

Lutetium Lu 177 dotatate (Lutathera®)

Place of Service
Office Administration
Outpatient Facility Infusion
Administration
Infusion Center Administration

HCPCS: A9513 per 1 mCi

Condition listed in policy (see criteria for details)

- [Carcinoid syndrome](#)
- [Gastroenteropancreatic neuroendocrine tumors \(GEP-NETs\)](#)
- [Lung and thymus neuroendocrine tumors](#)
- [Pheochromocytoma / Paraganglioma](#)
- [Well-differentiated Grade 3 neuroendocrine tumors \(G3 NETs\)](#)

AHFS therapeutic class: Radioactive agent

Mechanism of action: Radiolabeled somatostatin analog

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for lutetium Lu 177 dotatate (Lutathera®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Carcinoid syndrome

1. Disease is somatostatin receptor-positive

Covered Dose:

Up to 7.4 GBq (200 mCi) given intravenously every 7-9 weeks for a total of 4 doses

Coverage Period

One year (total of four doses)

ICD-10:

C7A.00, C7A.010-C7A.012, C7A.019-C7A.026, C7A.029, C7A.090-C7A.096, C7A.098, C7A.1, C7A.8, C7B.00-C7B.04, C7B.09, C7B.8, D3A.00, D3A.010-D3A.012, D3A.019-D3A.026, D3A.029, D3A.090-D3A.092, D3A.094-D3A.096, D3A.098, E34.0, Z85.020, Z85.030, Z85.040, Z85.060, Z85.110, Z85.230

Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

1. Disease is somatostatin receptor-positive

Covered Dose:

Up to 7.4 GBq (200 mCi) given intravenously every 7-9 weeks for a total of 4 doses

Coverage Period

One year (total of four doses)

ICD-10:

C25.4, C7A.00, C7A.010-C7A.012, C7A.019-C7A.026, C7A.029, C7A.090-C7A.096, C7A.098, C7A.1, C7A.8, C7B.00-C7B.04, C7B.09, C7B.8, D3A.00, D3A.010-D3A.012, D3A.019-D3A.026, D3A.029, D3A.090-D3A.092, D3A.094-D3A.096, D3A.098, E16.1, E16.3, E16.8, E34.0, Z85.020, Z85.030, Z85.040, Z85.060, Z85.07, Z85.110, Z85.230, Z85.858

Lung and thymus neuroendocrine tumors

1. Unresectable, recurrent, or metastatic disease, **AND**
2. Disease is somatostatin receptor-positive

Covered Dose:

Up to 7.4 GBq (200 mCi) given intravenously every 7-9 weeks for a total of 4 doses.

Coverage Period

One year (total of four doses)

ICD-10:

C7A.00, C7A.090, C7A.091, C7A.098, C7A.1, C7A.8, C7B.00-C7B.04, C7B.09, E34.0, C7B.8, Z85.110, Z85.230

Pheochromocytoma/Paraganglioma

1. Locally unresectable disease or distant metastases, **AND**
2. Disease is somatostatin receptor-positive

Covered Dose:

Up to 7.4 GBq (200 mCi) given intravenously every 7-9 weeks for a total of 4 doses.

Coverage Period

One year (total of four doses)

ICD-10:

C74.10-C74.12, C74.90-C74.92, C75.5, C7B.8, Z85.858

Well-differentiated Grade 3 neuroendocrine tumors (G3 NETs)

1. Locally advanced unresectable or metastatic disease, **AND**
2. Disease is somatostatin receptor-positive

Covered Dose:

Up to 7.4 GBq (200 mCi) given intravenously every 7-9 weeks for a total of 4 doses.

Coverage Period

One year (total of four doses)

ICD-10:

C74.10-C74.12, C74.90-C74.92, C75.5, C7B.8, Z85.858

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for lutetium Lu 177 dotatate (Lutathera®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

370 MBq/mL (10 mCi/ml) of lutetium Lu 177 dotatate solution supplied in 30 mL single-dose vial containing 7.4 GBq (200 mCi) ± 10% of lutetium Lu 177 dotatate

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Lutathera® (Lutetium Lu 177 dotatate) [Prescribing information]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; 6/2022.
- National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors (Volume 1.2023). Available at <http://www.nccn.org>

(7) Policy Update

Date of last review: 2Q2024

Date of next review: 2Q2025

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*