Review Criteria

Review Area: SPECIALTY DRUGS

Date Implemented: 10/30/2018
Last Review Date: 10/30/2018
CPOC Approval: 01/10/2019

Specific Item/Procedure/Service: LUTATHERA

Approved Criteria Set:

- ☐ InterQual
- ■ LMP
- ☐ LMP as an internal IQ edit
- ☐ BMS Criteria (based on Policy Manual
- ☐ BMS Approved Criteria

Local Medical Policy: Developed Criteria Specific

Applicable HCPCS/CPT Codes: A9513 Injection Lutetium Lu 177, dotatate, therapeutic, 1 mCi (Lutathera)

Applicable ICD10 Codes: (if diagnosis specific restricted)

Background/Overview with Rationale: Lutathera (lutetium Lu 177 dotatate) is used for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendrocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

Criteria:

Initial Evaluation

Lutathera will be approved when ALL of the following are met:

1. ONE of the following:
   A. The patient has a diagnosis of somatostatin-positive, gastroenteropancreatic neuroendocrine tumor (GEP-NETS) AND ALL of the following:
      - The patient has locally advanced, inoperable, or metastatic carcinoid tumor; **AND**
      - Appropriate imaging study has been performed to document over-expression of somatostatin receptor of gastroenteropancreatic neuroendocrine tumor(s) (GEP-NET) (i.e. somatostatin receptor scintigraphy; or 68-Ga-Dotate PET/CT scan); **AND**
      - 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**

- 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**
- Will discontinue long-acting somatostatin analog (e.g. octreotide LAR) for at least 4 weeks prior to initiating the requested agent, **OR**

B. The patient has another FDA approved indication for the requested agent, **AND**

2. The prescriber is a specialist (e.g., oncologist) or the prescriber has consulted with a specialist, **AND**
3. The patient does NOT have any FDA labeled contraindications to the requested agent, **AND**
4. The requested dose is within 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 per deciliter or creatinine clearance of 50 ml/minute; Hgb 8.0 g/dl; WBC < 2000/mm3; platelets < 75,000 mm3; total bilirubin > 3 x upper limit of normal); **AND**
6. Patient is 18 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 3-20%.

Length of Approval: GEP-NETs – 12 months for maximum 4 doses per lifetime; All other FDA approved diagnosis – 12 months.

Renewal Evaluation

Lutathera will be approved when ALL of the following are 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.
3. The patient has NOT exceeded 4 treatment doses in lifetime.

Length of Approval: GEP-NETs – 12 months for maximum 4 doses per lifetime; All other FDA approved diagnosis – 12 months.

The requested agent will also be approved when the following are met:

1. The patient has been previously approved, AND

2. Treatment-related toxicities (e.g., anemia, hepatotoxicity, neutropenia, renal toxicity, thrombocytopenia) are resolved prior to re-starting the requested agent

Length of Approval: 12 months

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.

References: https://lutathera.com/ Accessed 10/30/2018

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 10/30/2018

https://www.drugs.com/newdrugs/fda-approves-lutathera-lutetium-lu-177-dotatate-gastroenteropancreatic-neuroendocrine-tumors-4686.html Accessed 10/30/2018

Review Date	Approving Authority/Responsible Party	Date Approved:
10/30/2018	Sherri Young, DO, FAAFP, Medical Director, WV KEPRO	11/05/2018
11/05/2018	Dr. James Becker, MD BMS Medical Director	11/05/2018
11/05/2018	Brian Thompson, Pharm D	11/05/2019
01/10/2019	CPOC	01/10/2019