

## Corporate Medical Policy

### Therapeutic Radiopharmaceuticals in Oncology

**File Name:** therapeutic\_radiopharmaceuticals\_in\_oncology  
**Origination:** 4/2018  
**Last Review:** 10/2024

#### Description of Procedure or Service

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Radiopharmaceuticals, also known as radionuclides, are composed of a radioisotope coupled to an organic molecule and are used for diagnostic and therapeutic purposes. The organic molecule targets the radioisotope to specific organs, tissues, or cells. Examples of radionuclides include peptide receptor radioligand therapy and metaiodobenzylguanidine (MIBG).

The peptide receptor radioligand therapy lutetium 177 (Lu 177) dotatate (Lutathera<sup>®</sup>) 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.

#### Gastroenteropancreatic Neuroendocrine Tumors

Neuroendocrine cells are widely distributed throughout the body, and tumors arising from these cells can occur in most organs. In the digestive system, including the tubular gastrointestinal tract and the pancreas, neuroendocrine tumors are generally divided into two major categories, well-differentiated neuroendocrine tumors (NETs) and poorly differentiated (high-grade) neuroendocrine carcinomas. These two major categories of neuroendocrine tumors behave differently in terms of biologic aggressiveness and in approach to treatment.

Well-differentiated gastroenteropancreatic neuroendocrine tumors (GEP-NETs), which have been referred to as carcinoid tumors or pancreatic islet cell tumors, are generally indolent, but all are potentially malignant, and the clinical course may be highly variable. Symptomatic disease may be due to either tumor bulk, including pain and/or bowel obstruction, or due to secretion of serotonin and other vasoactive substances, sometimes referred to as carcinoid syndrome.

The general treatment approach to well-differentiated GEP-NETs involves resecting potentially resectable disease, including metastasectomy. Unresectable, asymptomatic disease may involve observation, especially if tumor burden is limited, or initial therapy with a somatostatin analog if tumor burden is high. Unresectable, symptomatic disease usually involves initial therapy with a somatostatin analog (e.g. octreotide), and dose escalation as needed for control of symptoms of carcinoid syndrome and control of tumor growth. Patients with radiologic or symptom progression despite somatostatin analog therapy may benefit from noncurative debulking therapy or nonsurgical liver-directed therapy. Patients with more widespread disease that is not eligible for liver-directed therapy may benefit from systemic treatment with molecularly targeted agents, such as everolimus.

Lutetium 177 (Lu 177) dotatate (Lutathera<sup>®</sup>) is a targeted form of systemic radiotherapy that binds to cell surface somatostatin receptors, and once internalized, induces cellular damage by free radical formation. Most GEP-NETs express high-affinity receptors for somatostatin, and somatostatin-based imaging can provide information on tumor burden and location. Lutetium 177 (Lu 177) dotatate has been proposed as a treatment option in patients with GEP-NETs who progress despite first-line therapy.

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## Prostate-specific Membrane Antigen (PSMA)-positive Metastatic Castration-resistant Prostate Cancer

Metastatic castration-resistant prostate cancer remains clinically challenging despite multiple drug classes that delay progression of disease. Prostate-specific membrane antigen (PSMA) is expressed in metastatic castration-resistant prostate cancer. Radioligand therapies such as lutetium-177-PSMA-617 can selectively target prostate cancer cells in patients who have a PSMA-positive gallium-68-labeled PSMA-11 positron-emission tomographic-computed tomographic scan.

## Pheochromocytoma/Paraganglioma

Pheochromocytomas are rare catecholamine-secreting neuroendocrine tumors that are derived from chromaffin cells of the adrenal medulla in most cases. Presenting less frequently, ectopic or extra-adrenal pheochromocytomas that originate from para-aortic sympathetic ganglia are termed paragangliomas. However, both tumors are similar in clinical presentation and treatment approach and are often referred to collectively as PPGL (pheochromocytoma and paraganglioma). These tumors release catecholamines and associated norepinephrine metabolites, which result in hypertension, arrhythmia, and/or hyperglycemia, and occur in less than 0.2% of patients with hypertension. Other symptoms, which are often paroxysmal in presentation, include headaches, sweating, tachycardia, chest pain, nausea, vomiting, and anxiety.

Standard initial treatment of PPGL following diagnosis is surgical resection combined with pharmacological blood pressure control. Locally unresectable tumors and distant metastases are instead treated with radiation therapy and cytoreductive resection when possible, iobenguane I 131 therapy in iobenguane scan positive tumors, or systemic chemotherapy. In patients with distant metastases, curative surgery is not a treatment option and the five-year survival rate is approximately 12 percent. The goals of treatment for metastatic, recurrent, or unresectable disease are thus aimed at reducing symptoms and controlling tumor progression. Prior to the approval of iobenguane I 131 (Azedra®), there have been no FDA-approved treatments for metastatic, recurrent, or unresectable PPGL. Standard non-approved treatment options have included chemotherapy (e.g. cyclophosphamide, vincristine, and dacarbazine [CVD]) and conventional, low-specific-activity I 131 at high doses.

Lutetium 177 (Lu 177) dotatate is given by intravenous infusion. It is a radiopharmaceutical and must be handled with appropriate safety measures to minimize radiation exposure.

### **Related Policies:**

Radioembolization for Primary and Metastatic Tumors of the Liver  
Cryosurgical Ablation of Primary and Metastatic Liver Tumors  
Maximum Units of Service

***\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

## **Policy**

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**BCBSNC will provide coverage for lutetium 177 (Lu 177) dotatate (Lutathera®) and Lutetium 177 (Lu 177) vipivotide tetraxetan (Pluvicto) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

## **Benefits Application**

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

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## When Therapeutic Radiopharmaceuticals are covered

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Lutetium 177 (Lu 177) dotatate (Lutathera) is considered medically necessary for the treatment of adult patients with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) or bronchopulmonary or thymus neuroendocrine tumors when the following criteria are met:

- The patient has unresectable, locally advanced or metastatic disease, **AND**
- The patient has had disease progression despite somatostatin analog therapy or molecularly targeted therapy (e.g. everolimus), **AND**
- An appropriate imaging study has been performed to document over-expression of somatostatin receptors by the target lesions, **AND**
- The tumor is well-differentiated with a Ki-67 index of 20% or less, as documented in a pathology report. (see Policy Guidelines)

Lutetium 177 (Lu 177) vipivotide tetraxetan (Pluvicto) is considered medically necessary for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer when the following criteria are met:

- The patient has unresectable metastatic disease; **AND**
- The patient had a PSMA-positive gallium-68-labeled PSMA-11 positron-emission tomographic-computed tomographic scan; **AND**
- The patient has disease progression despite advanced androgen therapy, e.g., at least one androgen-receptor-pathway inhibitor, as demonstrated by prostate specific antigen (PSA) progression after at least four weeks; **AND**
- The patient has disease progression after at least one taxane regimen.

Radiopharmaceuticals are eligible for coverage for indications supported by an NCCN (National Comprehensive Cancer Network) 1 or 2A recommendation when all requirements, e.g. performance status, disease severity, previous failures, and mono-versus combination therapy, as well as the requested dose and treatment duration are met.

## When Therapeutic Radiopharmaceuticals are not covered

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Lutetium 177 (Lu 177) dotatate (Lutathera) is considered **investigational** and therefore not covered when the above criteria are not met, including for the treatment of pheochromocytomas and paragangliomas.

Lutetium 177 (Lu 177) vipivotide tetraxetan (Pluvicto) is considered **investigational** and therefore not covered when the above criteria are not met.

Treatment with lutetium 177 (Lu 177) dotatate or lutetium 177 (Lu 177) vipivotide tetraxetan greater than the Food and Drug Administration (FDA)-approved regimen are considered **investigational**.

Retreatment with lutetium 177 (Lu 177) dotatate or Lutetium 177 vipivotide tetraxetan is considered **investigational**.

## Policy Guidelines

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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

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index of <3%, and well-differentiated, intermediate-grade neuroendocrine tumors have a Ki-67 index of 3-20%.

GEP-NETs include those arising from the foregut (gastroduodenal), midgut (distal small intestine and proximal colon), hindgut (distal colorectal) and pancreas.

## **Lutetium 177 (Lu 177) dotatate (Lutathera)**

The recommended Lutathera dosage is 7.4 GBq (200 mCi) administered intravenously every 8 weeks for a total of 4 doses. Lutathera dosing may be modified based on adverse reactions.

Before initiating Lutathera, discontinue any long-acting somatostatin analogs for at least 4 weeks and short-acting octreotide at least 24 hours prior to each Lutathera dose. During Lutathera treatment, administer long-acting octreotide 30 mg intramuscularly 4 to 24 hours after each Lutathera dose and short-acting octreotide for symptomatic management. Do not administer long-acting octreotide within 4 weeks of each subsequent Lutathera dose and withhold short-acting octreotide for at least 24 hours before each Lutathera dose. Following Lutathera treatment, continue long-acting octreotide 30 mg intramuscularly every 4 weeks after completing Lutathera until disease progression or for up to 18 months following treatment initiation.

Pre-medicate with antiemetics 30 minutes before recommended amino acid solution. Initiate recommended intravenous amino acid solution 30 minutes before Lutathera infusion; continue during and for 3 hours after Lutathera infusion.

According to the manufacturer's safety information, Lutathera must be handled with appropriate safety measures to minimize radiation exposure, and pregnancy status in females of reproductive potential should be verified prior to initiating Lutathera. Other warnings and precautions for Lutathera listed within the prescribing information include: myelosuppression, secondary myelodysplastic syndrome (MDS) and leukemia, renal toxicity, hepatotoxicity, neuroendocrine hormonal crisis, embryo-fetal toxicity, and infertility risk.

In January 2018, the U.S. Food and Drug Administration approved Lutathera (lutetium Lu 177 dotatate) for the treatment of somatostatin receptor-positive GEP-NETs in adults, largely based on support from the NETTER-1 trial. This phase 3, open-label, randomized, multicenter clinical trial included 229 patients with advanced, progressive, well-differentiated midgut neuroendocrine tumors. Patients received either <sup>177</sup>Lu-Dotatate every 8 weeks for up to 4 infusions plus best supportive care including octreotide (n=116) or high-dose octreotide alone (n=113). The majority of patients in the <sup>177</sup>Lu-Dotatate group (77%) received all four infusions of <sup>177</sup>Lu-Dotatate. The treatment groups were well balanced in terms of clinical characteristics and tumor grade, with 83% of patients having metastatic disease to the liver. The ileum was the primary tumor site in 73% of patients. The primary end point was progression-free survival (PFS), which, at 20 months, was 65.2% (95% confidence interval [CI], 50.0-76.8) in the <sup>177</sup>Lu-Dotatate group versus 10.8% (95% CI, 3.5-23.0) in the control group. Median PFS was 8.4 months in the control group and not reached in the <sup>177</sup>Lu-Dotatate group (p<0.001). Secondary end points included objective tumor response rate, which was 18% in the <sup>177</sup>Lu-Dotatate group and 3% in the control group (p<0.001). The rates of grade 3 and 4 adverse events were similar between the groups; however, grade 3 or 4 neutropenia, thrombocytopenia and lymphopenia were reported in 1%, 2%, and 9% of patients, respectively, in the <sup>177</sup>Lu-Dotatate group versus none of control group patients.

Long-term safety and survival were evaluated in an investigator-sponsored, open-label, single-arm, single-institution (Erasmus) retrospective study of over 1200 patients with somatostatin receptor positive neuroendocrine tumors who received <sup>177</sup>Lu-Dotatate treatment. Primary tumor sites included bronchus, foregut, midgut, hindgut, pancreas and unknown. Patient populations were heterogeneous for baseline tumor status (progressive versus nonprogressive) and treatments received prior to <sup>177</sup>Lu-Dotatate. Of these patients, the safety analysis included 610 patients, 360 (60%) of which had metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs), treated with a cumulative dose of at least 100 mCi (3.7 GBq) <sup>177</sup>Lu-Dotatate. Median follow-up was 78 months. Long-term

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toxicity included acute leukemia in four patients (0.7%) and myelodysplastic syndrome in nine patients (1.5%). There was no therapy-related long-term renal or hepatic failure. Overall response rate, defined as complete or partial response, in patients with midgut and pancreatic NETs with progressive disease at baseline was 84% and 81%, respectively. Median overall survival for GEP-NETs was only reported for pancreas (71 months [95% CI 56-86]) and midgut (60 months [52-68]), due to small numbers of other gastrointestinal primaries. A subset analysis of PFS in patients with midgut tumors and progressive disease at baseline was 24 months [95% CI 18-30].

Lutetium 177 (Lu 177) dotatate (Lutathera) has not been approved by the FDA to treat pheochromocytomas and paragangliomas.

## **Lutetium 177 (Lu 177) vipivotide tetraxetan (Pluvicto)**

Lu-PMSA-617 delivers beta-particle radiation selectively to PSMA-positive cells. The recommended dose administered intravenously is 7.4 GBq (200mCi) every 6 weeks for up to 6 doses. In 2022, the FDA approved Lu-177 vipivotide tetraxetan largely based on the VISION trial, a phase 3 trial investigating the efficacy and safety of <sup>177</sup>Lu-PMSA-617 plus protocol-permitted standard of care in a cohort with previously treated metastatic castration-resistant prostate cancer who were shown PSMA positive per positron-emission tomographic (PET) scanning. The median follow up time as 20.9 months. <sup>177</sup>Lu-PSMA-617 plus standard care significantly was found superior to standard care for imaging-based progression-free survival (median, 8.7 vs 3.4 months, confidence interval {CI} 0.29 – 0.57) and overall survival (median 15.3 vs 11.3 months, CI 0.52 – 0.74). Lu-PSMA-617 adverse events were higher in the treatment arm (52% vs 38%), but quality of life was not reported to be adversely affected.

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: A9513, A9699, A9607, A9800*  
*ICD-10 code: C61*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## **Scientific Background and Reference Sources**

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Specialty Matched Consultant Advisory Panel 5/2022

Medical Director review 5/2022

Development and Update of Guidelines <https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines>

Medical Director review 6/2022

Specialty Matched Consultant Advisory Panel 5/2023

Medical Director review 5/2023

Specialty Matched Consultant Advisory Panel 5/2024

Medical Director review 5/2024

Medical Director review 10/2024

## Policy Implementation/Update Information

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### **For Policy Titled: “Lutathera® (lutetium Lu 177 dotatate)”**

- 4/13/18 New policy developed. Lutathera is considered medically necessary for the treatment of adult patients with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) when the following criteria are met: the patient has unresectable, locally advanced or metastatic disease, AND the patient has had disease progression despite somatostatin analog therapy or molecularly targeted therapy (e.g. everolimus), AND an appropriate imaging study has been performed to document over-expression of somatostatin receptors by the target lesions, AND the tumor is well-differentiated with a Ki-67 index of 20% or less, as documented in a pathology report (see Policy Guidelines). Added HCPCS code A9699 to “Billing/Coding” section. References added. Medical Director review 4/2018. (krc)
- 6/29/18 Added HCPCS code C9031 to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 5/23/2018. No change to policy statement. (an)
- 11/30/18 Under “When Covered” section added additional indication for Lutathera for bronchopulmonary or thymus neuroendocrine tumors. Added HCPCS code A9513 to Billing/Coding section for effective date 1/1/2019. References added. Medical Director review 11/2018. (krc)

### **For Policy Re-titled: “Therapeutic Radiopharmaceuticals in Oncology”**

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- 12/31/18 Policy title revised from “**Lutathera® (lutetium Lu 177 dotatate)**” to “**Therapeutic Radiopharmaceuticals in Oncology**”. Updated Description section, Policy Statement, and Policy Guidelines to include newly approved Azedra with medical necessity statement: “High-specific activity (HSA) iobenguane I 131 (Azedra) may be considered medically necessary for the treatment of adult and pediatric (age 12 years or older) patients with pheochromocytoma or paraganglioma.” Added HCPCS code C9408 to Billing/Coding section and deleted code C9031 for effective date 1/1/2019. References added. Medical Director review 12/2018. (krc)
- 6/11/19 References added. Specialty Matched Consultant Advisory Panel review 5/15/2019. No change to policy statement. (krc)
- 12/31/19 Added HCPCS code A9590 to Billing/Coding section and deleted codes A9699 and C9408 effective 1/1/2020. (krc)
- 6/23/20 Reference added. Specialty Matched Consultant Advisory Panel review 5/20/2020. (krc)
- 6/1/21 Reference added. Specialty Matched Consultant Advisory Panel review 5/2021. Medical Director review. (bb)
- 5/31/22 The following reimbursement policy was added to related policies: Maximum Units of Service. Archived policies removed from related policies section. References added. The following statement added to When Covered Section: “Lutetium 177 (Lu 177) vipivotide tetraxetan (Pluvicto) is considered medically necessary for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer when the following criteria are met: The patient has unresectable metastatic disease; AND; The patient had a PSMA-positive gallium-68-labeled PSMA-11 positron-emission tomographic-computed tomographic scan; AND; The patient has disease progression despite advanced androgen therapy, e.g., at least one androgen-receptor-pathway inhibitor, as demonstrated by prostate specific antigen (PSA) progression after at least four weeks; AND; The patient has disease progression after at least one taxane regimen. Billing/Coding section updated to add code A9699 – effective 10/1/2022; added ICD-10 code C61. Specialty Matched Consultant Advisory Panel review 5/2022. Medical Director review 2022. (tt)
- 6/30/22 When covered section updated to add “Radiopharmaceuticals are eligible for coverage for indications supported by an NCCN (National Comprehensive Cancer Network) 1 or 2A recommendation when all requirements, e.g. performance status, disease severity, previous failures, and mono- versus combination therapy, as well as the requested dose and treatment duration are met.” Policy Guidelines updated. References updated. Medical Director review 6/2022. (tt)
- 8/23/22 Policy statement updated to include coverage of Lutetium 177 (Lu 177) vipivotide tetraxetan (Pluvicto). No change to policy intent. Medical Director review 8/2022. (tt)
- 9/30/22 Added HCPCS codes A9607 and A9800 to Billing/Coding section. Effective 10/1/22. (tt)
- 5/30/23 References added. Specialty Matched Consultant Advisory Panel review 5/2023. Medical Director review 2023. No change to policy statement. (tt)
- 5/29/24 References added. Specialty Matched Consultant Advisory Panel review 5/2024. Medical Director review 2024. No change to policy statement. (tt)
- 11/13/24 Description, policy statement, coverage criteria, policy guidelines updated to remove reference iobenguane I 123 as the product has been withdrawn from the market by the manufacturer. Removed CPT code A9590 from Billing/Coding section. Medical Director review 10/2024. (tt)



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