

Clinical Policy: Lutetium Lu 177 Dotatate (Lutathera)

Reference Number: PA.CP.PHAR.384

Effective Date: 10.17.18

Last Review Date: 07/17/19

[Coding Implications](#)

[Revision Log](#)

Description

Lutetium Lu 177 dotatate (Lutathera[®]) is a radiolabeled somatostatin analog.

FDA Approved Indication(s)

Lutathera is indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (NETs), including foregut, midgut, and hindgut NETs in adults.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness[®] that Lutathera is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Neuroendocrine Tumors (must meet all):

1. Diagnosis of a somatostatin receptor-positive NET of one of the following origins (a or b):
 - a. Gastrointestinal tract or pancreas;
 - b. Lung or thymus (off-label);
2. Prescribed by or in consultation with an oncologist;
3. Disease is metastatic or locally advanced;
4. Member experienced disease progression while on a long-acting somatostatin analog (e.g., octreotide, lanreotide);
5. Member has not received ≥ 4 doses of Lutathera;
6. Dose does not exceed 7.4 GBq (200 mCi) every 8 weeks, up to a total of 4 doses.

Approval duration: 32 weeks (no more than 4 total doses)

B. Pheochromocytoma/Paraganglioma (off-label) (must meet all):

1. Diagnosis of a somatostatin receptor-positive pheochromocytoma/paraganglioma;
2. Prescribed by or in consultation with an oncologist;
3. Disease is metastatic or locally unresectable;
4. Member has not received ≥ 4 doses of Lutathera;
5. Dose does not exceed 7.4 GBq (200 mCi) every 8 weeks, up to a total of 4 doses.

Approval duration: 32 weeks (no more than 4 total doses)

C. Other diagnoses/indications

1. Refer to the off-label use policy diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Member has not received ≥ 4 doses of Lutathera;
4. If request is for a dose increase, new dose does not exceed 7.4 GBq (200 mCi) every 8 weeks, up to a total of 4 doses.

Approval duration: 32 weeks (no more than 4 total doses)

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months; or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CT: computed tomography

FDA: Food and Drug Administration

NET: neuroendocrine tumor

NCCN: National Comprehensive Cancer Network

PET: positron emission tomography

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Somatuline [®] Depot (lanreotide)	120 mg SC every 4 weeks	120 mg/month
Sandostatin [®] LAR Depot (octreotide LAR)*	30 mg IM once monthly (20 mg may be used for pancreatic NETs)	30 mg/month

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

**Off-label for the treatment of NETs (octreotide is only FDA-approved for the treatment of symptoms associated with carcinoid tumors) – NET dosing recommendations are per the NCCN guidelines*

Appendix C: Contraindications

Not applicable

Appendix D: General Information

- Somatostatin receptor expression can be detected by somatostatin receptor-based imaging, which includes ^{68}Ga -dotatate PET/CT (preferred per the NCCN) and somatostatin receptor scintigraphy.
- The NCCN Neuroendocrine and Adrenal Tumors guidelines recommend the use of Lutathera:
 - For somatostatin receptor-positive bronchopulmonary/thymus, gastrointestinal, and pancreatic NETs that have progressed following therapy with octreotide or lanreotide and are locoregionally advanced or have distant metastases (category 2A, except for mid-gut tumors [category 1]); and
 - For the primary treatment of somatostatin receptor-positive pheochromocytoma/paraganglioma that is locally unresectable or has distant metastases (category 2A).
- Use of Lutathera with long-acting somatostatin analogs:
 - Before initiating Lutathera: Long-acting somatostatin analogs (e.g., long-acting octreotide) should be discontinued for at least 4 weeks prior to initiation of Lutathera. Short-acting octreotide can be administered as needed up to 24 hours prior to initiating Lutathera.
 - During Lutathera treatment: Long-acting octreotide 30 mg should be administered intramuscularly between 4 to 24 hours after each Lutathera dose. Long-acting octreotide should not be administered within 4 weeks of each subsequent Lutathera dose. Short-acting octreotide may be given for symptomatic management during Lutathera treatment, but must be withheld for at least 24 hours before each Lutathera dose.
 - Following Lutathera treatment: Long-acting octreotide 30 mg intramuscularly should be continued every 4 weeks after completing Lutathera until disease progression or for up to 18 months following treatment initiation.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
GEP-NET	7.4 GBq (200 mCi) IV every 8 weeks for a total of 4 doses	See regimen
NET of lung or thymus origin, pheochromocytoma, paraganglioma*		

**Off-label – dosing recommendations are per the NCCN guidelines*

VI. Product Availability

Single-dose vial for injection: 370 MBq/mL (10 mCi/mL)

VII. References

1. Lutathera Prescribing Information. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; January 2018. Available at: <https://www.lutathera.com>. Accessed May 7, 2018.
2. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors. Version 2.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed May 7, 2018.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 7, 2018.

4. Strosberg J, El-Haddad G, Wolin E, et al. Phase 3 trial of ¹⁷⁷Lu-dotatate for midgut neuroendocrine tumors. N Engl J Med. 2017; 376(2): 125-135.
5. Brabander T, van der Zwan WA, Teunissen JJM, et al. Long-term efficacy, survival, and safety of [¹⁷⁷Lu-DOTA⁰,Tyr³]octreotate in patients with gastroenteropancreatic and bronchial neuroendocrine tumors. Clin Cancer Res. 2017; 1-8.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
A9699	Radiopharmaceutical, therapeutic, not otherwise classified

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	