INITIAL ANTI-TUMOR TREATMENT STRATEGY:
PET imaging using the radiopharmaceutical diagnostic imaging agent fluorodeoxyglucose F-18 (FDG) (procedure code A9552) is covered to determine the appropriate initial anti-tumor treatment strategy for patients with:

- brain,
- breast,
- colorectal,
- esophagus,
- head and neck (excluding Central Nervous System),
- lung,
- lymphoma,
- melanoma,
- myeloma,
- ovarian,
- pancreas,
- soft tissue sarcoma,
- testicular cancers, and
- certain situations involving cervical cancer as provided below.
For these applications, PET imaging improves physician decision making in determining initial anti-tumor treatment strategy in patients and promotes improved health outcomes.

One PET study is covered 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.

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

**Cervix**
PET imaging is considered not medically necessary for initial diagnosis of cervical cancer related to initial treatment strategy.

PET scans are covered as an adjunct test for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers following conventional imaging that is negative for extra-pelvic metastasis.

Only one PET scan is eligible for staging in patients who have biopsy proven cervical cancer when the patient’s treating physician determines that the PET study is needed to determine the location and/or extent of the tumor for the diagnostic or therapeutic purposes described above.

**Lung**
*Small Cell Lung Cancer (SCL)* - PET scans are considered medically necessary for staging of persons with small cell lung cancer that has been determined to be clinical stage I SCL cancer (T 1-2, N0) after standard staging evaluation (including CT of the chest and upper abdomen, bone scan, and brain imaging).

*Characterization of Solitary Pulmonary Nodules (SPNs)* - PET scans are considered medically necessary for the characterization of suspected SPNs when the general medical necessity criteria for oncologic indications are met and the following conditions are met:

- An indeterminate or possibly malignant lesion, more than 1 cm and not exceeding 4 cm in diameter, has been detected (usually by CT); and
- A concurrent thoracic CT has been performed, which is necessary to ensure that the PET scan is properly coordinated with other diagnostic modalities.

The primary purpose of the PET scan of a solitary pulmonary nodule should be to determine the likelihood of malignancy in order to plan the management of the patient.
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.

Pancreas
PET is 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 or equivocal.

Testicular
PET is only covered for advanced testicular germ cell tumors in patients with a CT documented residual mass after chemotherapy treatment and normal or elevated serum markers to assess for viable tumor, or to differentiate between fibrosis and/or necrosis.

Breast
PET imaging for diagnosis and initial staging of axillary nodes (code G0252) is considered not medically necessary.

Melanoma
PET is covered to determine the initial treatment strategy for melanoma. However, the evaluation of regional lymph nodes in melanoma (code G0219) is considered not medically necessary.

SUBSEQUENT ANTI-TUMOR TREATMENT STRATEGY:
PET imaging also improves physician decision making in determining subsequent treatment strategy in patients with:

- brain,
- breast,
- colorectal,
- esophagus,
- head and neck (excluding Central Nervous System),
- lung,
- lymphoma,
- melanoma,
- myeloma,
- ovarian,
- pancreas,
- soft tissue sarcoma,
- testicular
• and thyroid cancers, and
• certain situations involving cervical cancer.

Tumors in other anatomic areas 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 antitumor treatment strategy or improves health outcomes in patients.

However, a subsequent PET study may be covered for tumor types other than those listed above, when the patient’s treating physician determines that the PET study is needed to determine the need and develop a treatment plan for subsequent antitumor 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 indicate 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.

**Thyroid**

PET is covered for subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and have a negative I-131 whole body scan. All other uses for subsequent treatment strategy are considered not medically necessary.

**Bone Metastases of Cancer**

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. Imaging to detect bone metastases can also be performed when a patient, following completion of initial treatment, is symptomatic with bone pain suspicious for metastases from a known primary tumor.

• As such, PET imaging with NaF-18 (procedure code A9580) is covered for suspected or biopsy-proven bone metastases when the patient’s treating physician determines 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.

PET and PET/CT scans performed for oncologic indications not listed in this policy as covered will be denied as not medically necessary.

**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. The principles of surveillance
are similar to those of traditional screening tests used for the early detection of disease. Surveillance has also been called “tertiary prevention.” Tertiary preventive services are those that are provided to persons who have or have had a disease in order to prevent further complications.

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 purposes.

Additional studies are needed to determine the usefulness of PET in the surveillance setting compared to the results obtained using other diagnostic and imaging techniques.

**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.

**Description**

**PET**

PET is a nuclear imaging technology that uses positron emitting radiotracers coupled to organic molecules (e.g., glucose) to obtain both metabolic and physiologic information pertaining to a specific anatomic area. These radiotracers are produced by a nuclear generator or cyclotron and administered intravenously as a radiopharmaceutical diagnostic imaging agent prior to imaging.
PET provides cross-sectional images of an anatomic area to identify metabolic, biochemical, hemodynamic, pharmacologic, and physiologic processes for the diagnosis and treatment management of diseases.

**PET/CT**

PET/CT is a multi-modality imaging technique that is useful in certain clinical situations because data acquired from CT and PET studies yields complementary information. In PET/CT imaging, the anatomic information from CT images is combined or "fused" with the physiologic information obtained from PET images to localize tumors or lesions especially in regions of complex anatomy, such as in the head, neck, chest, abdomen, and pelvis.

There are two methods of PET/CT imaging. One method involves the use of special computer software that combines or "fuses" the anatomic information from previously acquired CT images with the physiologic or functional information obtained from a separate PET study. This software fusion method is more labor intensive and at times unsuccessful, because the patient is imaged by two different modalities during two different imaging sessions. The patient is not in the same position or alignment for both studies. Further, the patient's movement is different during two separate imaging sessions, such as with the involuntary and uncontrollable motion of internal organs.

The other method uses a “hybrid” PET/CT scanner that takes both PET and CT images at the same imaging session. When compared to PET studies performed alone, the images of a single combined PET/CT study improves lesion classification and staging performance and reduces scanning time. In this situation, the patient remains positioned on the same bed for both imaging modalities, minimizing both temporal motion and spatial differences between the images acquired. In addition, using a PET/CT scanning system for both modalities makes the images available for viewing while the patient is still in the scanner.

This policy focuses on the oncologic applications of PET and PET/CT imaging when performed to diagnose and treat various malignancies.