STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

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Office of Pharmacy Services
Prior Authorization Criteria
Lutathera® (lutetium Lu 177 dotatate)
Billed under: A9513
Effective 9/8/2025

LUTATHERA is a somatostatin analog (SSA) FDA approved for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

Initial authorization requires review by the Medical Director and may be approved when all of the following criteria is met:

1. Must be prescribed by an Oncologist; **AND**

2. The patient has ONE of the following:
   a. A diagnosis of somatostatin-positive, GEP-NET **AND ALL** of the following:
      i. The patient has locally advanced, inoperable, or metastatic carcinoid tumor; **AND**
      ii. Appropriate imaging study has been performed to document over-expression of somatostatin receptors (SSTR) of GEP-NETs (i.e., somatostatin receptor scintigraphy (SRS) or gallium-68 DOTATATE (68Ga-DOTATATE) PET/CT scan); **AND**
      iii. The tumor is well differentiated with a Ki-67 index of 20% or less as documented in a pathology report (see Policy Guidelines below*); **AND**
      iv. Has received long-acting SSA (SSA therapy for a duration of at least 12 weeks) with disease progression noted during treatment; **AND**
      v. Will discontinue long-acting SSA (e.g., octreotide long-acting repeatable (LAR)) for at least four weeks prior to initiating the requested agent; **OR**
   b. Another FDA approved indication for the requested agent; **AND**

3. The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**

4. The requested dose is within the FDA labeled dosing for the requested indication; **AND**

5. The patient has adequate bone marrow, renal and hepatic function (the following would be contraindications: serum creatinine > 1.7 mg/dL or creatinine clearance < 50 mL/minute; hemoglobin < 8.0 g/dL; WBC < 2000/mm^3; platelets < 75,000 mm^3; total bilirubin > 3 x upper limit of normal); **AND**

6. Patient is 12 years of age or older; **AND**

7. Documented negative pregnancy test (in females) immediately prior to starting therapy; **AND**

8. Patient has NOT exceeded four treatment doses in lifetime.

* Well-differentiated neuroendocrine tumors include low grade (G1) and intermediate-grade (G2) tumors, which correlate with a defined Ki-67 proliferation index, as determined by an immunohistochemical stain. Well-differentiated, low grade neuroendocrine tumors have a Ki-67 index of < 3%, and well-differentiated, intermediate grade neuroendocrine tumors have Ki-67 index of 3% to 20%.

Initial authorization approval for GEP-NETs is limited to 12 months for a maximum of four doses per lifetime.

Criteria for Continuation Approval requires the following conditions to be met:

1. The patient has been previously approved for the requested agent through the Medical Drug Review process; **AND**
2. Treatment-related toxicities (e.g., anemia, hepatotoxicity, neutropenia, renal toxicity, thrombocytopenia) are resolved prior to re-starting the requested agent; **AND**
3. The patient has NOT exceeded four treatment doses in lifetime.

References:

1. Lutathera [package insert]. Millburn, NJ: Novartis AG; 2024. https://www.novartis.com/us-en/sites/novartis_us/files/lutathera.pdf (Accessed 9/8/2025)
2. NCCN Clinical Practice Guidelines. Neuroendocrine Tumors. Version 3.2017 – June 13,2017. Available at: https://www.nccn.org/professionals/physician_gls/PDF/neuroendocrine.pdf (Accessed 08/12/2022)
3. https://www.drugs.com/newdrugs/fda-approves-lutathera-lutetium-lu-177-dotatate-gastroenteropancreatic-neuroendocrine-tumors-4686.html (Accessed 8/12/2022)

Please refer to the members' contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member according to BMS coverage and policy guidelines.