	Lutathera, 370 MBq/ml, sterile preservative-free and clear, colorless to slightly yellow solution for intravenous use.

ICD-10 Diagnoses

Code	Description
C7A	Malignant neuroendocrine tumor
C7A.0	Malignant carcinoid tumors
C7A.00	Malignant carcinoid tumor of unspecified site
C7A.01	Malignant carcinoid tumor of the small intestine
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.02	Malignant carcinoid tumors of the appendix, large intestine, and rectum
C7A.020	Malignant carcinoid tumors of the appendix
C7A.021	Malignant carcinoid tumors of the cecum
C7A.022	Malignant carcinoid tumors of the ascending colon
C7A.023	Malignant carcinoid tumors of the transverse colon
C7A.024	Malignant carcinoid tumors of the descending colon
C7A.025	Malignant carcinoid tumors of the sigmoid colon
C7A.026	Malignant carcinoid tumors of the rectum
C7A.029	Malignant carcinoid tumors of the large intestine, unspecified portion
C7A.09	Malignant carcinoid tumor of other sites
C7A.090	Malignant carcinoid tumors of the bronchus and lung
C7A.091	Malignant carcinoid tumors of the thymus
C7A.092	Malignant carcinoid tumors of the stomach
C7A.093	Malignant carcinoid tumors of the kidney
C7A.094	Malignant carcinoid tumors of the foregut, unspecified
C7A.095	Malignant carcinoid tumors of the midgut, unspecified
C7A.096	Malignant carcinoid tumors of the hindgut, unspecified
C7A.098	Malignant carcinoid tumors of other sites
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant 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 tuors 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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/2/2024	Annual Review: Updated formatting, added dosing limits
EmblemHealth & ConnectiCare	06/06/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	09/06/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	12/30/2020	Annual review: no policy changes
EmblemHealth & ConnectiCare	10/14/2019	Annual review
EmblemHealth & ConnectiCare	1/1/2019	Added A9513, Removed A9699, C9399, J3490, J9999, Added NDC 69488-0003-01, Added Diagnosis codes C7B.00, C7B.01, C7B.02, C7B.04, C25.0, C25.1, C25.2, C25.4, C25.7, C25.8, C25.9

References

1. Lutathera injection prescribing information. Millburn, NJ: Advanced Accelerator Applications USA, Inc: May 2020.
2. U.S. Food and Drug Administration. FDA approves new treatment for certain digestive tract cancers. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm594043.htm. Accessed April 30th, 2018
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Neuroendocrine and Adrenal Tumors, version 1.2018. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed April 2018