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.

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

All other indications are considered experimental/investigational and are not a covered benefit.

Compendial uses
- Neuroendocrine tumors (NETs) of the lung and thymus (carcinoid tumors)
- Pheochromocytoma/paraganglioma

II. CRITERIA FOR INITIAL APPROVAL

A. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
Authorization of 12 months may be granted for treatment of somatostatin receptor-positive GEP-NETs.

B. Neuroendocrine tumors (NETs) of the lung and thymus (carcinoid tumors)
Authorization of 12 months may be granted for treatment of somatostatin receptor-positive NETs of the lung and thymus (carcinoid tumors)

C. Pheochromocytoma/paraganglioma
Authorization of 12 months may be granted for treatment of somatostatin receptor-positive pheochromocytoma/paraganglioma

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCE

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 January 29, 2019.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Neuroendocrine and Adrenal Tumors (Version 4.2018) https://www.nccn.org. Accessed January 28, 2019.