

Medical Policy:

Lutathera® (lutetium Lu 177 dotatate) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.45	March 18, 2025	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 $\leq 20\%$; **AND**
- F. The patient has a Karnofsky performance-status score of ≥ 60 ; **AND**
- G. The patient is at least 12 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.092	Malignant carcinoid tumors of the stomach
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
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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/18/2025	Annual Review: Updated ICD-10 Codes. No criteria changes.
EmblemHealth & ConnectiCare	5/29/2024	Revision: Updated age limitations from 18 years to 12 years of age.

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