MEDICAL POLICY

Medical Policy Title	**Radiopharmaceuticals for the Treatment of Cancer**
Policy Number	**6.01.44**
Current Effective Date	**September 17, 2026**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

This policy does not address the use of radiotracers for advanced diagnostic procedures.

I. Requests for radiopharmaceutical treatments in excess of their U.S. Food and Drug Administration (FDA) approved regimen, will be considered **investigational**.

II. Xofigo injection (Radium Ra 223 Dichloride)

A. Xofigo is considered **medically appropriate** when **ALL** the following criteria are met:

1. Diagnosis of medically or surgically castration-resistant prostate cancer,
2. Presence of symptomatic bone metastases;
3. No known visceral metastatic disease or bulky regional lymph nodes greater than three (3) cm on imaging performed within the past 30 days.

III. Pluvicto (Lutetium Lu 177 Vipivotide Tetraxetan)

A. Pluvicto is considered **medically appropriate** when **ALL** the following criteria are met:

1. Prostate-specific membrane antigen (PSMA)-positive;
2. Metastatic castration-resistant prostate cancer (mCRPC);
3. Have been treated with at least one (1) androgen-receptor pathway inhibitor (i.e., enzalutamide and/or abiraterone);
4. Have been treated with one (1) or two (2) taxane-based regimens **OR** are considered appropriate to delay taxane-based chemotherapy;
5. Have at least one PSMA-positive metastatic lesion and no PSMA-negative lesions* PSMA PET/CT scan.

*PSMA negative lesions are defined as metastatic disease that lacks PSMA uptake including bone with soft tissue components ≥ 1.0 cm, lymph nodes ≥ 2.5 cm in short axis, solid organ metastases ≥ 1.0 cm in size.

IV. Strontium-89 Chloride

A. Strontium-89 is considered **medically appropriate** for the treatment of bone pain in

patients with confirmed skeletal metastases.

V. Lutathera (Lutetium or Lu 177 dotatate)

A. Peptide receptor radionuclide therapy using Lutathera is considered **medically appropriate** when **ALL** the following requirements are met:

1. Treatment is for **any** of the following:
    a. somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETS) of the foregut, midgut and hindgut that are either inoperable or metastatic;
    b. SSTR positive tumors of the pancreas that are either inoperable metastatic; or
    c. SSTR positive bronchopulmonary or thymic-tumors, which are either inoperable or metastatic; **or**
    d. pheochromocytomas or paragangliomas;

AND

2. For well-differentiated G1 or G2 neuroendocrine tumors with a Ki-67 < 20%; or well-differentiated G3 neuroendocrine tumors with a Ki-67 < 55%;
3. Positive somatostatin receptor scintigraphy with correlative MRI or CT imaging of metastatic measurable disease or 68-Ga-Dotate PET scan positive for metastatic disease*;
4. Progression of the disease following treatment with somatastatin-analogs (SSA);
5. The absence of **all** the following contraindications:
    a. serum creatinine: 1.7 mg or greater per deciliter or creatinine clearance of less than 50 ml/minute;
    b. Hgb. 8.0 g/dl or less;
    c. WBC less than 2000/mm3; **and**
    d. Platelets less than 75,000 mm3.

*In the absence of metastatic disease, documentation should include a surgical or medical consult and the reason for inoperability.

VI. HICON (sodium iodide I 131 solution/ capsules)

A. HICON (sodium iodide I 131 solution/ capsules) is considered **medically appropriate** for the treatment of thyroid carcinoma (i.e., follicular, papillary, Hürthle cell) when **ANY** of the following criteria are met:

1. Remnant ablation after surgery in T1b/T2 localized disease when there are no other adverse pathologic, laboratory, or imaging features;
2. Adjuvant therapy under **any** of the following circumstances:

a. gross extrathyroidal extension;
b. a primary tumor greater than 4 cm;
c. postoperative unstimulated thyroglobulin (Tg) greater than 10ng/mL;
d. six or more positive lymph nodes or bulky lymph nodes; **or**
e. for follicular or Hürthle cell/Oncocytic, extensive vascular invasion (≥4 foci);

3. Presence of proven and documented unresectable or metastatic disease based on pathology or pretherapy radioiodine scan.

RELATED POLICIES

Corporate Medical Policy

6.01.29 Positron Emission Tomography (PET) Oncologic Applications

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The dose regimen of Xofigo is 55 kBq (1.49 mCi) per kg body weight, given in six (6) injections at four (4) week intervals.

II. The dose regimen of Pluvicto is 7.4 GBq (200 mCi) given by intravenous (IV) injection or infusion every six (6) weeks for up to six (6) doses. The frequency depends on how the cancer responds and how the patient tolerates therapy.

III. The recommended dose of Strontium-89 Chloride is 148 MBq, 4 mCi, administered IV over one (1) to two (2) minutes or a dose of 1.5-2.2 MBq/kg, 40-60 uCi/kg body weight. Repeated administration of Strontium-89 Chloride should be based on an individual patient's response to therapy, current symptoms, and hematologic status, and are generally not recommended at intervals of less than 90 days.

IV. The recommended dose of Lutathera is 7.4 GBq (200 mCi) every eight (8) weeks for a total of four (4) doses.

V. The recommended dose regimen of HICON is based on thyroid gland size and uptake. The dose for the treatment of thyroid carcinoma is 1,110 MBq to 3,700 MBq (30 mCi to 100 mCi) administered orally. The National Comprehensive Cancer Network (NCCN) recommends 30-50 mCi for remnant ablation, 75-150mCi for adjuvant therapy.

DESCRIPTION

Radiopharmaceuticals deliver radiation to the cancer cells within their microenvironment, providing a more targeted approach. This is done either by using delivery vehicles that bind preferentially to a specific target or may be taken up by a tumor based on its environment. Radiopharmaceuticals have different emission properties which deliver radiation using either alpha or beta particles. Response to treatment with radiopharmaceuticals may occur after one single injection or up to five injections, and therefore, is quicker than chemotherapy which may occur after many months/cycles. Adverse events

from treatment may also be less.

Xofigo

On May 15, 2013, the FDA approved radium-223 marketed under the name Xofigo injection (Bayer HealthCare Pharmaceuticals Inc). Xofigo is an alpha-emitting agent for treatment of patients with symptomatic, bone-metastatic, castration resistant prostate cancer (CRPC). Xofigo has a half-life of 11.4 days, and releases 94% of its energy as alpha-particles with very little beta or gamma-emission. Xofigo mimics calcium and forms complexes with the bone mineral hydroxyapatite at areas of increased bone turnover, such as bone metastases. Alpha-emission consists of particles with high energy and a short range, causing non-repairable breakage of double-strand DNA in adjacent cells, which results in a highly localized cytotoxic effect in the target areas, and causes an anti-tumor effect on bone metastases. The alpha particle range from Xofigo is less than 100 micrometers (less than 10 cell diameters) which limits damage to the surrounding normal tissue and reduces marrow toxicity.

Xofigo is administered intravenously, given once per month for six months, by an appropriately licensed facility, usually in nuclear medicine or radiation therapy departments. Hematologic evaluation of patients must be performed at baseline and prior to every dose of Xofigo. Prior to the initial dose, patients must have absolute neutrophil count (ANC) greater than or equal to 1.5×10^9/L, platelet count greater than or equal to 100×10^9/L, and hemoglobin greater than or equal to 10 g/dL. Before subsequent administrations of Xofigo, the ANC should be greater than or equal to 1×10^9/L and the platelet count greater than or equal to 50×10^9/L. Xofigo should be discontinued if a delay of six to eight weeks does not result in the return of blood counts to these levels. Non-hematologic side effects are generally mild, and include nausea, diarrhea, and vomiting. These symptoms are likely related to the fact that Xofigo is predominantly eliminated by fecal excretion. Whenever possible, patients should use a toilet, and the toilet should be flushed several times after each use. Clothing soiled with Xofigo or patient fecal matter or urine should be washed promptly and separately from other clothing. Caregivers should use universal precautions, such as washing hands, wearing gloves and barrier gowns when handling patients' bodily fluids to avoid contamination.

Pluvicto

Formally known as 177Lu-PSMA-617, Pluvicto (Novartis) was approved by the FDA on March 23, 2022, for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

July 2026 the FDA further approved Pluvicto in combination with androgen receptor pathway inhibitor therapy for PSMA-positive metastatic hormone-sensitive prostate cancer (mHSPC), moving radioligand therapy into an even earlier disease stage.

Pluvicto is the first targeted radioligand therapy. The half-life is 6.647 days by emitting beta-particle radiation. Pluvicto emits beta-particle radiation selectively to PSMA-positive cells surrounding microenvironment. In early-phase studies in previously treated patients with metastatic castration resistant prostate cancer, Pluvicto has shown biochemical and radiographic response rates, reduced pain, and low toxicity.

Strontium-89 Chloride

On July 11, 2013, the FDA approved Strontium-89 chloride for relief of bone pain in patients with painful skeletal metastases. Strontium-89 Chloride acts similarly to calcium, localizing in bone mineral and is absorbed in sites of osteogenesis, especially at sites of metastases, compared to normal healthy bone. Strontium-89 Chloride is a beta-emitter with a maximum range in tissue of ~ 8 mm and has a half-life of 50.5 days. The recommended dose of Strontium-89 Chloride is 148 MBq, 4 mCi, administered IV over one to two minutes or a dose of 1.5- 2.3 MBq/kg, 40-60 uCi/kg body weight. Repeated administration of Strontium-89 Chloride should be based on an individual patient's response to therapy, current symptoms, and hematologic status, and are generally not recommended at intervals of less than 90 days. Bone marrow toxicity in the white blood cells and platelets is variable from patient to patient and must be monitored following administration of Strontium-89 Chloride. Relief of pain may not occur for seven to 20 days post injection and some patients have experienced a transient increase in pain at 36 to 72 hours after injection. Strontium-89 Chloride is excreted by the kidney and should be administered with caution in patients with renal dysfunction.

Lutathera (lutetium or Lu 177 dotatate)

Lutathera (lutetium or Lu 177 dotatate) (Novartis, formerly Advanced Accelerator Applications) was approved by the FDA on January 26th, 2018. It is also commonly referred to as "Lu 177". It is classified as a peptide receptor radionuclide. It 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 Lutathera induces cellular damage by formation of free radicals in somatostatin receptor-positive cells and adjacent cells. It is considered as an alternative treatment option to first-line somatostatin analogues.

HICON (Sodium iodide I 131)

The primary treatment of choice for differentiated thyroid carcinoma is surgery, followed by radioactive iodine (RAI) ablation for select patients. HICON (Sodium iodide I 131) also referred to as 131I, is a radioactive therapeutic agent, when given orally, (via capsule or solution) is naturally taken up through the blood by the thyroid, causing decay via beta emission and associated gamma emission. RAI has been in use since the 1940's, but the high concentration version of the drug received FDA approval on January 24th, 2003 (DraxImage). Serum thyroglobulin (Tg) levels can indicate the existence of distant metastases. RAI is given after total thyroidectomy to eliminate the normal thyroid remnant, ensure that Tg levels are undetectable after surgery, to reduce the risk of recurrence (adjuvant treatment), and to treat persistent or recurrent disease (treatment of known disease). Tumors that do not take up iodine, i.e., anaplastic (undifferentiated) and medullary thyroid carcinomas cannot be treated with RAI.

SUPPORTIVE LITERATURE

The Alpharadin in Symptomatic Prostate Cancer Patients (ALSYMPCA) trial Parker et al (2013) was a phase 3, randomized, double-blind, placebo-controlled study that randomized 921 patients with symptomatic bone-metastatic CRPC to six injections every week of either radium-223(50 kBq/kg) or placebo. Patients were symptomatic with two or more bone metastases, without visceral metastases and had received docetaxel or were ineligible for docetaxel treatment. Median overall survival (OS) in the Xofigo arm was 14.9 months compared to 11.2 months in the placebo arm. Median time-to-first

skeletal related event was significantly improved in the treatment arm (13.6 months) compared to placebo (8.4 months). Time-to-alkaline-phosphatase-progression and time-to-PSA-progression was also improved in the treatment group. More adverse events were observed in the Xofigo group, with discontinuation of treatment due to adverse events occurring in 13 percent of the patients in the Xofigo and 20 percent of the patients in the placebo arm. The significantly improved OS in the treatment group met the predetermined boundary for discontinuing the study early and the trial was terminated due to evidence of significant treatment benefit of Xofigo.

The ERA 223 Smith M et al (2019) was a randomized, double-blind, placebo-controlled phase 3 trial. It included 165 oncology and urology centers in 19 countries, which assessed the efficacy and safety of combination therapy with abiraterone acetate plus prednisone or prednisolone and Xofigo in patients with asymptomatic or mildly symptomatic, chemotherapy-naïve, castration-resistant prostate cancer and bone metastases. A total of 806 patients with a minimum of two bone metastases and no known visceral or brain metastases were randomized 1:1 to either Xofigo combination therapy or placebo combination therapy. The primary endpoint was occurrence of a symptomatic skeletal event, defined as use of external beam radiotherapy to relieve skeletal symptoms, a new symptomatic pathological bone fracture, spinal cord compression, or tumor-related orthopedic surgical intervention. The study showed that the combination of abiraterone acetate plus prednisone or prednisolone and Xofigo did not improve symptomatic skeletal event-free survival or OS and was associated with an increased frequency of fractures. Based on the results of this study, the manufacturer, Bayer HealthCare Pharmaceuticals Inc, does not recommend Xofigo for use in combination with abiraterone acetate plus prednisone/prednisolone outside of clinical trials.

In early-phase studies in previously treated patients with metastatic castration resistant prostate cancer, Lutetium Lu 177 vipivotide tetraxetan (Pluvicto) has shown biochemical and radiographic response rates, reduced pain, and low toxicity.

The VISION trial, an international multi-center phase 3 trial compared treatment with Pluvicto and standard care to standard care alone in patients with metastatic castration-resistant prostate cancer previously treated with at least one androgen-receptor-pathway inhibitor and one or two taxane regiments Sartor et al (2021). A total of 891 patients with a PSMA-positive gallium-68-labeled PSMA PET scan and who had progressed on androgen-receptor-pathway inhibitors and taxane therapy were randomized 2:1 to Pluvicto and standard care or standard care alone. Imaging-based progression free survival (PFS), OS, objective response, disease control, and time to symptomatic skeletal events were evaluated. Both PFS and (OS) were longer in the Pluvicto and standard care group (median 8.8 months and 15.3 months, respectively) compared to standard care alone (3.4 months and 11.3 months, respectively). Pluvicto and standard care group experienced more grade 3 and 4 adverse events (52.7%) than the standard care group (38.0%) but quality of life was not adversely affected. The authors concluded that Pluvicto along with standard care prolongs PFS and OS when compared to standard care alone in patients with metastatic castration – resistant prostate cancer.

The FDA approval for the use of Lutathera is based on the results of two published studies. The NETTER 1 study (Strosberg et al 2021) compared treatment with Lutathera to octreotide in patients with inoperable, progressive somatostatin receptor-positive midgut carcinoid tumors. Eligibility included a Ki67 index of 20% or lower, OctreoScan uptake greater than or equal to that of the

normal liver, creatinine clearance of 50 mL/min or greater, no prior treatment with PRRT, and no prior external radiation therapy to more than 25% of the bone marrow. The primary outcome was progression free survival (PFS). A total of 229 patients were randomized to Lutathera 200 mCi for four infusions every eight weeks concurrently with long-acting octreotide (30 mg) or high-dose octreotide alone (60 mg). Baseline characteristics were balanced between the groups. It was noted that 74% of patients had an ileal primary and 96% had metastatic disease in the liver. At the data-cutoff date for the primary analysis, PFS at 20 months was 65.2% in the Lutathera arm vs 10.8% in the control group. The response rate was 18% in the Lutathera group vs 3% in the control group. In an updated analysis, progressive disease was seen in 23% of the Lutathera group and 69% of the control group. Median progression free survival was not reached for the experimental group and was 8.5 months for the control group. Median OS was also not reached in the experimental group but was 27.4 months in the control arm.

Singh and colleagues (2024) published the phase 3 NETTER-2 trial, assessing the use of ^{177}Lu-Dotatate in a first-line metastatic setting. Participants (n=226) with newly diagnosed higher grade 2 and grade 3 somatostatin receptor-positive, advanced gastroenteropancreatic neuroendocrine tumors were randomized 2:1. The ^{177}Lu-Dotatate group received 4 cycles of IV [1^{77}Lu] Lu-DOTA-TATE plus IM octreotide 30mg long-acting repeatable (LAR) followed by octreotide 30 mg LAR every 4 weeks. The control group was given high-dose octreotide 60mg LAR every 4 weeks. Tumor assessments were conducted at baseline, 16 weeks, 24 weeks, and then every 12 weeks until disease progression or death. The primary end point was progression free survival. The ^{177}Lu-Dotatate group outperformed the control group demonstrating a progression free survival of 22.8 month versus 8.5 months for the control group. Authors concluded that first line ^{177}Lu-Dotatate plus octreotide LAR should be considered a new standard of care in first-line therapy for patients with grade 2 or 3 advanced gastroenteropancreatic neuroendocrine tumors.

In the PSMAfore phase 3 randomized controlled trial, Morris and colleagues (2024) evaluated the efficacy of Lu-PSMA-617 versus a change in androgen receptor pathway inhibitor (ARPI) therapy in taxane-naive patients with progressive metastatic castration-resistant prostate cancer (mCRPC). A total of 468 patients were randomized equally to receive either Lu-PSMA-617 or a switch to another ARPI (abiraterone or enzalutamide). Lu-PSMA-617 significantly prolonged rPFS with a median of 9.3 months compared to 5.55 months in the ARPI group (HR 0.41; 95% CI: 0.29–0.56; $p < 0.0001$). The PSA50 response rate was 57.6% in the Lu-PSMA-617 group versus 20.4% in the ARPI group, and ORR was 50.7% versus 14.9%, respectively. Time to PSA progression was also longer with Lu-PSMA-617 (10.55 months vs. 4.24 months; HR 0.37; 95% CI: 0.29–0.48). Overall, the PSMAfore trial supports Lu-PSMA-617 as a superior alternative to ARPI switching in taxane-naive mCRPC patients, offering better disease control, improved PSA and radiographic responses, and a favorable safety profile.

PROFESSIONAL GUIDELINE(S)

The National Comprehensive Cancer Network (NCCN) Guidelines for Prostate Cancer (V.6.2026) principles of radiopharmaceutical therapy states that Radium-223 is an alpha-emitting radiopharmaceutical that has been shown to extend survival in patients who have castration-resistant prostate cancer (CRPC) with symptomatic bone metastases, but no visceral metastases. Radium-223

alone has not been shown to extend survival in patients who have visceral metastases or bulky nodal disease greater than three to four cm. Radium-223 differs from beta-emitting agents, such as strontium-89, which are palliative and have no survival advantage. Radium-223 causes double-strand DNA breaks and has a short radius of activity. Grade 3-4 hematologic toxicity (2 percent neutropenia, 3 percent thrombocytopenia, 6 percent anemia) occurs at a low frequency. At the present time, except on a clinical trial, Radium-223 is not intended to be used in combination with chemotherapy due to the potential for additive myelosuppression. Concomitant use of denosumab or zoledronic acid does not interfere with the beneficial effects of Radium-223 on survival. Lu-177-PSMA-617 is a beta-emitting radiopharmaceutical that selectively binds to PSMA receptors on prostate cancer cells. In patients with PSMA-positive disease, Lu-177-PSMA-617 has been shown to improve OS in patients with progressive metastatic castration-resistant prostate cancer (mCRPC) previously treated with androgen reception inhibitors and taxane chemotherapy. It has also been shown to improve rPFS in taxane-naïve patients with PSMA-positive mCRPC who were previously treated with an androgen receptor inhibitor compared with changing to a different androgen receptor inhibitor. NCCN also states that F-18 piflufolastat PSMA and F-18 flotufolastat PSMA can be used in the same space due to multiple reports describing the equivalency of these imaging agents.

The NCCN Guidelines for Bone Cancer (V.2.2025) state to consider the use of radiopharmaceuticals, including radium-223, for the treatment of metastatic disease.

NCCN, in the V.1.2025 Guidelines for Thyroid Carcinoma, recommends postoperative RAI when a number of clinical factors predict a significant risk of recurrence, distant metastases, or disease-specific mortality, including carcinoma type, size of primary tumor, post operative Tg level, vascular invasion, presence of metastases, etc. RAI is not typically indicated for patients considered to have a low risk of recurrence, or after lobectomy, or for patients that have metastatic disease that is not amenable to RAI therapy, meaning iodine refractory disease. NCCN states that RAI may be used for patients without gross residual disease, but that data is conflicting.

The NCCN Guidelines for Neuroendocrine and Adrenal Tumors (V.2.2025) supports the use Lutetium Lu 177 dotatate for the treatment of SSTR-positive gastroenteropancreatic NETs, including foregut, midgut and hindgut NETs. Currently, there are no randomized data, but there are reports of treatment efficacy and favorable outcomes when PRRT is used for pheochromocytomas, paragangliomas, and lung/thymic NETs. If feasible, participation in clinical trials of PRRT is strongly recommended for patients with such rare groups of NET.

Tuttle et al (2019) issued a joint statement for the use of ^{131}I therapy for the treatment of differentiated thyroid cancer from the American Thyroid Association (ATA), the European Association of Nuclear Medicine and the Society of Nuclear Medicine and Molecular Imaging, and the European Thyroid Association. The societies defined terminology that should be used to communicate the goals of ^{131}I therapy. Adapted from the joint statement:

	^{131}I Therapy		
Goal	**Remnant Ablation**	**Adjuvant Treatment**	**Treatment of Known Disease**

Initial staging	✓	✓	✓
Facilitate follow-up	✓	✓	✓
Improve disease-specific survival	-	✓	✓
Decrease recurrence	-	✓	-
Improve progression-free survival	-	✓	✓
Curative intent	-	✓	✓
Palliative intent	-	-	✓

The categories for thyroid cancer staging by the American Thyroid Association are low, intermediate, and high risk, which provides risk for recurrence. Preoperative staging and risk of recurrence determine the need for radiotherapy after surgery and following surveillance. The evidence for the use of ^{131}I in the post operative setting of differentiated thyroid carcinoma is limited to retrospective studies. Although numerous have been published, findings are inconsistent regarding improvement in outcomes. The joint consensus states that, “Even though most guidelines make recommendations with regard to the postoperative use of ^{131}I based primarily on staging systems that predict risk of recurrence or disease specific mortality, the actual goal of ^{131}I therapy can only be determined once the postoperative disease status has been assessed. Regardless of initial risk stratification, patients with biochemical, structural, or functional evidence of persistent disease can only be candidates for “treatment of known disease.” Patients demonstrating no histological, biochemical, or imaging evidence of persistent disease after appropriate initial surgery may be candidates for observation, remnant ablation, or adjuvant treatment.”

REGULATORY STATUS

The United States Food and Drug Administration (FDA) is responsible for ensuring the safety, efficacy, and quality of drugs sold in the United States. This includes both prescription and over-the-counter medications. Refer to the FDA Drug website. Available from: https://www.fda.gov/drugs [accessed 2026 Aug 18]

The FDA maintains information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products. Available from: Drug Safety and Availability | FDA [accessed 2026 Aug 18]

On March 28, 2025, the Food and Drug Administration expanded the indication for lutetium Lu 177 vipivotide tetraxetan (Pluvicto, Novartis Pharmaceuticals Corporation) to include adults with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibitor (ARPI) therapy and are considered

appropriate to delay taxane-based chemotherapy.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
77750	Infusion or instillation of radioelement solution (includes 3-month follow-up care)
79101	Radiopharmaceutical therapy, by intravenous administration
79005	Radiopharmaceutical therapy, by oral administration
79403	Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (list separately in addition to code for primary procedure)
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug

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HCPCS Codes

Code	Description
A4641	Radiopharmaceutical, diagnostic, not otherwise classified
A9513	Lutetium Lu 177, dotatate injection, therapeutic, 1mCi (Lutathera)
A9517	Iodine I-131 sodium iodide capsule(s), therapeutic, per mCi (HICON)
A9530	Iodine I-131 sodium iodide solution, therapeutic, per mCi (HICON)
A9600	Strontium sr-89 chloride, therapeutic, per mCi
A9606	Radium RA-223 dichloride, therapeutic, per UCI (Xofigo)
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 mCi (Pluvicto)

Code	Description
C9399	Unclassified drugs or biologicals

ICD10 Codes

Code	Description
C61	Malignant neoplasm of prostate
C7A.010-C7A.019	Malignant carcinoid tumors of the small intestine (code range)
C7A.020-C7A.026	Malignant carcinoid tumors of the appendix, large intestine, and rectum (code range)
C7A.029	Malignant carcinoid tumor of the large intestine, unspecified portion
C7A.092	Malignant carcinoid tumor of the stomach
C7A.094-C7A.096	Malignant carcinoid tumor of the foregut, midgut, and hindgut, unspecified (code range)
C7B.00-C7B.09	Secondary neuroendocrine tumor (code range)
C7B.8	Other secondary neuroendocrine tumors
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
D40.0	Neoplasm of uncertain behavior of prostate
V58.0	Radiotherapy
Z85.46	Personal history of malignant neoplasm of prostate

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Radiopharmaceuticals for the treatment of cancer are not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

08/21/14, 04/16/15, 04/21/16, 04/20/17, 04/19/18, 05/16/19, 04/16/20, 05/21/20, 05/20/21, 07/21/22, 05/18/23, 09/21/23, 09/19/24, 09/18/25, 09/17/26

Date	Summary of Changes
09/17/26	• Annual review; policy intent unchanged.
09/18/25	• Annual review; new indication for pluvicto added to the policy. Azedra and Zevalin removed from policy as both are no longer commercially available for use.
01/01/25	• Summary of changes tracking implemented.
08/21/14	• Original effective date