SPECIALTY GUIDELINE MANAGEMENT

LUTATHERA (lutetium Lu 177 dotatate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

B. Compendial Uses

- 1. Carcinoid syndrome
- 2. Neuroendocrine tumors (NETs) of the lung and thymus (carcinoid tumors)
- 3. Pheochromocytoma/paraganglioma

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Somatostatin receptor status as detected by somatostatin receptor-based imaging

III. CRITERIA FOR INITIAL APPROVAL

A. Neuroendocrine tumors (NETs)

- Tumors of the gastrointestinal (GI) tract (carcinoid tumors)
 Authorization of 12 months and 4 doses total may be granted for treatment of somatostatin receptor-positive NETs of the gastrointestinal tract when both of the following criteria are met:
 - a. Member has clinically significant tumor burden or progressive locoregional advanced disease and/or distant metastases.
 - b. Member experienced disease progression on octreotide or lanreotide.

2. Tumors of the pancreas

Authorization of 12 months and 4 doses total may be granted for treatment of somatostatin receptor-positive NETs of the pancreas when both of the following criteria are met:

- a. Member has progressive locoregional advanced disease and/or distant metastases.
- b. Member experienced disease progression on octreotide or lanreotide.
- 3. Neuroendocrine tumors (NETs) of the lung and thymus (carcinoid tumors) Authorization of 12 months and 4 doses total may be granted for treatment of somatostatin receptor-positive NETs of the lung and thymus when all of the following criteria are met:
 - a. Member has locoregional unresectable or distant metastatic disease.

Lutathera 2513-A SGM P2019a

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b. Member experienced disease progression on octreotide or lanreotide.

B. Carcinoid Syndrome

Authorization of 12 months and 4 doses total may be granted for treatment of poorly controlled carcinoid syndrome when all of the following criteria are met:

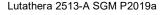
- 1. Member has somatostatin receptor-positive neuroendocrine tumors of the gastrointestinal tract, lung or thymus.
- 2. Member experienced progression on octreotide or lanreotide.
- 3. Lutathera will be used in combination with either a) octreotide LAR or lanreotide for persistent symptoms (i.e., flushing, diarrhea) or b) telotristat for persistent diarrhea.

C. Pheochromocytoma/paraganglioma

Authorization of 12 months and 4 doses total may be granted for treatment of somatostatin receptor-positive pheochromocytoma/paraganglioma when the member has locally unresectable disease or distant metastases.

IV. REFERENCES

- 1. Lutathera [package insert]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.: July 2018.
- 2. The NCCN Drugs & Biologics Compendium[®] © 2019 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed September 12, 2019.
- 3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Neuroendocrine and Adrenal Tumors (Version 1.2019) https://www.nccn.org. Accessed September 12, 2019.



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