Reference number(s)
4236-A

STANDARD MEDICARE PART B 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
Somatostatin receptor status as detected by somatostatin receptor-based imaging

III. CRITERIA FOR INITIAL APPROVAL

A. Neuroendocrine tumors (NETs)

1. 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 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 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 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.

IV. REFERENCES

1. Lutathera [package insert]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; July 2018.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 24, 2020.