Clinical Policy Title:	lutetium lu 177 dotatate
Policy Number:	RxA.399
Drug(s) Applied:	Lutathera®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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. Age ≥ 18 years;
4. Disease is metastatic or locally advanced, and unresectable;
5. Member experienced disease progression while on a long-acting somatostatin analog (e.g., octreotide, lanreotide);
6. Dose does not exceed 7.4 GBq (200 mCi) every 8 weeks, up to a total of 4 doses.

Approval Duration
Commercial: 224 days (no more than 4 total doses)
Medicaid: 224 days (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. Age ≥ 18 years;
4. Disease is metastatic or locally advanced, and unresectable;
5. Dose does not exceed 7.4 GBq (200 mCi) every 8 weeks, up to a total of 4 doses.

Approval Duration
Commercial: 224 days (no more than 4 total doses)
Medicaid: 224 days (no more than 4 total doses)

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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
Commercial: 224 days (no more than 4 total doses**)**
Medicaid: 224 days (no more than 4 total doses)

References

1. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors. Version 2. 2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed April 18, 2023.
2. 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. Available at: https://pubmed.ncbi.nlm.nih.gov/28076709/. Accessed April 18, 2023.
3. Bose KS, Sarma RH. Delineation of the intimate details of the backbone conformation of pyridine nucleotide coenzymes in aqueous solution. Biochem Biophys Res Commun. 1975;66(4):1173-1179. Available at: https://pubmed.ncbi.nlm.nih.gov/2/. Accessed April 18, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Initial and Continued approval duration was updated to include Medicaid & Commercial approval duration. 4. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 5. References were reviewed and updated.	7/21/2020	9/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.3 was updated to include “Pregnancy status in females of reproductive potential…” 2. Initial Approval Criteria I.B.5 was updated to include “Member experienced disease progression while on…” 3. References were reviewed and updated.	06/01/2021	09/14/2021
Policy was reviewed: 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	03/23/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.3: Updated to remove prior criteria pertaining to indication Neuroendocrine Tumors, “Pregnancy status in females of reproductive potential prior to initiating Lutathera® has been verified.”	04/18/2023	07/13/2023

2. Initial Approval Criteria, I.B.5: Updated to remove prior disease progression criteria "Member experienced disease progression while on a somatostatin analog (e.g., octreotide, lanreotide)." 3. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023