Review Criteria

Program: *Charleston, WV Office WV BMS DHHR*	**Date Implemented:** *01/10/2019*
Review Area: *Specialty Drugs*	**Last Review Date:** *08/12/2022*
Criteria Number: *WV.SP.MC.004 Specialty Drugs LMP LUTATHERA*	**CPOC Approval Date:** *10/7/2021*

Specific Item/Procedure/Service: *(may be a review process, equipment, drug, etc.)* ***Please verify that you have checked to see if this criteria has been created by another account by checking the box below:*** ☒	*LUTATHERA*
Approved Criteria Set:	☐ InterQual® ☐ LMP as an internal IQ edit ☐ Client Criteria (based on Policy Manual) ☒ Client Approved Criteria
Local Medical Policy:	**Developed Criteria Specific**
Applicable HCPCS/CPT Codes:	**C9031-lutetium Lu 177 dotatate**
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
References: *(URAC v. 7.3: HUM 1 – Review Criteria Requirements: Please include the names of the appropriate providers or prescribers with current knowledge relevant to the criteria or scripts under review (i.e. appropriate actively practicing physicians, pharmacists, and other providers with current knowledge relevant to the criteria or scripts under review) who participated in the review process)*	**https://lutathera.com/ Accessed 08/12/2022** 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 https://www.drugs.com/newdrugs/fda-approves-lutathera-lutetium-lu-177-dotatate-gastroenteropancreatic-neuroendocrine-tumors-4686.html Accessed 08/12/2022

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.

Revision Summary

Review Date	Doc. Id No.	Rev #	Approving Authority/Responsible Party	Description of Changes/Comments
11/5/2018	MCWVSP.004	1	Sherri Young, DO, FAAFP, Medical Director, WV KEPRO	Review
01/10/2019	MCWVSP.004	1	CPOC	CPOC Approval
9/16/2019	MCWVSP.004	2	Karen Wilkinson, BSN RN ACM Medical Utilization Management, RN Clinical Review Manager	Operational Review
9/19/2019	MCWVSP.004	2	Karen Wilkinson, BSN RN ACM Medical Utilization Management, RN Clinical Review Manager	Operational Approval

10/24/2019	MCWVSP.004	2	CPOC	CPOC Approval
08/21/2020	MCWVSP.004	3	Karen Wilkinson, BSN RN ACM UM RN Clinical Review Manager	Operational Review
08/24/2020	MCWVSP.004	3	Karen Wilkinson, BSN RN ACM UM RN Clinical Review Manager	Operational Approval
10/7/2020	MCWVSP.004	3	CPOC	CPOC Approval
08/30/2021	MCWVSP.004	4	Paul Kuryla, MD Medical Director Kepro	Review
09/07/2021	MCWVSP.004	4	Karen Wilkinson, BSN RN ACM UM RN Clinical Review Manager	Operational Review and Approval
10/07/2021	MCWVSP.004	4	CPOC	CPOC Approval
08/18/2022	MCWVSP.004		Paul Kuryla, MD Medical Director Kepro	Operational Review
08/18/2022	MCWVSP.004		Brian Thompson, PharmD BMS	Operational Review