MEDICAL POLICY – 6.01.525
Therapeutic Radiopharmaceuticals in Oncology

Introduction

Radiopharmaceuticals are a way of delivering radiation to the body. They combine both specific drugs and precise amounts of radiation. Depending on the drug and the type of radiation, the drug can either be swallowed or delivered directly into a vein. The drug and radiation then travel throughout the body. The specified organ then takes up the drug, which delivers the radiation to its intended target. In small amounts, this technique is used to help diagnose medical problems. In larger doses, radiopharmaceuticals are used to treat some types of cancer. This policy describes when the radiopharmaceutical lutetium 177 (Lu 177) dotatate may be used for cancers of the digestive system called gastroenteropancreatic (GEP-NET) which have been resistant to other treatments.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
### Treatment

<table>
<thead>
<tr>
<th>Initial Treatment (Lutathera®)</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lutetium 177</strong> (Lu 177) dotatate treatment is considered medically necessary when <strong>ALL</strong> of the following conditions are met:</td>
<td></td>
</tr>
<tr>
<td>- Patient is an adult (≥18 years of age)</td>
<td></td>
</tr>
<tr>
<td>- Patient has documented low or intermediate grade (Ki-67 index ≤20%), locally advanced or metastatic, gastroenteropancreatic (including foregut, midgut, and hindgut)</td>
<td></td>
</tr>
<tr>
<td>- Patient has documented somatostatin receptor expression of a neuroendocrine tumor as detected by somatostatin receptor-based imaging ($^{68}$Ga-dotate positron emission tomography [PET]) or somatostatin receptor scintigraphy</td>
<td></td>
</tr>
<tr>
<td>- Patient has documented disease progression while on octreotide long-acting release therapy as demonstrated on computed tomography (CT) or $^{68}$Ga-dotate positron emission tomography (PET)</td>
<td></td>
</tr>
<tr>
<td>- Patient is not receiving long-acting somatostatin analogues for at least 4 weeks prior to initiating Lu 177 dotatate</td>
<td></td>
</tr>
<tr>
<td>- Patients does not have severe renal impairment (creatinine clearance, &lt;40 mL/min)</td>
<td></td>
</tr>
<tr>
<td>- Patient has adequate bone marrow and hepatic function as determined by the treating physician</td>
<td></td>
</tr>
<tr>
<td>- Patient has documented <strong>Karnofsky Performance Status</strong> score of 60 or greater</td>
<td></td>
</tr>
</tbody>
</table>

### Continuation of Treatment

| Continuation of **Lu 177** dotatate is considered medically necessary when **ALL** of the following conditions are met: |
| - No recurrent grade 2, 3, or 4 thrombocytopenia (see **Table 1**) |
| - No recurrent grade 3 or 4 anemia and neutropenia (see **Table 1**) |
| - No recurrent hepatotoxicity (see **definition** below) |
| - No recurrent grade 3 or 4 nonhematologic toxicity (see **Table 1**) |
| - No renal toxicity requiring a treatment delay of 16 weeks or longer (see **definition** below) |

### Treatment

<table>
<thead>
<tr>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lutetium 177</strong> (Lu 177) dotatate treatment is considered investigational in all other situations in which the above criteria are not met.</td>
</tr>
</tbody>
</table>
Treatment | Investigational
--- | ---
Lu 177 dotatate treatment greater than a total of 4 doses as per the Food and Drug Administration-approved regimen is considered investigational.

Length of Approval

<table>
<thead>
<tr>
<th>Approval</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial authorization</td>
<td>Lutetium 177 (Lu 177) dotatate may be approved up to 1 year up to a total of 4 doses.</td>
</tr>
</tbody>
</table>

Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met.

For initial treatment, the record should include the following:

- History and physical supporting the diagnosis of low or intermediate grade (Ki-67 index ≤20%), locally advanced or metastatic, gastroenteropancreatic (including foregut, midgut, and hindgut)
- Result of somatostatin receptor-based imaging ($^{68}$Ga-dotate positron emission tomography or computed tomography, which is preferred) or somatostatin receptor scintigraphy confirming somatostatin receptor expression of a neuroendocrine tumor
- Documentation that disease has progressed while on octreotide long-acting release therapy
- Documentation that patient is not receiving long-acting somatostatin analogues for at least 4 weeks prior to initiating Lu 177 dotatate
- Result of creatinine clearance (<30 mL/min), confirming that patient does not have severe renal impairment
- Documentation of adequate bone marrow and hepatic function
- Documented Karnofsky Performance Status score of 60 or greater

For continuation of treatment, documentation of the following:

- No recurrent grade 2, 3, or 4 thrombocytopenia
- No recurrent grade 3 or 4 anemia and neutropenia
- No recurrent hepatotoxicity
- No recurrent grade 3 or 4 nonhematologic toxicity
- No renal toxicity requiring a treatment delay of 16 weeks or longer
**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9513</td>
<td>Lutetium lu 177, dotatate, therapeutic, 1 millicurie (new code effective 1/1/19)</td>
</tr>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td>J9999</td>
<td>Not otherwise classified, antineoplastic drugs</td>
</tr>
</tbody>
</table>

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**Related Information**

The recommended dose of lutetium 177 (Lu 177) dotatate is 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses.

There are theoretical concerns regarding the competition between somatostatin analogues and Lu 177 dotatate for somatostatin receptor binding. Therefore, the following is recommended:

- Do not administer long-acting somatostatin analogues for 4 to 6 weeks prior to each Lu 177 dotatate treatment
- Stop short-acting somatostatin analogues 24 hours before each Lu 177 dotatate treatment
- Both long-acting and short-acting somatostatin analogues can be resumed 4 to 24 hours after each Lu 177 dotatate treatment

Lu 177 dotatate is a radiopharmaceutical and should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals.

Lu 177 dotatate should be discontinued permanently if the patient develops hepatotoxicity defined as bilirubinemia greater than 3 times the upper limit of normal (grade 3 or 4), or hypoalbuminemia less than 30 g/L with a decreased prothrombin ratio less than 70%.
Lu 177 dotatate should be discontinued permanently if patient develops renal toxicity defined as a creatinine clearance of less than 40 mL/min calculated using Cockcroft-Gault equation with actual body weight, or 40% increase in baseline serum creatinine, or 40% decrease in baseline creatinine clearance calculated using Cockcroft-Gault equation with actual body weight.

Table 1 describes the grading of severity used in the Common Toxicity Criteria for Adverse Events (version 4.03).

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.</td>
</tr>
<tr>
<td>2</td>
<td>Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living and refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.</td>
</tr>
<tr>
<td>3</td>
<td>Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living and refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.</td>
</tr>
<tr>
<td>4</td>
<td>Life-threatening consequences; urgent intervention indicated.</td>
</tr>
<tr>
<td>5</td>
<td>Death related to adverse event.</td>
</tr>
</tbody>
</table>

Table 2. Karnofsky Performance Status

<table>
<thead>
<tr>
<th>Karnofsky Performance Status Scale Definitions Rating (%) Criteria</th>
<th>Rating (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to carry on normal activity and to work; no special care needed</td>
<td>100</td>
</tr>
<tr>
<td>90</td>
<td>Able to carry on normal activity; minor signs or symptoms of disease</td>
</tr>
<tr>
<td>80</td>
<td>Normal activity with effort; some signs or symptoms of disease</td>
</tr>
<tr>
<td>Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed</td>
<td>70</td>
</tr>
<tr>
<td>60</td>
<td>Requires occasional assistance, but is able to care for most of his personal needs</td>
</tr>
<tr>
<td>50</td>
<td>Requires considerable assistance and frequent medical care</td>
</tr>
<tr>
<td>Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly</td>
<td>40</td>
</tr>
<tr>
<td>30</td>
<td>Severely disabled; hospital admission is indicated although death not imminent</td>
</tr>
<tr>
<td>20</td>
<td>Very sick; hospital admission necessary; active</td>
</tr>
</tbody>
</table>
Evidence Review

**Description**

Radiopharmaceuticals are composed of a radioisotope bond to an organic molecule and are used for diagnostic and therapeutic purposes. The organic molecule conveys the radioisotope to specific organs, tissues, or cells. Lutetium 177 (Lu 177) dotatate, classified as peptide receptor radionuclide therapy, is a radiolabeled-somatostatin analogue that binds to somatostatin receptor expressing cells, including malignant somatostatin receptor-positive tumors such as neuroendocrine tumors. It is then internalized and beta particle emission from Lu 177 induces cellular damage by formation of free radicals in somatostatin receptor-positive and neighboring cells.

**Background**

**Neuroendocrine Tumors**

Neuroendocrine tumors are a heterogeneous group of tumors that originate from the neuroendocrine cells in the diffuse neuroendocrine system anywhere in the body but more commonly in the gastrointestinal tract and the respiratory system. Approximately 61% of all neuroendocrine tumors originate from gastrointestinal system or pancreas and are referred to as gastroenteropancreatic neuroendocrine tumors. Lung neuroendocrine tumors may also be referred to as pulmonary neuroendocrine tumors, pulmonary carcinoids, or bronchopulmonary neuroendocrine tumors. Gastroenteropancreatic neuroendocrine tumors may further be characterized as functional or nonfunctional based on whether they secrete hormones that result in clinical symptoms particularly serotonin, which results in “carcinoid syndrome” that is characterized by flushing and diarrhea.

Neuroendocrine tumors are classified as orphan diseases by the Food and Drug Administration (FDA). Based on an analysis of Surveillance, Epidemiology, and End Results Program registry

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**Karnofsky Performance Status Scale Definitions Rating (%) Criteria**

<table>
<thead>
<tr>
<th>Rating</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Moribund; fatal processes progressing rapidly</td>
</tr>
<tr>
<td>0</td>
<td>Dead</td>
</tr>
</tbody>
</table>

data from 1973 to 2012, the overall incidence of neuroendocrine tumors has been reported to be in the range of 6.98 per 100,000 people per year.\(^1\)

**Diagnosis**

Neuroendocrine tumors are not easy to diagnose because of the rarity of the condition. Symptoms are often nonspecific or mimic other disorders such as irritable bowel syndrome (in the case of gastroenteropancreatic neuroendocrine tumors) or asthma (in the case of a lung neuroendocrine tumors) resulting in an average diagnosis delay of 5 to 7 years after symptom onset.\(^2\) In many cases, diagnosis is incidental to imaging for another unrelated cause. Most gastroenteropancreatic neuroendocrine tumors express somatostatin receptors that can be imaged using a radiolabeled form of the somatostatin analogue octreotide (eg, \(^{111}\text{In}\)-pentetretotide).

**Treatment Approach**

There is a general lack of prospective data to guide the treatment of neuroendocrine tumors. Gastroenteropancreatic neuroendocrine tumors are chemotherapy-responsive neoplasms, and platinum-based chemotherapy represents the backbone of treatment for both early and advanced-stage tumors.\(^3\) Surgery alone or followed by chemotherapy along with treatment of hormone-related symptoms may be the initial approach for localized disease. For asymptomatic patients with slow progression, observation with routine surveillance imaging is an option. The prognosis for patients with metastatic well-differentiated gastroenteropancreatic neuroendocrine tumors is highly variable. Based on retrospective analyses of large databases, the prognosis for patients with metastatic gastroenteropancreatic neuroendocrine tumors is variable. The median overall survival (from diagnosis) for patients with metastatic pancreatic neuroendocrine tumors has been reported to range from 2 to 5.8 years\(^4,5\) while the median overall survival for small bowel neuroendocrine tumors has been reported as 7.9 years.\(^6\)
Pharmacologic Treatment

First-Line Treatment Options

Somatostatin Analogues (Octreotide and Lanreotide)

Somatostatin is a peptide that binds to somatostatin receptors that are expressed in a majority of carcinoid tumors and inhibits the secretion of a broad range of hormones. Somatostatin analogues (eg, octreotide, lanreotide) were initially developed to manage the hormonal symptoms related to neuroendocrine tumors, they were found to exert antiproliferative activity, and clinical studies have demonstrated prolonged progression-free survival (PFS) in patients with neuroendocrine tumors treated with somatostatin analogues. However, the role of somatostatin analogues in patients with nonfunctioning neuroendocrine tumors is unclear.

Commercially available long-acting release forms of octreotide and lanreotide (eg, Sandostatin LAR, Somatuline Depot), which are administered intramuscularly on a monthly basis, have largely eliminated the need for daily self-injection of short-acting subcutaneous formulations.

Second-Line Treatment Options

Currently, there are no data to support a specific sequence of therapies and only streptozocin (Zanosar®), everolimus (Afinitor®/Zortress®), and sunitinib (Sutent®) are FDA approved for the treatment of pancreatic neuroendocrine tumors.

Mechanistic Target of Rapamycin Inhibitors

The mechanistic target of rapamycin is an enzyme that regulates cell metabolism and proliferation in response to environmental stimuli. It is upregulated in a variety of malignancies in response to stimulation by growth factors and cytokines. Whole-exome genomic analysis has shown that approximately 15% of pancreatic neuroendocrine tumors are associated with somatic variants in genes associated with the mechanistic target of rapamycin pathway. Everolimus, an oral mechanistic target of rapamycin inhibitor, has been shown to significantly prolong PFS vs placebo in patients with pancreatic neuroendocrine tumors (RADIANT-3 trial). Note that everolimus is approved by the FDA for adults with progressive neuroendocrine tumors of pancreatic origin and adults with progressive, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin that are unresectable, locally advanced or metastatic. The RADIANT-2 trial patients with progressive advanced neuroendocrine tumors...
associated with carcinoid syndrome failed to show a statistically significant improvement in the primary end point of PFS.\textsuperscript{15}

\textbf{Tyrosine Kinase Receptor Inhibitors}

Neuroendocrine tumors frequently overexpress the vascular endothelial growth factor and receptor. Sunitinib, is a multi-targeted tyrosine kinase inhibitor that targets multiple signaling pathways and growth factors and receptors including vascular endothelial growth factor and receptor 1, 2, and 3.\textsuperscript{12} It has been shown that daily sunitinib at a dose of 37.5 mg improves PFS, overall survival, and the overall response rate as compared with placebo among patients with advanced pancreatic neuroendocrine tumors.\textsuperscript{16} Note that sunitinib is FDA approved for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors in patients with unresectable locally advanced or metastatic disease.

\textbf{Chemotherapy}

Response to chemotherapy for advanced neuroendocrine tumors of the gastrointestinal tract and lung is highly variable and, at best, modest. Tumor response rates are generally low and no PFS benefit has been clearly demonstrated. Therefore, the careful selection of patients is critical to maximize the chance of response and avoid unnecessary toxicity. In advanced neuroendocrine tumors, platinum-based regimens are generally used. They include cisplatin and etoposide (most widely used), carboplatin and etoposide, 5-fluorouracil, capecitabine, dacarbazine, oxaliplatin, streptozocin, and temozolomide.\textsuperscript{17}

\textbf{Lutetium 177 Dotatate}

Lutetium 177 dotatate is a radiolabeled-somatostatin analogue that binds to somatostatin receptor expressing cells, including malignant somatostatin receptor-positive tumors. It is then internalized and beta particle emission from lutetium 177 induces cellular damage by formation of free radicals in somatostatin receptor-positive and neighboring cells.

\textbf{Summary of Evidence}

For individuals with a treatment-refractory gastroenteropancreatic neuroendocrine tumor including foregut, midgut, and hindgut tumors who receive Lu 177 dotatate, the evidence
includes a randomized, open-labeled trial and a retrospective cohort study. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. The randomized controlled trial results showed a consistent statistically significant and clinically meaningful effect on overall response rate, progression-free survival, and overall survival among patients treated with Lu 177 dotatate compared to those treated with long-acting octreotide. The results of the retrospective cohort study were consistent with the treatment effect observed in the randomized controlled trial and provide additional support for a clinical benefit of Lu 177 dotatate in patients with a gastroenteropancreatic neuroendocrine tumor. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with a treatment-refractory bronchopulmonary or thymus neuroendocrine tumors who receive Lu 177 dotatate, the evidence includes a retrospective cohort study. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. The retrospective cohort study included a small number of patients with bronchopulmonary (n=23) or thymus (n=2) neuroendocrine tumors. Among the 23 patients with bronchopulmonary neuroendocrine tumor, the median progression-free survival was 20 months, the median time to progression was 25 months, and median overall survival was 52 months. Stratified results of 2 patients with thymus neuroendocrine tumors were not reported. The Food and Drug Administration in its review of the ERASMUS study for patients with gastroenteropancreatic neuroendocrine tumor concluded that time to event analyses such as time to progression, progression-free survival, and overall survival were not interpretable in the context of the single-arm ERASMUS study because of missing data at baseline, high dropout rates and open-label design of the study. Of note, despite the current evidence base, National Comprehensive Cancer Network guidelines give a category 2A recommendation for use of Lu 177 dotatate for the treatment of bronchopulmonary and thymic locoregional advanced or distant metastases neuroendocrine tumors if there is clinically significant tumor burden and low grade (typical) or evidence of progression or intermediate grade (atypical). The evidence is insufficient to determine the effects of technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.
Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03325816a</td>
<td>Phase I/II Trial of Anti-PD-1 Checkpoint Inhibitor Nivolumab and 177Lu-DOTA0-Tyr3-Octreotate for Patients With Extensive-Stage Small Cell Lung Cancer</td>
<td>56</td>
<td>Dec 2022</td>
</tr>
<tr>
<td>NCT03206060</td>
<td>Lu-177-DOTATATE (Lutathera) in Therapy of Inoperable Pheochromocytoma/ Paraganglioma</td>
<td>90</td>
<td>Jan 2024</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The National Comprehensive Cancer Network

The National Comprehensive Cancer Network guidelines (v.3.2018) for neuroendocrine and adrenal tumors added key eligibility criteria for patients treated with lutetium 177 dotate for neuroendocrine tumors. Eligibility criteria include low or intermediate grade neuroendocrine tumor (proliferation index Ki-67 < 20%), detection of somatostatin receptor expression using somatostatin-based receptor imaging, and adequate bone marrow, renal and hepatic function.

Table 4 summarizes the National Comprehensive Cancer Network guidelines for neuroendocrine and adrenal tumors.23

Table 4. Recommendations for Use of Lutetium 177 Dotate for Neuroendocrine Tumors

<table>
<thead>
<tr>
<th>Treatment Category</th>
<th>Recommendation Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid-gut locoregional advanced or distant metastases gastrointestinal neuroendocrine tumors after disease progression on somatostatin analogues</td>
<td>1</td>
</tr>
<tr>
<td>Bronchopulmonary/thymic locoregional advanced or distant metastases neuroendocrine tumors if there is clinically significant tumor burden and low grade (typical) or evidence of progression or intermediate grade (atypical)</td>
<td>2A</td>
</tr>
<tr>
<td>Treatment Category</td>
<td>Recommendation Category</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Locoregional advanced or distant metastases gastrointestinal neuroendocrine tumors after disease progression on somatostatin analogues</td>
<td>2A</td>
</tr>
<tr>
<td>Locoregional advanced or distant metastases pancreatic neuroendocrine tumors after disease progression on somatostatin analogues</td>
<td>2A</td>
</tr>
</tbody>
</table>

**Medicare National Coverage**

There is no national coverage determination.

**Regulatory Status**

On January 26, 2018, Lutathera® (lutetium 177 dotatate) was approved by FDA for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors, including foregut, midgut, and hindgut neuroendocrine tumors in adults.

**References**


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/01/19</td>
<td>New policy, approved March 19, 2019. This policy replaces 6.01.60. Policy created with literature review through October 2018. The use of lutetium 177 dotatate may be considered medically necessary for patients with gastroenteropancreatic tumors when criteria are met.</td>
</tr>
</tbody>
</table>

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200 Independence Avenue SW, Room 509F, HHH Building

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