Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Lutathera (lutetium Lu 177 dotatate)

Override(s)	Approval Duration
Lutathera (lutetium Lu 177 dotatate)	1 year

Medications
Lutathera (lutetium Lu 177 dotatate) 10 Mci/Ml (370 Mbq/Ml) Intravenous Solution

APPROVAL CRITERIA

Requests for Lutathera (lutetium Lu 177 dotatate) may be approved if the following criteria are met:

I. Individual has a diagnosis of one of the following:
   A. Locally advanced, inoperable, or metastatic well-differentiated somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut and hindgut neuroendocrine tumors;

   OR

   B. Locally advanced or distant metastatic bronchopulmonary or thymus neuroendocrine tumors (NCCN 2A) when the following criteria are met:
      1. Individual is 18 years of age or older; **AND**
      2. Tumor has progressed while receiving greater than or equal to 4 months of somatostatin analog therapy (such as octreotide LAR or lanreotide) with evidence of tumor progression on imaging; **AND**
      3. Individual has target lesions overexpressing somatostatin receptors confirmed by an appropriate somatostatin receptor-based imaging study (such as ^{68}Ga-dotatate PET/CT or somatostatin receptor scintigraphy); **AND**
      4. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2; **AND**
      5. Individual has not received prior treatment with a radiolabeled somatostatin analog;

   OR

   C. Locally unresectable or metastatic pheochromocytoma **or** paraganglioma when the following criteria are met:
      1. Individual is 18 years of age or older; **AND**
      2. Individual has target lesions overexpressing somatostatin receptors confirmed by an appropriate somatostatin receptor-based imaging study (such as ^{68}Ga-dotatate PET/CT or somatostatin receptor scintigraphy); **AND**
      3. Individual has an ECOG performance status of 0 to 2; **AND**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

4. Individual has not received prior treatment with a radiolabeled somatostatin analog.

Requests for Lutathera (lutetium Lu 177 dotatate) may **not** be approved for the following:

I. All other indications not included above.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
4. Lutathera® (lutetium Lu 177 dotatate) [product information]. Giacosa (TO), Italy. January 2018.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on April 12, 2019.
    a. B-Cell Lymphomas. V2.2019. Revised March 6, 2019.
    b. Neuroendocrine and Adrenal Tumors. V1.2019. Revised March 5, 2019.