



## FEP Medical Policy Manual

### FEP 6.01.26 Oncologic Applications of Positron Emission Tomography Scanning (Genitourinary)

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#### Related Policies:

5.21.191 Pluvicto

6.01.06 - Miscellaneous (Noncardiac, Nononcologic) Applications of Fluorine 18 Fluorodeoxyglucose Positron Emission Tomography

6.01.20 - Cardiac Applications of Positron Emission Tomography Scanning

6.01.51 - Interim Positron Emission Tomography Scanning in Oncology to Detect Early Response During Treatment

## Oncologic Applications of Positron Emission Tomography Scanning (Genitourinary)

### Description

#### Description

Positron emission tomography (PET) scans are based on the use of positron-emitting radionuclide tracers coupled to organic molecules, such as glucose, ammonia, or water. The radionuclide tracers simultaneously emit 2 high-energy photons in opposite directions that can be simultaneously detected (referred to as coincidence detection) by a PET scanner, comprising multiple stationary detectors that encircle the area of interest.

#### OBJECTIVE

The objective of this evidence review is to examine whether the use of positron emission tomography for the diagnosis, staging and restaging, and/or surveillance improves the net health outcome in individuals with genitourinary cancers.

#### POLICY STATEMENT

All policy statements apply to both positron emission tomography (PET) scans and PET plus computed tomography (CT) scans (ie, PET scans with or without PET/CT fusion).

For the clinical situations indicated that may be considered medically necessary, this assumes that the results of the PET scan will influence treatment decisions. If the results will not influence treatment decisions, these situations would be considered not medically necessary.

## Bladder Cancer

PET scanning may be considered **medically necessary** in the staging or restaging of muscle-invasive bladder cancer when CT or magnetic resonance imaging are not indicated or remained inconclusive on distant metastasis.

PET scanning is considered **investigational** for bladder tumors that have not invaded the muscle (stage less than cT2).

## Penile Cancer

PET scanning may be considered **medically necessary** for staging and restaging in individuals with suspected inguinal lymph node positive disease.

PET scanning is considered **investigational** in all other aspects of managing penile cancer.

## Prostate Cancer

PET scanning with carbon 11 choline and fluorine 18 fluciclovine may be considered **medically necessary** for evaluating suspected or biochemically recurrent prostate cancer after primary treatment to detect small volume disease in soft tissues.

PET scanning with gallium 68-prostate-specific membrane antigen and piflufolastat fluorine-18 may be considered **medically necessary** for any of the following applications:

- Individuals with diagnosed prostate cancer in need of staging information and:
  - NCCN unfavorable intermediate-, high-, or very-high-risk prostate cancer (see Policy Guidelines); OR
  - NCCN unfavorable intermediate-, high-, or very-high-risk prostate cancer with equivocal results or oligometastatic disease on initial conventional imaging (see Policy Guidelines).
- Individuals with suspected recurrence of prostate cancer based on serum PSA level who have received:
  - Radical prostatectomy with PSA level persistence or rise from undetectable level (see Policy Guidelines); OR
  - Definitive radiotherapy with PSA rise above nadir (see Policy Guidelines).
- Individuals with treated prostate cancer (including active surveillance/observation) in need of imaging as part of a workup for progression (see Policy Guidelines).
- Individuals with metastatic prostate cancer for whom lutetium Lu-177 vipivotide tetraxetan PSMA-directed therapy is indicated.

Use of gallium 68-prostate-specific membrane antigen and piflufolastat fluorine-18 in known or suspected prostate cancer is considered **investigational** for all other indications, including diagnosis, primary staging of very-low, low- or favorable intermediate-risk prostate cancer, and evaluation of response to therapy.

PET scanning for all other indications in known or suspected prostate cancer is considered **investigational**.

## Renal Cell Carcinoma

PET scanning is considered **investigational** in all aspects of managing renal cancer.

## Testicular Cancer

PET scanning may be considered **medically necessary** in evaluation of residual mass following chemotherapy of stage IIB and III seminomas (the scan should be completed no sooner than 6 weeks after chemotherapy).

Except as noted above for seminoma, PET scanning is considered **investigational** in evaluation of testicular cancer, including but not limited to the following applications:

- Initial staging of testicular cancer,

- Distinguishing between viable tumor and necrosis/fibrosis after treatment of testicular cancer, and
- Detection of recurrent disease after treatment of testicular cancer.

## Cancer Surveillance

PET scanning is considered **investigational** when used as a surveillance tool for individuals with cancer or with a history of cancer. A scan is considered surveillance if performed more than 6 months after completion of cancer therapy (12 months for lymphoma) in individuals without objective signs or symptoms suggestive of cancer recurrence (see Policy Guidelines section).

## POLICY GUIDELINES

### Patient Selection

As with any imaging technique, the medical necessity of positron emission tomography (PET) scanning depends in part on what imaging techniques are used before or after the PET scanning. Due to its expense, PET scanning is typically considered after other techniques, such as computed tomography (CT), magnetic resonance imaging (MRI), or ultrasonography, provide inconclusive or discordant results. In individuals with melanoma or lymphoma, PET scanning may be considered an initial imaging technique. If so, the medical necessity of subsequent imaging during the same diagnostic evaluation is unclear. Thus, PET should be considered for the medically necessary indications above only when standard imaging (eg, CT, MRI) is inconclusive or not indicated.

Patient selection criteria for PET scanning may also be complex. For example, it may be difficult to determine from claims data whether a PET scan in a patient with malignant melanoma is being done primarily to evaluate extranodal disease or regional lymph nodes. Similarly, it may be difficult to determine whether a PET scan in a patient with colorectal cancer is being performed to detect hepatic disease or evaluate local recurrence. Due to the complicated hierarchy of imaging options in individuals with malignancy and complex patient selection criteria, a possible implementation strategy for this policy is its use for retrospective review, possibly focusing on cases with multiple imaging tests, including PET scans.

Use of PET scanning for surveillance as described in the policy statement and policy rationale refers to the use of PET to detect disease in asymptomatic individuals at various intervals. This is not the same as the use of PET for detecting recurrent disease in symptomatic individuals; these applications of PET are considered within tumor-specific categories in the policy statements.

### Prostate-Specific Membrane Antigen Positron Emission Tomography

Appropriate selection of patients for prostate-specific membrane antigen (PSMA) PET imaging may be guided according to National Comprehensive Cancer Network (NCCN) and Society of Nuclear Medicine and Molecular Imaging (SNMMI) criteria (see policy section <sup>68</sup>Ga-PSMA PET, <sup>68</sup>Ga-PSMA PET/CT, Piflufolostat-F<sup>18</sup> PET, and Piflufolostat-F<sup>18</sup> PET/CT Guidelines). NCCN and SNMMI recommendations for use of PSMA PET in individuals with newly diagnosed prostate cancer in need of staging are based on the following NCCN risk criteria:

Risk Group	Clinical/Pathological Features
Very Low	Has all of the following: <ul style="list-style-type: none"> <li>• cT1c</li> <li>• Grade Group 1</li> <li>• PSA &lt;10 ng/mL</li> <li>• Fewer than 3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/core</li> <li>• PSA density &lt;0.15 ng/mL/g</li> </ul>
Low	Has all of the following but does not qualify for very low risk: <ul style="list-style-type: none"> <li>• cT1 - cT2a</li> <li>• Grade Group 1</li> </ul>

	<ul style="list-style-type: none"> <li>• PSA &lt;10 ng/mL</li> </ul>
Intermediate	<p>Has all of the following:</p> <ul style="list-style-type: none"> <li>• No high-risk group features</li> <li>• No very-high-risk group features</li> <li>• Has one or more intermediate risk factor: <ul style="list-style-type: none"> <li>◦ cT2b - cT2c</li> <li>◦ Grade Group 2 or 3</li> </ul> </li> <li>• PSA 10 - 20 ng/mL</li> </ul>
Favorable Intermediate	<p>Intermediate risk criteria, AND all of the following:</p> <ul style="list-style-type: none"> <li>• 1 intermediate risk factor</li> <li>• Grade Group 1 or 2</li> <li>• &lt;50% biopsy cores positive (e.g., &lt;6 of 12 cores)</li> </ul>
Unfavorable Intermediate	<p>Intermediate risk criteria AND one or more of the following:</p> <ul style="list-style-type: none"> <li>• 2 or 3 intermediate risk factors</li> <li>• Grade Group 3</li> <li>• ≥50% biopsy cores positive (e.g., ≥6 of 12 cores)</li> </ul>
High	<p>Has no very-high-risk features and has exactly one high-risk feature:</p> <ul style="list-style-type: none"> <li>• cT3a OR</li> <li>• Grade Group 4 or Grade Group 5 OR</li> <li>• PSA &gt;20 ng/mL</li> </ul>
Very High	<p>Has at least one of the following:</p> <ul style="list-style-type: none"> <li>• cT3b - cT4</li> <li>• Primary Gleason pattern 5</li> <li>• 2 or 3 high-risk features</li> <li>• &gt;4 cores with Grade Group 4 or 5</li> </ul>

Individuals who meet unfavorable intermediate-, high- and very-high risk criteria are suitable candidates for PSMA PET bone and/or soft tissue imaging, either following equivocal results on initial conventional imaging (e.g., MRI) or as alternative to conventional imaging.

PSMA PET imaging is not recommended for staging newly diagnosed individuals in very low, low, or favorable intermediate NCCN risk groups, or for individuals with suspected prostate cancer based on elevated PSA, increasing PSA on serial measurements, and/or clinical signs (e.g., abnormal digital rectal exam).

Use of PSMA PET imaging is appropriate for individuals who have undergone radical prostatectomy or radiation therapy for prostate cancer with subsequent suspected persistence or recurrence. Specific considerations for use of PSMA PET are:

- Following radical prostatectomy AND:
  - Failure of PSA to fall to undetectable levels; OR
  - Previously undetectable PSA with a subsequent detectable PSA that increases on ≥2 measurements
- Following definitive radiation therapy AND:
  - A PSA rise ≥2 ng/mL above the nadir; OR

- o A positive digital rectal exam.

PSMA PET may also be considered when PSA has been confirmed to be increasing after radiation therapy even if the increase above nadir is not yet 2 ng/mL, particularly in candidates with a favorable prognosis for salvage local therapy.

PSMA PET use is appropriate in individuals who have previously been treated for prostate cancer (including those under active surveillance/observation) who require imaging as part of a workup for progression. NCCN guidelines include recommended workup protocols, which vary according to prior treatment and cancer stage. The guidelines recommend use of PSMA PET bone and soft tissue imaging when conventional imaging results are equivocal, but also state that PSMA PET imaging is more accurate than conventional imaging at detecting micrometastatic disease, and as such, the guidelines note that conventional imaging is not a necessary prerequisite to PSMA PET imaging.

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

## FDA REGULATORY STATUS

As of October 2023, the following radiopharmaceuticals have been granted approval by the FDA, to be used with PET for genitourinary cancer-related indications (see Table 1).<sup>1</sup>

**Table 1. Radiopharmaceuticals Approved for Use With PET for Oncologic Applications**

Radiopharmaceutical	Manufacturer	Name	Carcinoma-Related Indication With PET
Carbon-11 choline (C-11)	Various		Suspected prostate cancer recurrence based on elevated blood PSA after therapy and noninformative bone scintigraphy, CT, or MRI
Fluorine-18 fluorodeoxyglucose (FDG)	Various		Suspected or existing diagnosis of cancer, all types
Fluorine-18 fluciclovine	Blue Earth Diagnostics	Axumin™	Suspected prostate cancer recurrence based on elevated blood PSA levels after treatment
Gallium-68 PSMA-11	University of California, Los Angeles and the University of California, San Francisco		PSMA positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum PSA level
Piflufolostat fluorine-18	Progenics Pharmaceuticals, Inc	Pylarify	PSMA positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum PSA level

FDA-approval given to the University of California, Los Angeles and the University of California, San Francisco.

CT: computerized tomography; ER: estrogen receptor; MRI: magnetic resonance imaging; NET: neuroendocrine tumors; PET: positron emission tomography; PSA: prostate-specific antigen; PSMA: prostate-specific membrane antigen.

Two kits used for the preparation of Gallium-68 PSMA-11 have received FDA approval: the Illucix (Telix Pharmaceuticals) kit, approved in December 2021; and the Locametz (Advanced Accelerator Applications/Novartis) kit, approved in March 2022.<sup>2</sup> The preparation kits are for use in individuals with PSMA-positive prostate cancer with suspected metastasis who are candidates for initial definitive therapy, or with suspected recurrence based on elevated serum PSA level. In addition, Locametz is approved for selection of patients with metastatic prostate cancer, for whom lutetium Lu-177 vipivotide tetraxetan (Pluvicto™; Novartis) PSMA-directed therapy is indicated.

## RATIONALE

### Summary of Evidence

#### Bladder Cancer

For individuals who have suspected or diagnosed bladder cancer in need of staging or restaging information who receive fluorine 18 ( $^{18}\text{F}$ ) coupled with fluorodeoxyglucose (FDG) PET or FDG-PET/computed tomography (CT), the evidence includes a systematic review and meta-analysis. Relevant outcome is test validity. Pooled analyses showed relatively high sensitivity and specificity for muscle-invasive bladder cancer. Clinical guidelines include positron emission tomography (PET) and PET/CT as considerations in staging muscle-invasive bladder cancer, though CT, magnetic resonance imaging, and chest radiographs are also appropriate techniques for staging purposes. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are asymptomatic after completing bladder cancer treatment who receive FDG-PET or FDG-PET/CT, there is no evidence. Relevant outcome is test validity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

#### Penile Cancer

For individuals who have suspected or diagnosed node negative penile cancer and in need of staging or restaging information who receive FDG-PET or FDG-PET/CT, the evidence includes a systematic review. Relevant outcome is test validity. The evidence has shown that PET had a low sensitivity, and no comparisons were made with other modalities. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have suspected or diagnosed node positive penile cancer and in need of staging or restaging information who receive FDG-PET or FDG-PET/CT, the evidence includes a systematic review and a retrospective comparative study. Relevant outcome is test validity. In individuals with suspected inguinal lymph node positive disease, PET/CT may offer increased sensitivity compared to CT alone for staging. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are asymptomatic after completing penile cancer treatment who receive FDG-PET or FDG-PET/CT, there is no evidence. Relevant outcome is test validity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

#### Prostate Cancer

For individuals who have suspected or diagnosed prostate cancer and in need of staging or restaging information who receive  $^{11}\text{C}$ -choline PET,  $^{11}\text{C}$ -choline PET/CT,  $^{18}\text{F}$ -fluciclovine PET, or  $^{18}\text{F}$ -fluciclovine PET/CT, the evidence includes several meta-analyses. Relevant outcome is test validity. Meta-analyses have reported that use of  $^{11}\text{C}$ -choline and  $^{18}\text{F}$ -fluciclovine radiotracers result in similar sensitivities and specificities. Prospective studies in men with biochemical recurrence after primary treatment have reported that a majority of management decisions were changed based on  $^{18}\text{F}$ -fluciclovine PET/CT results among men with suspected recurrence. One of those studies evaluated the impact on clinical outcomes and reported an increase in 3-year event-free survival rates. Further study is needed to compare PET and PET/CT with other imaging techniques, such as MRI and radionuclide bone scan. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are asymptomatic after completing prostate cancer treatment who receive  $^{11}\text{C}$ -choline PET,  $^{11}\text{C}$ -choline PET/CT,  $^{18}\text{F}$ -fluciclovine PET, or  $^{18}\text{F}$ -fluciclovine PET/CT, there is no evidence. Relevant outcome is test validity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have suspected prostate cancer who receive  $^{68}\text{Ga}$ -prostate-specific membrane antigen (PSMA) PET,  $^{68}\text{Ga}$ -PSMA PET/CT, piflufolastat- $^{18}\text{F}$  PET, and piflufolastat- $^{18}\text{F}$  PET/CT, the evidence includes a systematic review. Relevant outcome is test validity. The systematic review found similar diagnostic accuracy for PSMA PET and MRI for detection of clinically significant prostate cancer, but evidence was too limited to draw conclusions as only 3 studies of 228 individuals were included in the analysis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have diagnosed prostate cancer and in need of staging or restaging information who receive  $^{68}\text{Ga}$ -prostate-specific membrane antigen (PSMA) PET,  $^{68}\text{Ga}$ -PSMA PET/CT, piflufolastat- $\text{F}^{18}$  PET, and piflufolastat- $\text{F}^{18}$  PET/CT, the evidence includes systematic reviews and prospective, multicenter trials. Relevant outcome is test validity. Systematic reviews have found PSMA PET to have similar diagnostic accuracy across prostate cancer risk groups in newly diagnosed individuals, and to be similar to magnetic resonance imaging (MRI) for staging intermediate/high-risk prostate cancer. Systematic reviews of studies conducted in individuals with biochemical recurrence found high proportions with positive PSMA PET imaging, often leading to change in management. Individual prospective trials have generally found that PSMA PET provides a high specificity for detecting pelvic lymph node or distant metastases in newly diagnosed individuals with high-risk disease and a clinically relevant positive predictive values (PPV) in individuals with biochemical recurrence. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are asymptomatic after completing prostate cancer treatment who receive  $^{68}\text{Ga}$ -PSMA PET,  $^{68}\text{Ga}$ -PSMA PET/CT, piflufolastat- $\text{F}^{18}$  PET, and piflufolastat- $\text{F}^{18}$  PET/CT, there is no evidence on clinical outcomes. Relevant outcome that has been studied is test validity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## Renal Cell Carcinoma

For individuals who are diagnosed with renal cell carcinoma and in need of staging or restaging information who receive FDG-PET or FDG-PET/CT, the evidence includes a systematic review and meta-analysis. Relevant outcome is test validity. The review concluded that PET has the potential to detect metastatic or recurrent lesions in individuals with renal cell cancer but that additional prospective studies are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## Testicular Cancer

For individuals with diagnosed testicular cancer in need of staging or restaging information who receive FDG-PET or FDG-PET/CT, the evidence includes an Agency for Healthcare Research and Quality (AHRQ) systematic review and assessment. Relevant outcome is test validity. Results have shown that PET or PET/CT can evaluate residual masses following chemotherapy for seminoma. Clinical guidelines include PET/CT to inform management decisions that may offer clinical benefit. There is no evidence supporting the use of PET or PET/CT in nonseminoma individuals. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have suspected testicular cancer or who are asymptomatic after completing testicular cancer treatment who receive FDG-PET or FDG-PET/CT, there is no evidence. Relevant outcome is test validity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Current National Comprehensive Cancer Network, American College of Radiology, and other relevant U.S.-based guidelines are summarized in each section of the Rationale.

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

The Medicare coverage policy on positron emission tomography scans, which was updated in 2013, is summarized in Appendix Table 5.<sup>49</sup>



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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	
June 2013	Replace policy	Policy updated with literature review. References 22-35 added, Policy statements revised with NMN added to breast cancer, colorectal cancer, soft tissue sarcomas and thyroid cancer. Thyroid cancer

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

Date	Action	Description
		revised to include both differentiated and poorly differentiated disease, Prostate cancer moved to section on Other Oncologic Applications, also added to this section, are diagnosis of brain tumors, restaging of gastric cancer, staging of multiple myeloma, evaluation of neuroendocrine tumors and staging of inguinal lymph nodes in patients with squamous cell carcinoma of the penis.
June 2014	Replace policy	Policy was revised with literature search adding references 37-40, 42-75. PET for gastric cancer as medically necessary for initial work up and staging and for evaluation of recurrent gastric cancer when other imaging modalities are inconclusive.
June 2015	Replace policy	Policy revised with literature review; references 1, 42-43, 46, 48-50, 58, 62, 72, 77, 84, and 87 added. Policy statements unchanged.
September 2017	Replace policy	Policy revised with literature review through March 23, 2017; references 37,41, 48-50, 59-63, 67, 69-70, 73, 76-80, 85, 94-98, 103, 109-110, 112, 115,119-120, and 126 added. Additional details added to policy statements. The following statements were changed to medically necessary: staging or restaging of brain cancer; evaluation of response to treatment in head and neck cancer; and testing with 11C-choline for evaluating response to primary treatment in prostate cancer. Two additional indications were added
December 2019	Replace policy	Policy revised with literature review through August 9, 2019; references on NCCN updated. Policy statements unchanged
December 2020	Replace policy	Policy revised with literature review through July 15, 2020; references added. Policy statements unchanged.
December 2021	Replace policy	Policy revised with literature review through August 5, 2021; references added. PET scanning for patients with suspected inguinal lymph node positive disease was added as medically necessary for staging patients. The following statements were revised to include newly approved radiotracers: "PET scanning with gallium 68 and copper 64 may be considered medically necessary as a technique for staging neuroendocrine tumors either during initial staging or for restaging at follow-up" and "PET scanning with gallium 68-prostate-specific membrane antigen and piflufolastat fluorine-18 is considered investigational in all aspects of managing prostate cancer."
June 2022	Replace policy	Prostate Cancer policy statement revised: "PET scanning with gallium 68-prostate-specific membrane antigen (Locametz) or another FDA approved PSMA-11 imaging agent specifically to select mCRPC patients for use of a targeted radioligand therapeutic agent (Pluvicto) is medically necessary
December 2022	Replace policy	Policy revised with literature review through July 12, 2022; references added. Clinical input incorporated on the use of PSMA PET imaging. The following policy statement was changed: "PET scanning with gallium 68-prostate-specific membrane antigen and piflufolastat fluorine-18 is considered medically necessary for any of the following applications: -Individuals with diagnosed prostate cancer in need of staging information and: NCCN unfavorable intermediate-, high-, or very-high-risk prostate cancer in need of staging information (see Policy Guidelines); OR NCCN unfavorable intermediate-, high-, or very-high-risk prostate cancer with equivocal results or oligometastatic disease on initial conventional imaging in need of staging information (see Policy Guidelines). -Individuals with suspected recurrence of prostate cancer based on serum PSA level who have received: radical prostatectomy with PSA level persistence or rise from undetectable level (see Policy Guidelines); OR definitive radiotherapy with PSA rise above nadir (see Policy Guidelines). -Individuals with treated prostate cancer (including active surveillance/observation) in need of imaging as part of a workup for progression (see Policy Guidelines). -Individuals with metastatic prostate cancer for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated. And the following policy statement was added: "Use of gallium 68-prostate-specific membrane antigen and piflufolastat fluorine-18 in known or suspected prostate cancer is considered investigational for all other indications, including initial diagnosis and evaluation of response to therapy."
March 2024	Replace policy	Policy updated with literature review through October 13, 2023; no references added. Extensively pruned policy by removing indications other than genitourinary cancers. Other indications moved to new policies 6.01.61, 6.01.62, 6.01.63, 6.01.64, 6.01.65, 6.01.66. and 6.01.67. Policy statements on genitourinary cancers unchanged.