

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Lutathera (lutetium Lu 177 dotatate)

DRUG.00098

Override(s)	Approval Duration
Lutathera (lutetium Lu 177 dotatate)	1 year

Medications
Lutathera (lutetium Lu 177 dotatate) 10 Mci/MI (370 Mbq/MI) Intravenous Solution

APPROVAL CRITERIA

I. Lutathera (lutetium Lu 177 dotatate) may be approved for the treatment of the following tumors when the following criteria are met:

A. Individual is using for the treatment of locally advanced, inoperable, or metastatic well-differentiated gastroenteropancreatic neuroendocrine tumors including foregut, midgut and hindgut neuroendocrine tumors;

OR

B. Individual is using for locally advanced bronchopulmonary or thymus neuroendocrine tumors;

AND

C. Individual is 18 years of age or older; **AND**

D. Tumor has progressed while receiving greater than or equal to 4 months of somatostatin analog therapy (such as octreotide LAR or lanreotide) with evidence of tumor progression on imaging; **AND**

E. Individual has target lesions overexpressing somatostatin receptors confirmed by an appropriate somatostatin receptor-based imaging study (such as, ⁶⁸Ga-dotatate PET/CT or somatostatin receptor scintigraphy); **AND**

F. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2; **AND**

G. Individual has not received prior treatment with a radiolabeled somatostatin analog;

OR

II. Lutathera (lutetium Lu 177 dotatate) may be approved as *primary* treatment for locally

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New Program Date 07/25/2018

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0277-18

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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unresectable or metastatic pheochromocytoma **or** paraganglioma when the following criteria are met:

- A. Individual is 18 years of age or older; **AND**
- B. Individual has target lesions overexpressing somatostatin receptors confirmed by an appropriate somatostatin receptor-based imaging study (such as ⁶⁸Ga-dotatate PET/CT or somatostatin receptor scintigraphy); **AND**
- C. Individual has an ECOG performance status of 0 to 2; **AND**
- D. Individual has not received prior treatment with a radiolabeled somatostatin analog.

Lutathera (lutetium Lu 177 dotatate) may **not** be approved when the above criteria are not met and for all other indications.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Lutathera [Product Information]. Colletterto Giacosa, Italy. Advanced Accelerator Applications, S.r.l., and Advanced Accelerator Applications USA, Inc., NJ; January 26, 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208700s000lbl.pdf. Accessed on May 29, 2018.
2. National Comprehensive Cancer Network®. NCCN Drugs & Biologics Compendium® (electronic version). For additional information visit the NCCN website: <http://www.nccn.org>. Accessed on May 29, 2018.
3. National Institutes of Health (NIH). Lu-177-DOTATATE (Lutathera) in therapy of inoperable pheochromocytoma/ paraganglioma. NLM Identifier: NCT03206060. Last updated April 4, 2018. Available at: <https://clinicaltrials.gov/ct2/show/NCT03206060>. Accessed on May 29, 2018.
4. National Institutes of Health (NIH). Phase I/II trial of anti-PD-1 checkpoint inhibitor nivolumab and 177Lu-DOTA0-Tyr3-octreotate for patients with extensive-stage small cell lung cancer. NLM Identifier: NCT03325816. Last updated March 2, 2018. Available at: <https://clinicaltrials.gov/ct2/show/NCT03325816>. Accessed on May 29, 2018.
5. NCCN Clinical Practice Guidelines in Oncology® (NCCN). © 2018 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org>. Accessed on May 29, 2018.
 - Neuroendocrine and Adrenal Tumors (V2.2018). Revised May 4, 2018.

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