LUTATHERA® (lutetium Lu 177 dotatate) is a radiolabeled somatostatin analog that binds to somatostatin receptor expressing cells, including malignant somatostatin receptor-positive tumors, and is then internalized. Beta emission from Lu 177 causes cellular damage by formation of free radicals in somatostatin receptor-positive cells and neighboring cells.

INDICATION(S): LUTATHERA® (lutetium Lu 177 dotatate) is indicated for the treatment of:
- For patients with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) including foregut, midgut, and hindgut neuroendocrine tumors in adults

REASONS FOR PA:

- Cost
- Potential for misuse
- Toxicity

CRITERIA for APPROVAL:

1. Patient is an adult (≥18 years of age); and
2. Patient has documented low or intermediate grade (Ki-69 index ≤20%), locally advanced or metastatic, gastroenteropancreatic (including foregut, midgut, and hindgut) or bronchopulmonary or thymus neuroendocrine tumor; and
3. Patient has documented somatostatin receptor expression of a neuroendocrine tumor as detected by somatostatin receptor-based imaging (68Ga-dotate positron emission tomography or computed tomography, which is preferred) or somatostatin receptor scintigraphy; and
4. Patient has documented disease progression while on octreotide long-acting release therapy; and
5. Patient is not receiving long-acting somatostatin analogues for at least 4 weeks prior to initiating Lu 177 dotatate; and
6. Patient does not have severe renal impairment (creatinine clearance, <30 mL/min); and
7. Patient has adequate bone marrow and hepatic function as determined by the treating physician; and
8. Patient has documented Karnofsky Performance score of 60 or greater.

REASONS for DENIAL of BENEFIT:

1. Patient has hypersensitivity to LUTATHERA (lutetium Lu 177 dotatate) or any of its components
2. Patient does not meet above criteria

RENEWAL CRITERIA:

1. No recurrent grade 2, 3, or 4 thrombocytopenia; and
2. No recurrent grade 3 or 4 anemia and neutropenia; and
3. No recurrent hepatotoxicity; and
4. No recurrent grade 3 or 4 nonhematologic toxicity; and
5. No renal toxicity requiring a treatment delay of 16 weeks or longer; and
6. Patient has demonstrated a response to therapy

History: New policy 11/2018

BENEFIT APPROVAL:

Initial approval for a period of 8 weeks. Renewal approval period: 6 months. Max of 4 doses total