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
Lutathera is indicated for the treatment of somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in pediatric patients 12 years and older and adults.

B. Compendial Uses
1. Carcinoid syndrome
2. Neuroendocrine tumors (NETs) of the lung and thymus (carcinoid tumors)
3. Pheochromocytoma/paraganglioma
4. Well-differentiated grade 3 NETs with favorable biology

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 the member has recurrent, locoregional advanced disease and/or distant metastases and one of the following criteria is met:
   i. Member has clinically significant tumor burden, or
   ii. Member experienced disease progression on octreotide long-acting release (LAR) 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, or progressive recurrent, locoregional advanced disease and/or distant metastases.
   ii. Member experienced disease progression on octreotide LAR 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 recurrent or locoregional unresectable disease and has progressed on octreotide LAR or lanreotide
ii. Member has distant metastatic disease, has experienced progression on octreotide LAR or lanreotide, and meets one of the following criteria:
    a. Clinically significant tumor burden and low grade (typical carcinoid) histology
    b. Evidence of disease progression
    c. Intermediate grade (atypical carcinoid) histology
    d. Symptomatic disease

4. Well-differentiated grade 3 NETs with favorable biology
   Authorization of 12 months and 4 doses total may be granted for treatment of well-differentiated grade 3 unresectable locally advanced or metastatic NETs with favorable biology (e.g., relatively low Ki-67 [less than 55%], slow growing, positive somatostatin receptor [SSTR]-based PET imaging) when member meets one of the following criteria:
    i. Clinically significant tumor burden, or
    ii. Evidence of disease progression

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 LAR or lanreotide.
3. The requested medication 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 in combination with octreotide LAR or lanreotide.

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 meets one of the following criteria:

1. Member has locally unresectable disease, or
2. Member has distant metastases

IV. REFERENCES

1. Lutathera [package insert]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; April 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 03, 2024.