Lutathera® (lutetium Lu 177 dotatate)

Last Review Date: July 25th, 2018  Number: MG.MM.PH.45

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Definitions
Lutathera (lutetium Lu 177 dotatate) is a radiolabeled somatostatin analog indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. Lutathera binds to somatostatin receptors on cells, including malignant somatostatin receptor-positive tumor cells and is internalized upon binding. The beta emission from Lu 177 induces cellular damage by formation of free radicals in somatostatin receptor-positive cells and in neighboring cells. Lutathera is a radiopharmaceutical, so it must be handled with appropriate safety measures to minimize radiation exposure. It should be under the control of physicians who are qualified by specific training and experience. The physician’s training and experience must have been approved by a governmental agency authorized to license the use of radiopharmaceuticals.

The recommended dose of Lutathera is 7.4 gigabecquerel (GBq) administered intravenously (IV) every 8 weeks for a total of 4 doses. During treatment, long-acting octreotide 30 mg should be administered intramuscularly (IM) between 4 to 24 hours after each dose of Lutathera. Following completion of the 4 dose treatment of Lutathera, long-acting octreotide 30 mg should be administered IM every 4 weeks until disease progression or for up to 18 months.

Guideline
Lutathera is considered medically necessary when all of the following criteria are met:
• The patient has a diagnosis of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs); **AND**
• The patient’s disease is unresectable, locally advanced, or metastatic; **AND**
• The patient has had disease progression despite somatostatin analog therapy or molecularly targeted therapy (e.g. everolimus); **AND**
• Somatostatin receptor-positive GEP-NETs on all target lesions has been confirmed via Octreoscan; **AND**
• The tumor is well differentiated with a Ki-67 index ≤ 20%; **AND**
• The patient has a Karnofsky performance-status score of ≥ 60; **AND**
• The patient is at least 18 years of age; **AND**
• The patient is not currently pregnant or breastfeeding; **AND**
• If the patient is a sexually-active female of reproductive potential has had pregnancy status verified through a pregnancy test; **AND**
• The patient has a creatinine clearance ≥ 30 mL/min vy Cockcroft-gault; **AND**
• The patient’s total bilirubin ≤ 3 times upper limit normal; **AND**
• Lutathera is prescribed by or in consultation with an oncologist or physician who specialized in the treatment of GEP-NETs; **AND**
• Lutathera will be administered by physicians qualified by specific training and approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals; **AND**
• Long-acting somatostatin analogs will be discontinued at least 4 weeks prior to initiating Lutathera; **AND**
• Short-acting octreotide will be discontinued at least 24 hours prior to initiating Lutathera; **AND**
• Long-acting octreotide 30 mg will be administered IM 4 to 24 hours after each Lutathera dose; **AND**
• Long-acting octreotide 30 mg will be administered IM every 4 weeks following completion of Lutathera treatment until disease progression or for up to 18 months;

**Limitations/Exclusions**
• Approval will be granted for 4 doses of Lutathera
• Coverage cannot be renewed; a maximum of 4 doses will apply

**Applicable Procedure Codes**

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<td>Radiopharmaceutical, therapeutic, not otherwise classified</td>
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<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
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<td>J3490</td>
<td>Unclassified drugs</td>
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<td>J9999</td>
<td>Not otherwise classified, antineoplastic drugs</td>
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**Applicable Diagnosis Codes**

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<td>Malignant neuroendocrine tumor</td>
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<td>C7A.0</td>
<td>Malignant carcinoid tumors</td>
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References