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

Office of Pharmacy Services
Prior Authorization Criteria

Lutathera® (lutetium Lu 177 dotatate)
Billed under: A9513

LUTATHERA is 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, gastroenteropancreatic neuroendocrine tumor (GEP-NETs) **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 receptor of gastroenteropancreatic neuroendocrine tumor(s) (GEP-NETs) (i.e. somatostatin receptor scintigraphy; or 68-GaDotate 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. The patient has received long-acting somatostatin analog (SSA therapy for a duration of at least 12 weeks) with disease progression noted during treatment; **AND**
      v. Will discontinue long-acting somatostatin analog (e.g. octreotide LAR) for at least 4 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 of 50 mL/minute; hemoglobin 8.0 g/dL; WBC < 2000/mm3; platelets < 75,000 mm3; total bilirubin > 3 x upper limit of normal); **AND**

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

7. The patient has NOT exceeded 4 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 4 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 4 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 5/3/2024)
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 member's 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.