Reference number(s)
2513-A

Specialty Guideline Management Lutathera-Bexlutry-Bravnetsa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lutathera	lutetium Lu 177 dotatate
Bexlutry	lutetium Lu 177 dotatate
Bravnetsa	lutetium Lu 177 dotatate

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 Indications[1-3]

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

Bexlutry and Bravnetsa are indicated for the treatment of adults with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.

Compendial Uses[4]

- Carcinoid syndrome

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- Neuroendocrine tumors (NETs) of the lung and thymus (carcinoid tumors)
- Pheochromocytoma/paraganglioma
- Well-differentiated grade 3 NETs with favorable biology

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Somatostatin receptor status as detected by somatostatin receptor-based imaging

Coverage Criteria

Neuroendocrine tumors (NETs)[1-4]

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:

- Member has clinically significant tumor burden, or
- Member experienced disease progression on octreotide long-acting release (LAR) or lanreotide.

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:

- Member has symptomatic disease, clinically significant tumor burden, or progressive recurrent, locoregional advanced disease and/or distant metastases.
- Member experienced disease progression on octreotide LAR or lanreotide.

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:

- Member has recurrent or locoregional unresectable disease and has progressed on octreotide LAR or lanreotide
- Member has distant metastatic disease, has experienced progression on octreotide LAR or lanreotide, and meets one of the following criteria:
    - Clinically significant tumor burden and low grade (typical carcinoid) histology

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- Evidence of disease progression
- Intermediate grade (atypical carcinoid) histology
- Symptomatic disease

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:

- Clinically significant tumor burden, or
- Evidence of disease progression

Carcinoid Syndrome[4]

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:

- Member has somatostatin receptor-positive neuroendocrine tumors of the gastrointestinal tract, lung or thymus.
- Member experienced progression on octreotide LAR or lanreotide.
- 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.

Pheochromocytoma/paraganglioma[4]

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:

- Member has locally unresectable disease, or
- Member has distant metastases

References

1. Lutathera [package insert]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; October 2024.
2. Bexlutry [package insert]. Noblesville, IN: Curium US LLC; September 2026.
3. Bravnetsa [package insert]. Indianapolis, IN: Point Biopharma USA Inc.; September 2026.
4. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 08, 2026.

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