OVERVIEW
Lutathera, a radiolabeled somatostatin analog, is FDA approved 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 used by or under the control of physicians who are qualified by specific training and experience. The physician’s training and experience must have been approved by appropriate governmental agency authorized to license the use of radiopharmaceuticals. Lutathera contributes to a patient’s overall long-term radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Radiation can be detected in the urine for up to 30 days following Lutathera administration. Radiation exposure must be minimized to patients, medical personnel, and household contacts during and after treatment with Lutathera.

POLICY STATEMENT
This policy involves the use of Lutathera. Prior authorization is recommended for medical benefit coverage of Lutathera. Approval is recommended for those who meet the conditions of coverage in the Criteria, Dosing, Initial/Extended Approval, Duration of Therapy, and Labs/Diagnostics for the diagnosis provided. The requirement that the patient meet the Criteria for coverage of the requested medication applies to the initial authorization only. Waste Management applies for all covered conditions. Conditions Not Recommended for Approval are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Lutathera as well as the monitoring required for AEs and long-term efficacy, initial approval requires Lutathera be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the
initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

**RECOMMENDED AUTHORIZATION CRITERIA**
Coverage of Lutathera is recommended in those who meet the following criteria:

**Food and Drug Administration (FDA)-Approved Indications**

1. **Somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs).**

   **Criteria.** *The patient must meet the following criteria (a, b, c, d, e, f, g, h, i and j):*
   
   a) The patient is at least 18 years of age and not pregnant or breastfeeding; AND
   b) Lutathera is prescribed by or in consultation with an oncologist or a physician who specializes in the treatment of GEP-NETs; AND
   c) The patient has somatostatin receptor-positive foregut, midgut, and hindgut GEP-NETs on all target lesions confirmed via NETSPOT or Octreoscan [documentation required]; AND
   d) The patient has GEP-NETs that have metastasized or are locally advanced and inoperable; AND
   e) The patient had disease progression during treatment with Sandostatin LAR Depot or somatostatin analog therapy plus Afinitor; AND
   f) The patient has a Karnofsky performance-status score of at least 60; AND
   g) Lutathera will be administered under the control of physicians who are qualified by specific training and experience and are approved by an appropriate governmental agency authorized to license the use of radiopharmaceuticals; AND
   h) The patient will discontinue use of long-acting somatostatin analogs (e.g., Sandostatin® LAR Depot [octreotide acetate for injectable suspension]) for at least 4 weeks prior to initiation of Lutathera; AND
   i) The patient will discontinue use of short-acting therapy for at least 24 hours prior to initiation of Lutathera; AND
   j) During Lutathera treatment, Sandostatin LAR Depot 30 mg will be administered intramuscularly (IM) between 4 to 24 hours after each Lutathera dose.

**Dosing in Somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs).** *Dosing must meet the following:*

The recommended dose is 7.4 gigabecquerel (GBq) [200 millicuries {mCi}] administered IV every 8 weeks for a total of 4 doses. During Lutathera treatment, Sandostatin LAR Depot 30 mg should be administered intramuscularly (IM) between 4 to 24 hours after each Lutathera dose.

**Initial Approval/ Extended Approval.**

A) **Initial Approval:** Approve 4 doses; 8 month duration period

B) **Extended Approval:** not recommended

**Duration of Therapy in Somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs).** One dose of Lutathera is administered every 8 weeks for a total of 4 doses.
Labs/Diagnostics. NETSPOT or Octreoscan results.

Waste Management for All Indications.
Lutathera is available as a 370 MBq/mL (10 mCi/mL) injection of lutetium Lu 177 dotatate in a single-dose, sterile, preservative-free vial. It is supplied for administration in a 30 mL single-dose vial containing 7.4 GBq (200 mCi) ± 10% of lutetium Lu 177 dotatate at the time of injection.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Lutathera has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.
Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES
FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes A9513

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<thead>
<tr>
<th>HCPCS Code(s):</th>
<th>Description</th>
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<td>A9513</td>
<td>Lutetium Lu 177, dotatate, therapeutic, 1 millicurie (mCi)</td>
<td>1/1/2019</td>
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