Reference number(s)
2513-A

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)

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 both of the following criteria are met:
   i. Member has clinically significant tumor burden or progressive locoregional advanced disease and/or distant metastases.
   ii. 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:
   i. Member has symptomatic disease, clinically significant tumor burden, progressive locoregional advanced disease and/or distant metastases.
   ii. 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 one of the following criteria are met:

i. Member has locoregional unresectable disease and has progressed on octreotide or lanreotide
ii. Member has distant metastatic disease, has experienced progression on octreotide or lanreotide, and meets one of the following criteria:
    a. Clinically significant tumor burden and low grade (typical) histology
    b. Evidence of progression
    c. Intermediate grade (atypical) histology
    d. Symptomatic disease

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.; May 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 05, 2021.