Policy Position *Coverage is subject to the specific terms of the member’s benefit plan.*

Initial Anti-tumor Treatment Strategy

PET imaging using the radiopharmaceutical diagnostic imaging agent fluorodeoxyglucose F-18 (FDG) may be considered medical necessary to determine the appropriate initial anti-tumor treatment strategy for patients with:

- brain
- breast
- Certain situations involving cervical cancer as provided below
- colorectal
- esophagus
- head and neck (excluding Central Nervous System)
- lung
- lymphoma
- melanoma
- multiple myeloma
- ovarian
- pancreas
- testicular cancers
PET imaging using the radiopharmaceutical diagnostic imaging agent sodium fluoride-18 (NaF-18) is recognized as useful for imaging areas of altered osteogenic activity in bone. The treating physician may determine that the NaF-18 PET study is needed to determine the initial antitumor treatment strategy, or to guide subsequent antitumor treatment strategy after the completion of initial treatment.

In these situations, it will be necessary for the provider to submit medical records and/or additional documentation to determine coverage in this situation as described above.

**Procedure Codes**
A9552, A9580

One (1) PET study may be considered medically necessary for patients with solid tumors that are biopsy proven or strongly suspected based on other diagnostic testing, and the patient’s treating physician determines that a PET study is needed to determine the location and/or extent of the tumor for therapeutic purposes related to the initial treatment strategy, such as determining:

- whether the patient is a candidate for an invasive diagnostic or therapeutic procedure and the optimal anatomic location for that procedure, or
- the anatomic extent of the tumor when the anti-tumor treatment chosen depends on the extent of the tumor.

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

For the clinical situations indicated that may be considered medically necessary, this is with the assumption 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

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

There are several exceptions to the above initial anti-tumor treatment strategy guidelines. These are listed below by anatomic areas.

**Bone Cancer and Metastases**

PET scanning may be considered medically necessary in the staging of Ewing sarcoma and osteosarcoma.

PET scanning is considered experimental/investigational in the staging of chondrosarcoma.
PET Scan
Highmark 2015

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

**Brain Cancer**

PET scanning may be considered medically necessary for diagnosing and staging of brain cancer:

- Where lesions metastatic from the brain are identified but no primary is found,
- For restaging to distinguish recurrent tumor from radiation necrosis.

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

**Breast**

PET scanning may be considered medically necessary in the staging and restaging of breast cancer for the following application:

- Detecting locoregional or distant recurrence or metastasis (except axillary lymph nodes) when suspicion of disease is high and other imaging is inconclusive.

Pet scanning is considered experimental/investigational in the evaluation of breast cancer for all other applications, including but not limited to the following:

- Differential diagnosis in patients with suspicious breast lesions or an indeterminate/low suspicion finding on mammography.
- Staging axillary lymph nodes

Predicting pathologic response to neoadjuvant therapy for locally advanced disease.

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

**Cervix**

PET scans may be considered medically necessary in the initial staging of patients with locally advanced cervical cancer.

PET scans may be considered medically necessary in the evaluation of known or suspected recurrence.

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252
Colorectal Cancer

PET scanning may be considered medically necessary as a technique for:

- Staging and restaging to detect and assess resectability of hepatic or extrahepatic metastases of colorectal cancer, and
- To evaluate a rising and persistently elevated carcinoembryonic antigen (CEA) level when standard imaging, including CT scan, is negative.

PET scanning is considered experimental/investigational as:

- A technique to assess the presence of scarring versus local bowel recurrence in patients with previously resected colorectal cancer.
- A technique contributing to radiotherapy treatment planning.

Procedure Codes
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

Esophageal Cancer

PET scanning may be considered medically necessary in the

- Staging of esophageal cancer, and
- Determining response to preoperative induction therapy.

PET scanning is considered experimental/investigational in other aspects of the evaluation of esophageal cancer, including but not limited to the following applications:

- Detection of primary esophageal cancer.

Procedure Codes
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

Gastric Cancer

PET scanning may be considered medically necessary in the

- The initial diagnosis and staging of gastric cancer.
- Evaluation for recurrent gastric cancer following surgical resection, when other imaging modalities are inconclusive.

Procedure Codes
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252
Head and Neck Cancer:

PET scanning may be considered medically necessary in the evaluation of head and neck cancer in the diagnosis of suspected cancer, initial staging of disease, and restaging of residual or recurrent disease during follow up.

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

Lung

PET scanning may be considered medically necessary for any of the following applications:

- Patients with a solitary pulmonary nodule as a single scan technique (not dual-time) to distinguish between benign and malignant disease when prior CT scan and chest x-ray findings are inconclusive or discordant,
- As staging or restaging technique in those with known non-small lung cancer
- To determine resectability for patients with a presumed solitary metastatic lesion from lung cancer.

PET scanning is considered experimental/investigational in staging of small cell lung cancer.

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

Lymphoma, including Hodgkin's Disease

PET scanning may be considered medically necessary as a technique for staging lymphoma either during initial staging or for restaging at follow-up.

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

Melanoma

PET scanning may be considered medically necessary as a technique for assessing extranodal spread of malignant melanoma at initial staging or at restaging during follow-up treatment.
PET scanning is considered experimental/investigational as a technique to detect regional lymph node metastases in patients with clinically localized melanoma who are candidates to undergo sentinel node biopsy.

**Procedure Codes**

78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0219, G0235, G0252

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**Multiple Myeloma and Plasmacytomas:**

PET scanning may be considered medically necessary for evaluating suspected plasmacytomas (staging) in:

- Persons with multiple myeloma; or
- For re-staging of persons with solitary plasmacytomas.

**Procedure Codes**

78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

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**Ovarian Cancer**

PET scanning may be considered medically necessary in the evaluation of patients with signs and/or symptoms of suspected ovarian cancer recurrence (restaging) when standard imaging, including CT scan, is inconclusive.

PET scanning is considered experimental/investigational in the initial evaluation of known or suspected ovarian cancer in all situations.

**Procedure Codes**

78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

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**Pancreas**

PET may be considered medically necessary in patients with suspected pancreatic adenocarcinoma when the results of other imaging modalities (for example, CT, endoscopic retrograde cholangiopancreatography (ERCP), ultrasonography) are in doubt, inconclusive of equivocal.

PET scanning is considered experimental/investigational as a technique to evaluate other aspects of pancreatic cancer.

**Procedure Codes**

78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252
Sarcomas

PET scans for Ewing’s sarcoma and osteogenic sarcoma for both initial and subsequent anti-tumor treatment strategy. Ewing’s sarcoma or osteogenic sarcoma may be considered medically necessary:

- prior to resection of an apparently solitary metastasis,
- for grading unresectable lesions when the grade of the histopathological specimen is in doubt. It is eligible for both initial and subsequent anti-tumor treatment strategy,
- when predictive information (e.g., tumor recurrence, response to chemotherapy) is needed to determine clinical management.

**Procedure Codes**

78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

Soft Tissue Sarcoma

PET scanning is considered experimental/investigational in evaluation of soft tissue sarcoma, including but not limited to the following applications:

- Distinguishing between benign lesions and malignant soft tissue sarcoma
- Distinguishing between low grade and high grade soft tissue sarcoma
- Detecting locoregional recurrence
- Detecting distant metastasis
- Evaluating response to imatinib and other treatments for gastrointestinal stromal tumors.

Testicular

PET may be medically necessary in evaluation of residual mass following chemotherapy of stage IIB and III seminomas in patients with a CT documented residual mass after chemotherapy treatment. (The PET scan should be completed not sooner than 6 weeks following chemotherapy)

Except as noted above for above for seminoma, PET scanning is considered experimental/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
• Detection of recurrent disease after treatment of testicular cancer.

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

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**Thyroid**

PET scanning may be considered medically necessary in the restaging of patients with differentiated thyroid cancer when thyroglobulin (Tg) levels are elevated and have a negative I-131 whole body scan.

PET scanning is considered experimental/investigational in the evaluation of known or suspected differentiated or poorly differentiated thyroid cancer in all other situations.

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

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**Unknown Primary**

PET scanning may be considered medically necessary in patients with an unknown primary who meet **ALL** of the following criteria:

• In patients with a single site of disease outside the cervical lymph nodes; **and**
• Patient is considering local or regional treatment for a single site of metastatic disease; **and**
• After a negative workup for an occult primary tumor; **and**
• PET scan will be used to rule out or detect additional sites of disease that would eliminate the rationale for local or regional treatment.

PET scanning is considered experimental/investigational for other indications in patients with an unknown primary, including, but not limited to the following:

• As part of the initial workup of an unknown primary.
• As part of the workup of patients with multiple sites of disease.

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0219, G0235, G0252

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**Other Oncologic Applications**

Other oncologic applications of PET scanning, including but not limited to the following, are considered experimental/investigational:
• Diagnosis and management of known or suspected prostate cancer
• Diagnosis of brain tumors
• Staging of multiple myeloma
• Evaluation of neuroendocrine tumors
• Staging inguinal lymph nodes in patients with squamous cell carcinoma of the penis.

**Procedure Codes**
78811, 78812, 78813, 78814, 78815, 78816, A9552, A9580, A9586, G0235, G0252

Tumors in anatomic areas, other than those listed above, are considered not medically necessary and will be denied. The available scientific evidence is not adequate to determine whether PET imaging improves physician decision making in the determination of subsequent anti-tumor treatment strategy or improves health outcomes in patients.

A subsequent PET study may be medically necessary for tumor types other than those listed above, when the patient’s treating physician determines that the PET study is needed to determine if there is a need to develop a treatment plan for subsequent anti-tumor treatment.

It will be necessary for the provider to submit medical records and/or additional documentation to determine coverage in this situation. For example, the documentation should indication whether the prospective PET scan will lead to:

• A change in patient management to more appropriate palliative care;
• A change in patient management to more appropriate curative care;
• Improved quality of life;
• Improved survival.

**Surveillance**

Surveillance PET scanning is a study performed after the completion of treatment, in the absence of signs or symptoms of cancer recurrence or progression, for the purpose of detecting recurrence or progression, or predicting outcome. Surveillance has also been called “tertiary prevention.”

PET performed for surveillance is considered not medically necessary for the following reasons:

• There are no clinical trials evaluating PET as a method of cancer surveillance to improve patient outcomes.
• The sensitivity and specificity of PET scans in the surveillance setting is questionable given the possibility of false positives in these situations.
- There is little published literature from clinical trials and studies that address PET for surveillance. As such, there is inadequate direct or indirect scientific evidence supporting the efficacy of PET scanning for the purpose of surveillance.
- Because of the lack of outcome studies supporting the use of PET for surveillance in oncology, there are no standardized selection criteria.
- It is unknown how frequently and for which cancers PET is used for surveillance. Registries of PET utilization and analyses of claims data (such as the National Oncologic PET Registry or NOPR), do not report or appear to be capable of counting PET scans used for surveillance.
- CMS did not collect information on surveillance PET. Surveillance has not been identified by CMS as one of the possible indications for a PET scan.
- The length of time after the completion of the cancer treatment is not adequately defined to determine with certainty whether or not a PET study is performed for surveillance purpose.

**NOTE:**

A scan is considered surveillance if performed more than 6 months after completion of cancer therapy (12 months for lymphoma) in patients without objective signs or symptoms suggestive of cancer recurrence.

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**PET Scans Using a Coincidence Detection System**

The use of a non-dedicated PET scanner, also called a coincidence detection system will be denied as non-covered and therefore no payment can be made because it was performed on equipment that does not provide images that meet clinically accepted standards of quality.

**Procedure Codes**

S8085

**Modifiers PI and PS**

Modifiers –PI and –PS are to be used to identify those PET studies performed for initial (PI) or subsequent (PS) anti-tumor treatment strategy.

PI - Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to indicate the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing.

PS - Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to indicate the subsequent treatment strategy of cancerous tumors when the patient’s treating physician determines that the PET study is needed to plan subsequent anti-tumor strategy.
Place of Service: Outpatient

PET and PET/CT Scanning for Oncologic Indications is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

The policy position applies to all commercial lines of business

FEP Guidelines

This medical policy may not apply to FEP. Medical policy is not an authorization, certification, explanation of benefits, or a contract. Benefits are determined by the Federal Employee Program.

Denial Statements

Services that do not meet the criteria of this policy will not be considered medically necessary. A network provider cannot bill the member for the denied service unless: (a) the provider has given advance written notice, informing the member that the service may be deemed not medically necessary; (b) the member is provided with an estimate of the cost; and (c) the member agrees in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider’s records.

Services that do not meet the criteria of this policy will be considered experimental/investigational (E/I). A network provider can bill the member for the experimental/investigational service. The provider must give advance written notice informing the member that the service has been deemed E/I. The member must be provided with an estimate of the cost and the member must agree in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider’s records.

A network provider cannot bill the member for the non-covered service.