Subject: Positron Emission Tomography (PET) for Oncologic Applications

DESCRIPTION:

Positron emission tomography (PET), also known as PET imaging, PET scan, positron emission transverse tomography (PETT), or positron emission coincident imaging (PECI), is a noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body. Images are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals). A variety of radiotracers are used for PET imaging, including oxygen-15, nitrogen-13, carbon-11, and fluorine-18. Because of their short half-life, some tracers must be made locally using an onsite cyclotron. The radiotracer most commonly used in oncology imaging has been fluorine-18 coupled with fluorodeoxyglucose (FDG), which has a metabolism related to glucose metabolism. FDG has been considered useful in cancer imaging, since tumor cells show increased metabolism of glucose.

The efficacy, sensitivity and specificity of PET vary with the type of cancer. The medical indication of PET imaging for oncologic applications depends in part on what imaging techniques are used either before or after PET imaging. PET imaging is typically considered after other techniques provide inconclusive or discordant results, such as computed tomography (CT), magnetic resonance imaging (MRI), or ultrasonography.

Combined positron emission tomography (PET) computed tomography (CT) systems merge PET and CT imaging technology into one system to produce an image that provides both functional and anatomic information. CT uses x-rays to produce cross-sectional anatomic views of the area of interest.
The following applications in oncology apply for PET imaging:

Diagnosis: Diagnosis refers to use of PET imaging as part of the testing used in establishing whether or not an individual has cancer.

Staging: Staging refers to use of PET imaging to determine the stage (extent) of the cancer at the time of diagnosis, before any treatment is given. Imaging at this time is generally to determine whether or not the cancer is localized. This may also be referred to as initial staging.

Restaging: Restaging refers to PET imaging following treatment; evaluation of an individual in which a disease recurrence is suspected based on signs and/or symptoms and in determining the extent of malignancy following completion of a full course of treatment.

Surveillance: Surveillance refers to use of PET imaging in asymptomatic individuals (individuals without objective signs or symptoms of recurrent disease). PET imaging is completed 6 months or more following completion of treatment for cancer and 12 months or more for lymphoma following completion of treatment.

POSITION STATEMENT:

For all uses of positron emission tomography (PET) imaging relating to oncology, the following general criteria applies for the following indications:

Initial Treatment Management

**Diagnosis:** PET meets the definition of medical necessity only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomic location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET imaging. PET scans following a tissue diagnosis are performed for the purpose of staging, rather than diagnosis.

**Staging:** PET meets the definition of medical necessity for staging in clinical situations in which the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound), or the PET could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the member, and clinical management of the member would differ depending on the stage of the cancer identified.

Subsequent Treatment Management

**Restaging:** PET meets the definition of medical necessity for restaging after completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or metastasis, to determine the extent of a known recurrence, or if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the member. Restaging applies to testing after a course of treatment is completed.

**Monitoring:** Refers to the use of PET to monitor tumor response to treatment during the planned course of therapy (e.g., when a change in therapy is anticipated).
Positron emission tomography (PET) imaging with or without combined positron emission tomography/computed tomography (PET/CT) with an FDA approved radiopharmaceutical and radiotracer meets the definition of medical necessity for the following indications.

**Bladder Cancer**

PET imaging meets the definition of medical necessity in the staging or restaging of muscle-invasive bladder cancer when CT or MRI are not indicated or remained inconclusive on distant metastasis.

PET imaging is considered experimental or investigational for bladder tumors which have not invaded the muscle (stage < cT2). The evidence is insufficient to determine the effects of PET imaging on health outcomes.

**Bone Cancer (Sarcoma)**

PET imaging meets the definition of medical necessity in the staging or restaging of Ewing sarcoma and osteosarcoma.

PET imaging is considered experimental or investigational for staging of chondrosarcoma. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

**Breast Cancer**

PET imaging meets the definition of medical necessity in the staging or restaging of breast cancer for the following:

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

PET imaging is considered experimental or investigational in the evaluation of breast cancer for all other applications, including but not limited to the following. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

- Differential diagnosis in members with suspicious breast lesions or an indeterminate/low suspicion finding on mammography
- Staging of axillary lymph nodes
- Predicting pathologic response to neoadjuvant therapy for locally advanced disease.

**Cervical Cancer**

PET imaging for cervical cancer meets the definition of medical necessity for the following:

- For initial staging of locally advanced cervical cancer
- For evaluation of known or suspected recurrence.
- Chronic Lymphocytic Leukemia (CLL)

**Chronic Lymphocytic Leukemia (CLL)**

PET imaging for chronic lymphocytic leukemia (CLL) meets the definition of medical necessity as the initial study with biopsy proven cancer or for detecting suspected cancer based on diagnostic testing (e.g., bone marrow aspiration, biopsy, CBC).
Colorectal Cancer

PET imaging for colorectal cancer meets the definition of medical necessity for the following:

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

PET imaging is considered experimental or investigational for the following. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

- Assessment of the presence of scarring versus local bowel recurrence in members with previously resected colorectal cancer
- Radiotherapy treatment planning.

Endometrial Cancer

PET imaging for endometrial cancer meets the definition of medical necessity for the following:

- Detection of lymph node metastases
- Assessment of endometrial cancer recurrence.

Esophageal Cancer

PET imaging for esophagus cancer meets the definition of medical necessity for the following:

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

PET imaging is considered experimental or investigational in other aspects of the evaluation of esophageal cancer, including, but not limited to the detection of primary esophageal cancer. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

Gastric Cancer

PET imaging for gastric cancer meets the definition of medical necessity for the following:

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

Head and Neck Cancer

PET imaging of head and neck cancer meets the definition of medical necessity for the following:

- Initial diagnosis of suspected head and neck cancer
- Initial staging of disease and restaging of residual or recurrent disease during follow-up

Lung Cancer
PET imaging of the lung meets the definition of medical necessity for the following applications:

- As staging or restaging technique in those with known non-small cell lung cancer
- Members 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 are inconclusive or discordant
- To determine resectability for presumed solitary metastatic lesion from lung cancer
- Staging small cell lung cancer if limited stage is suspected based on imaging (e.g., MRI, CT)
- Restaging and monitoring lung cancer (small cell) if other imaging modalities (e.g., ultrasound, CT, MRI) are inconclusive in determining a treatment plan or if unable to perform imaging modalities.

PET imaging is considered experimental or investigational in staging of small-cell lung cancer if extensive stage is established and in all other aspects of managing small cell lung cancer. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

**Lymphoma (including Hodgkin’s disease)**

PET imaging for lymphoma meets the definition of medical necessity for staging lymphoma either during initial staging or for restaging at follow-up.

**Melanoma**

PET imaging for melanoma meets the definition of medical necessity for the following:

- For assessing extranodal spread of malignant melanoma at initial staging or during follow-up treatment for advanced disease (stage III or IV)

PET imaging is considered experimental or investigational in managing stage 0, I, or II melanoma. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

PET imaging is considered experimental or investigational to detect regional lymph node metastases in members with clinically localized melanoma who are candidates to undergo sentinel node biopsy. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

**Multiple Myeloma**

PET imaging for multiple myeloma meets the definition of medical necessity for the following:

- Staging or restaging of multiple myeloma when skeletal survey is negative.

**Neuroendocrine Cancer**

PET imaging with gallium 68 meets the definition of medical necessity for staging neuroendocrine tumors (e.g., carcinoid, pheochromocytoma) either during initial staging or for restaging at follow-up.

PET imaging meets the definition of medical necessity for restaging and monitoring of neuroendocrine cancer (e.g., carcinoid, pheochromocytoma) if other imaging modalities (e.g., ultrasound, CT, MRI) are inconclusive in determining a treatment plan or if unable to perform imaging modalities.

PET imaging with other radiotracers is considered experimental or investigational in all aspects of managing neuroendocrine tumors. The evidence is insufficient to determine the effects of PET imaging on health outcomes.
Ovarian Cancer

PET imaging for ovarian cancer meets the definition of medical necessity for the following:

- Evaluation of members with signs and/or symptoms of suspected ovarian cancer recurrence (restaging) when imaging (e.g., CT scan) is inconclusive.

PET imaging is considered experimental or investigational in the initial evaluation of known or suspected ovarian cancer. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

Pancreatic Cancer

PET imaging meets the definition of medical necessity in the initial diagnosis and staging of pancreatic cancer when other imaging (e.g., ultrasound, CT, or MRI) and biopsy are inconclusive.

PET imaging meets the definition of medical necessity for restaging and monitoring of pancreatic cancer only if other imaging (e.g., ultrasound, CT, MRI) is inconclusive in determining a treatment plan or if unable to perform imaging modalities.

PET imaging is considered experimental or investigational as a technique for evaluation of other aspects of pancreatic cancer. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

Prostate Cancer

PET imaging with carbon 11 choline meets the definition of medical necessity for evaluating suspected or biochemically recurrent prostate cancer after primary treatment to detect small volume disease in soft tissue.

PET imaging for restaging and monitoring of prostate cancer meets the definition of medical necessity only if other imaging (e.g., ultrasound, CT, MRI) is inconclusive in determining a treatment plan or if unable to perform imaging modalities.

PET imaging with gallium 68 is considered experimental or investigational in prostate cancer.

PET imaging for all other indications in known or suspected prostate cancer is considered experimental or investigational. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

Renal Cell Carcinoma

PET imaging is considered experimental or investigational in all aspects of managing renal cancer. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

Soft Tissue Sarcoma

PET imaging for restaging and monitoring of soft tissue sarcoma meets the definition of medical necessity only if other imaging (e.g., ultrasound, CT, MRI) is inconclusive in determining a treatment plan or if unable to perform imaging modalities.
PET imaging is considered experimental or investigational in evaluation of soft tissue sarcoma, including but not limited to the following applications. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

- Distinguishing between low grade and high grades of soft tissue sarcoma
- Distinguishing between benign lesions and malignant soft tissue sarcoma
- Detecting locoregional recurrence
- Detecting distant metastasis.

**Testicular Cancer**

PET imaging meets the definition of medical necessity in the evaluation of residual mass following chemotherapy of stage IIB and III seminomas (the PET imaging should be completed not sooner than 6 weeks following chemotherapy).

PET imaging for restaging and monitoring of testicular cancer meets the definition of medical necessity only if other imaging (e.g., ultrasound, CT, MRI) is inconclusive in determining a treatment plan or if unable to perform imaging modalities.

Except as noted above for seminoma, PET imaging is considered experimental or investigational in evaluation of testicular cancer, including but not limited to the following. There is limited evidence in the published peer-reviewed medical literature to support PET imaging for the following:

- 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.

**Cancer of Unknown Primary**

PET imaging of unknown primary meets the definition of medical necessity when ALL of the following criteria are met:

- For a single site of disease outside the cervical lymph nodes; AND
- Local or regional treatment for a single site of metastatic disease is being considered; AND
- After a negative work up for an occult primary tumor; AND
- PET imaging will be used to rule out or detect additional sites of disease that would eliminate the rationale for local or regional treatment.

PET imaging is considered experimental or investigational for other unknown primary including, but not limited to the following. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

- Initial work-up of an unknown primary
- Work-up for multiple sites of disease.

**Cancer Surveillance**
PET imaging is considered **experimental or investigational** when used as a surveillance tool for members with cancer or with a history of cancer. PET imaging is considered surveillance if performed more than 6 months after completion of cancer therapy (12 months for lymphoma) in members without objective signs or symptoms suggestive of cancer recurrence. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

**Surveillance/Remission**

The use of interim fluorine 18 fluorodeoxyglucose positron emission tomography positron emission tomography scans to determine response to tyrosine kinase inhibitor treatment in members with gastrointestinal stromal tumors **meets the definition medical necessity**.

The use of positron emission tomography scans to determine early response to treatment (positron emission tomography scans done during a planned course of chemotherapy and/or radiotherapy) in members including, but not limited to gastrointestinal stromal tumors on palliative or adjuvant therapy, is considered **experimental or investigational**. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

**Other**

PET imaging for vulvar and penile cancer requires Medical Director review of the general criteria; refer to initial treatment management (diagnosis, staging) and subsequent treatment management (restaging, monitoring).

PET imaging is considered **experimental or investigational** for all other indications including but not limited to the following. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

- PET mammography (PEM)
- PET magnetic resonance imaging (PET/MR, PET/MRI)
- Screening

PET imaging (full and partial-ring PET scanners only), for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g. initial staging of axillary lymph nodes) **does not meet the definition of medical necessity**. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

PET imaging for whole body melanoma **does not meet the definition of medical necessity**. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

**Indications for an Oncological F\(^{18}\) FDG, GA\(^{68}\) Dotatate, F\(^{18}\) Fluciclovine PET Scan**

**Initial Treatment Strategy**

F\(^{18}\) FDG, Ga\(^{68}\) Dotatate, F\(^{18}\) Fluciclovine PET scan is indicated for most solid tumors, including active myeloma, with biopsy proven cancer or strongly suspected, based on other diagnostic testing, including.

F\(^{18}\) FDG, Ga\(^{68}\) Dotatate, F\(^{18}\) Fluciclovine PET scan meets the definition of medical necessity for the following:

- Chronic lymphocytic leukemia (CLL): only when high-grade histologic transformation is suspected.
• Solitary pulmonary nodule (SPN): solitary or clearly dominant indeterminate pulmonary nodule ≥ 8mm in size without existing tissue diagnosis (Note: Member may have other non-suspicious nodules in the lung, such as granulomas and hamartomas).
• To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor; OR
• To determine if member is an appropriate candidate for an invasive diagnostic or therapeutic (e.g., surgery) procedure; OR
• To determine the optimal anatomic location for an invasive procedure and prior imaging is insufficient.

For the following solid tumors, initial staging is only indicated after prior inconclusive imaging:

• Bladder cancer, muscle invasive
• Chordoma
• Colorectal
• Endometrial cancer
• Gallbladder/extrahepatic cholangiocarcinoma
• Neuroendocrine tumors which are poorly differentiated, with prior negative Ga68 Dotatate/MIBG/Octreotide scan (includes pheochromocytoma/paraganglioma, extrapulmonary large/small cell)
• Ovarian/fallopian tube
• Pancreatic cancer (unless high risk features: borderline resectable, markedly elevated carbohydrate antigen (CA)19-9 >180 U/mL, large primary tumor/lymph nodes, very symptomatic (e.g., jaundice, symptomatic gastric outlet obstruction, venous thromboembolism, extreme pain, weight loss)
• Penile (for palpable nodes only)
• Sarcoma/Gastrointestinal stromal tumors (GIST)/Uterine/Rhabdomyosarcoma
• Skin squamous cell carcinoma
• Tumor of unknown origin/occult primary.

**Subsequent Treatment Strategy**

PET imaging **meets the definition of medical necessity** for the following:

Restaging or monitoring response to active treatment (including immunotherapy), and/or a single evaluation after completion/cessation of therapy. The interval should ideally be 6-12 weeks after surgery, and 12 weeks after radiation. PET imaging can be performed 1 - 3 weeks after neoadjuvant chemotherapy or neoadjuvant chemoradiation to assess stage for surgery. PET evaluation can also be done for suspicion of recurrence due to new or changing signs/symptoms, rising tumor markers, or inconclusive findings on CT or MRI.

Asymptomatic surveillance **does not meet the definition of medical necessity**. The evidence is insufficient to determine the effects of PET imaging on health outcomes.

• Cervical cancer
• Esophageal and esophagogastric cancer
• Head and neck cancer (not including Brain cancer/tumor; thyroid noted below)
- Lung cancer: Non-small cell and limited stage small cell cancer
- Lymphoma
- Melanoma: Only stage III, IV (excludes uveal melanoma)
- Merkel cell carcinoma
- Mesothelioma (if surgery is planned)
- Myeloma: Active/plasmacytoma
- Soft tissue sarcoma: Only stage II/III for response to neoadjuvant Rx
- Vulvar/vaginal

Subsequent PET imaging may be performed only if other imaging (i.e., ultrasound (US), computed tomography (CT), magnetic resonance imaging (MRI), nuclear medicine (NM)) is inconclusive/insufficient in determining a treatment plan or unable to be performed or with rising tumor markers and negative/insufficient other imaging.

PET imaging may be indicated if CT cannot be performed due to significant iodinated contrast allergy or chronic renal failure and MRI cannot be performed due to gadolinium contrast allergy or renal failure with glomerular filtration rate (GFR) < 30.

Solid malignancies: Except for those not covered for F^{18} FDG, Ga^{68} Dotatate, F^{18} Fluciclovine, where other imaging (i.e., US, CT, MRI, NM) is inconclusive in determining a treatment plan or unable to be performed. PET CT is to be used only if the cancer is known to be generally F^{18} FDG, Ga^{68} Dotatate, F^{18} Fluciclovine avid. Malignancies such as the following (not an all-inclusive list):

- Adenocarcinoma of the small bowel
- Anal/Vulvar/Penile carcinoma
- Bladder cancer (only if metastatic)
- Bone sarcoma
- Brain cancer (with metastasis to non-head areas)
- Breast cancer (female and males)
- Colorectal cancer: Resectable metastatic disease only
- Endometrial cancer: If candidate for surgery/locoregional therapy
- Extensive small cell lung cancer
- Gastric cancer
- Ovarian/malignant germ cell tumors/primary peritoneal cancer: Stage II-IV
- Poorly differentiated or dedifferentiated neuroendocrine tumors with prior negative Ga68 Dotatate/MIBG/Octreotide scan (includes pheochromocytoma/paraganglioma, extrapulmonary large/small cell)
- Rhabdomyosarcoma
- Sarcoma/ Gastrointestinal stromal tumors (GIST)/Uterine/Rhabdomyosarcoma
- Testicular cancer
- Tumor of unknown origin/occult primary
Thyroid Cancer

- Subsequent treatment strategy for recurrence or distant metastasis for thyroid cancer of papillary, follicular, or Hurthle cell origin and member has the following:
  - A thyroidectomy and radioiodine ablation initially; **AND**
  - Stimulated serum thyroglobulin > 5 ng/ml or high anti-thyroglobulin antibody (anti-Tg Ab) >1 year after treatment; **AND**
  - Current stimulated whole body I-131/ I-123 scan is negative.

- Medullary thyroid cancer when calcitonin levels ≥ 150 pg/mL post primary treatment.
- Anaplastic: Initial and restaging after prior inconclusive/insufficient CT/MRI.

Pediatrics Cancers

- Nasopharyngeal cancer: Initial staging after inconclusive/insufficient MRI; restaging.
- Neuroblastoma/other cancers under Ga68 imaging: Only with prior negative/ inconclusive MIBG/Octreotide/ Ga68 PETCT.
- Sarcoma: Initial staging and restaging.

Surveillance/Remission

Surveillance/remission PET imaging to assess for possible changes in status with no signs or symptoms of active cancer changes and member is not on any active treatment. Unless otherwise specified above, PET imaging is not indicated for surveillance/remission.

Indications for an Oncological Gallium 68 Dotatate PET/CT Scan

Initial Treatment Strategy or Subsequent Treatment Strategy

Gallium-68 Dotatate PET/CT scan **meets the definition of medical necessity** for the following neuroendocrine tumors:

- Gastrointestinal tract, pancreas, lung, thymus (carcinoid tumors).
- Pheochromocytoma, paraganglioma.
- Large or small cell carcinoma other than lung
- Medullary thyroid cancer for initial staging and restaging when calcitonin ≥ 150 pg/mL.
- Neuroendocrine tumors of unknown primary

**OR**

Gallium-68 Dotatate PET/CT scan **meets the definition of medical necessity** for the following syndromes:

- Multiple endocrine neoplasia 1 (MEN-1).
- Multiple endocrine neoplasia 2 (MEN-2).

Neuroendocrine tumors should be biopsy proven (required in unknown primary cases) or very strongly suspected based on other diagnostic testing and site specific multiphasic CT or MRI has been performed and reasonably deemed insufficient for the following:
• To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor; OR

• To determine if member is an appropriate candidate for an invasive diagnostic or therapeutic procedure; OR

• To determine the optimal anatomic location for an invasive procedure; OR

• Restaging or monitoring response to active treatment, and/or evaluation for suspicion of recurrence due to new or changing signs/symptoms and rising biomarkers (asymptomatic surveillance does not meet the definition of medical necessity).

**Surveillance/Remission**

Both somatostatin receptor imaging (Gallium-68 Dotatate PET) and F\(^{18}\) FDG, F\(^{18}\) Fluciclovine PET/CT are not recommended for routine surveillance.

**Indications for an Oncological \(^{18}\)F-Fluciclovine (Axumin) PET/CT Scan** (recurrent prostate cancer): Known prostate cancer for workup of recurrence and response to treatment, only if other imaging (CT, MRI) and bone scan is inconclusive/insufficient.

**\(^{18}\)F-Fluciclovine PET/CT:**

- Post radical prostatectomy with:
  - Failure of prostate-specific antigen (PSA) to fall to undetectable levels or PSA detectable and rising on at least 2 subsequent determinations.

- Post radiation therapy with:
  - Rising/persistent PSA (increase should be >2ng/ml unless doubling time <=8 months or member is a candidate for local salvage therapy).

**F\(^{18}\) FDG, Ga\(^{68}\) Dotatate, F\(^{18}\) Fluciclovine**

F\(^{18}\) FDG, Ga\(^{68}\) Dotatate, F\(^{18}\) Fluciclovine for the following is considered **not medically necessary**. The evidence is insufficient to determine the effects of F\(^{18}\) FDG, Ga\(^{68}\) Dotatate, F\(^{18}\) Fluciclovine on health outcomes.

- Adrenal (except pheochromocytoma/paraganglioma): Initial or restaging.
- Acute lymphoblastic leukemia (ALL)/acute myelogenous leukemia (AML): Unless prior imaging suggests lymphomatous involvement.
- Basal cell carcinoma (BCC) (of the skin).
- Bladder cancer non muscle-invasive (by imaging or tissue sample).
- Breast cancer: Initial staging for stage I and II breast cancer.
- Chordoma: Restaging.
- Gallbladder/extrahepatic cholangiocarcinoma: Restaging.
- Gastric Cancer: Initial staging if there is evidence of metastases (M1) or very early disease (T1).
- Hepatocellular/intrahepatic cholangiocarcinoma: Initial and restaging.
- Infection and/or Inflammation.
- Melanoma: Initial and restaging for stage I and II melanoma.
- Myeloma, smoldering: Except to discern smoldering from active myeloma with negative skeletal survey.
- Ovarian cancer: Restaging for stage I.
- Pancreatic cancer: Restaging.
- Pleural mesothelioma, malignant: Initial staging except for stage I-IIIA and presurgical.
- Prostate cancer: Initial or restaging.
- Renal cancer: Initial and restaging.
- Small bowel adenocarcinoma: Initial Staging.
- Small cell lung cancer: Staging (Initial or Restaging) for extensive disease.
- Squamous cell carcinoma, skin: Restaging.
- Vulvar cancer: <T2 or no suspicion of metastatic disease.

**BILLING/CODING INFORMATION:**

**CPT Coding:**

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<th>Description</th>
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<td>78811</td>
<td>Positron emission tomography (PET) imaging; limited area (e.g., chest, head/neck)</td>
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<tr>
<td>78812</td>
<td>Positron emission tomography (PET) imaging; skull base to mid-thigh</td>
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<tr>
<td>78813</td>
<td>Positron emission tomography (PET) imaging; whole body</td>
</tr>
<tr>
<td>78814</td>
<td>Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (e.g., chest, head/neck)</td>
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<td>78815</td>
<td>Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh</td>
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<tr>
<td>78816</td>
<td>Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body</td>
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**HCPCS Coding:**

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<th>Code</th>
<th>Description</th>
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<td>G0219</td>
<td>PET imaging whole body: melanoma for non-covered indications (non-covered)</td>
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<tr>
<td>G0235</td>
<td>PET imaging, any site, not otherwise specified</td>
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<tr>
<td>G0252</td>
<td>PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes), (non-covered)</td>
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**REIMBURSEMENT INFORMATION:**

PET scans are performed using a camera that has either been approved or cleared for marketing by the Food and Drug Administration (FDA) to image positron annihilation gamma photons in the body.

PET scans are performed using FDA approved radiotracer (e.g., Nitrogen -13 (as ammonia), oxygen-15 as H0, carbon-11) or radiopharmaceutical. The radiopharmaceutical may be manufactured on site or manufactured at a regional delivery center with delivery to the institution performing the PET scan. When the radiopharmaceutical is provided by an outside distribution center, there may be a separate charge for both the radiopharmaceutical and transportation of the radiopharmaceutical.

**LOINC Codes:**

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, plan of treatment and reason for positron emission tomography (PET) imaging.
**Documentation Table**

<table>
<thead>
<tr>
<th>LOINC Codes</th>
<th>LOINC Time Frame Modifier Code</th>
<th>LOINC Time Frame Modifier Codes Narrative</th>
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**PROGRAM EXCEPTIONS:**

Coverage for the radiology services referenced in this guideline performed and billed in an outpatient or office location will be handled through the BCBSF Radiology Management program for select products. The National Imaging Associates (NIA) will determine coverage for these services for select products. Refer to member’s contract benefits.

**Federal Employee Plan (FEP):** FEP is excluded from the National Imaging Associates (NIA) review; follow FEP guidelines.

**Medicare Advantage Products:**

No Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: Positron Emission Tomography (FDG) for Oncologic Conditions (220.6.17) and Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer (220.6.19) located at cms.gov.

**DEFINITIONS:**

**Neoadjuvant:** treatment given as a first step to shrink a tumor before the main treatment, which is usually surgery, is given. Examples of neoadjuvant therapy include chemotherapy, radiation therapy, and hormone therapy.

**Solid tumor:** an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them. Examples of solid tumors are sarcomas, carcinomas, and lymphomas. Leukemias (cancers of the blood) generally do not form solid tumors. (NCI, 2020)

**RELATED GUIDELINES:**

- Positron Emission Tomography (PET) Cardiac Applications, 04-78000-16
- Positron Emission Tomography (PET) Miscellaneous Applications, 04-78000-18

**OTHER:**

Other names used to report positron emission tomography (PET):
Combined Positron Emission Tomography-Computed Tomography (PET-CT)
Integrated PET/CT
positron emission transverse tomography (PETT)
positron emission coincident imaging (PECI)
PET-CT

REFERENCES:
1. Agency for Healthcare Research and Quality (AHRQ) Technology Assessment-Positron emission tomography for nine cancers (bladder, brain, cervical, kidney, ovarian, pancreatic, prostate, small cell lung, testicular), 12/01/08.
2. ACR-SPR Practice Guideline for Performing FDG-PET/CT in Oncology, Revised 2016.
3. American College of Radiology (ACR) Guideline for the Performance of FDG-PET Scintigraphy in Oncology, 01/01/01.
9. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.51 Interim Positron Emission Tomography Scanning in Oncology to Detect Early Response During Treatment, 10/19.
10. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.52 Positron Emission Mammography, 10/19.
11. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.56 Oncologic Applications of Positron Emission Tomography Scanning, 10/19.


64. Schoder H, Gonen M. Screening for cancer with PET and PET/CT: potential and limitations. The Journal of Nuclear Medicine 2007; 48(1): 4S-18S.


69. Towsend DW, Carney JPP, Yap JT et al. PET/CT today and tomorrow. The Journal of Nuclear Medicine 2004; 45(1): 4S-14S.


COMMITTEE APPROVAL:
This Medical Coverage Guideline (MCG) was approved by the BCBSF Medical Policy & Coverage Committee on 02/27/20.

GUIDELINE UPDATE INFORMATION:

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/15/03</td>
<td>Annual review. Developed separate policy for PET Scans Oncologic Applications.</td>
</tr>
<tr>
<td>04/23/04</td>
<td>Added coverage statement for G0296. Deleted Medicare &amp; More program exception for G0296.</td>
</tr>
<tr>
<td>11/15/04</td>
<td>Annual Review. No change in coverage statements. Revised NIA statements under Program Exceptions. Updated references.</td>
</tr>
<tr>
<td>01/01/05</td>
<td>HCPCS update. Deleted 78810. Added 78811, 78812, 78813, 78814, and 78815.</td>
</tr>
<tr>
<td>Date</td>
<td>Description</td>
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</tr>
<tr>
<td>02/15/05</td>
<td>HCPCS update. Added G0330 and G0331. Deleted 78814 and 78815, separate MCG to be developed.</td>
</tr>
<tr>
<td>05/15/05</td>
<td>Added coverage statement for combined PET-CT (78814, 78815, and 78816). Revised when services are covered and when services are not covered for PET imaging. Added coverage statement for cervical cancer. Added G0235. Revised reimbursement statement. Updated references.</td>
</tr>
<tr>
<td>02/15/06</td>
<td>HCPCS update, deleted G0253 and G0254. Updated references.</td>
</tr>
<tr>
<td>03/15/06</td>
<td>HCPCS update, deleted G0125, G0210, G0211, G0212, G0213, G0214, G0215, G0216, G0217, G0218, G0220, G0221, G0222, G0223, G0224, G0225, G0226, G0227, G0228, G0231, G0232, G0234, and G0296. Revised G0235 descriptor.</td>
</tr>
<tr>
<td>06/15/06</td>
<td>Revised description section. Revised when services are covered; expand coverage to include ovarian cancer and pancreatic cancer. Revised coverage statement for PET-CT. Revised when services are not covered. Added A9552. Revised reimbursement statement. Added CA-125 to definition section. Added program exception for Medicare Advantage products. Updated references.</td>
</tr>
<tr>
<td>12/28/06</td>
<td>Added ICD-9 diagnoses codes.</td>
</tr>
<tr>
<td>04/01/07</td>
<td>Deleted G0330 and G0331. Deleted monitoring of ovarian cancer for response to treatment from when services are not covered. Added monitoring of ovarian cancer for response to treatment to when services are covered for ovarian cancer.</td>
</tr>
<tr>
<td>07/01/07</td>
<td>Reformatted guideline. Maintain coverage statements. Added statement that multiple myeloma, testicular cancer, and vulvar cancer requires Medical Director Review. Revised investigational/experimental statement, added evaluation of soft tissue sarcoma. Revised reimbursement statement. Updated references.</td>
</tr>
<tr>
<td>01/01/08</td>
<td>HCPCS update. Revised 78811, 78812, 78813, 78814, 78815, and the descriptor for code 78816.</td>
</tr>
<tr>
<td>01/21/08</td>
<td>Updated Program Exceptions.</td>
</tr>
<tr>
<td>07/15/08</td>
<td>Scheduled review. No change in position statement. Updated references.</td>
</tr>
<tr>
<td>05/21/09</td>
<td>Removed Federal Employee Plan (FEP) from BCBSF Radiology Management program exception statement. Added FEP program exception statement: FEP is excluded from the National Imaging Associates (NIA) review; follow FEP guidelines.</td>
</tr>
<tr>
<td>07/01/09</td>
<td>Updated BCBSF Radiology Management program exception; added BlueSelect.</td>
</tr>
<tr>
<td>11/15/09</td>
<td>Annual review. Added renal/kidney cancer to experimental or investigational position statement. Added program exception for Medicare. Updated references.</td>
</tr>
<tr>
<td>01/01/10</td>
<td>Revised BCBSF Radiology Management program exception section.</td>
</tr>
<tr>
<td>05/15/10</td>
<td>Added coverage criteria for NaF-18 PET imaging for bone metastasis cancer to program exception for Medicare Care Advantage products.</td>
</tr>
<tr>
<td>11/15/10</td>
<td>Annual review: expanded indications that meets the definition of medical necessity for breast cancer (added staging and restaging for detection of locoregional or distant recurrence or metastasis), cervical cancer (added initial staging of locally advanced cervical cancer), colorectal cancer (added staging and restaging to hepatic or extrahepatic metastasis and evaluation of rising and persistently elevated CEA level), esophageal cancer (added determining response to preoperative induction therapy, lung cancer (added to determine respectability for presumed solitary metastatic lesion from the lung), Ovarian cancer (Added evaluation of signs and symptoms of suspected ovarian cancer recurrence), pancreatic cancer (revised position statement, PET imaging meets the definition of medical necessity in the initial diagnosis and staging), testicular cancer (added in the evaluation of residual mass following chemotherapy of stage IIB and III seminomas), thyroid cancer (added staging of differentiated thyroid cancer). Added the following to experimental or investigational: differential diagnosis in patients with suspicious breast lesions or an indeterminate/low suspicion finding on mammography, PET bone scanning PET mammography (PEM), detection of primary esophageal cancer, diagnosis and management of known or suspected prostate cancer, evaluation of testicular cancer, evaluation of known or suspected differentiated thyroid cancer, evaluation of known or suspected cervical cancer, and cancer surveillance. Added ICD-10 diagnoses codes, updated Medicare program exception, and updated references.</td>
</tr>
<tr>
<td>10/01/11</td>
<td>Revision; related ICD-9 code 793.11 added and formatting changes.</td>
</tr>
<tr>
<td>11/15/11</td>
<td>Annual review; maintain position statements. Updated Medicare Advantage program exception. Updated references.</td>
</tr>
<tr>
<td>04/01/12</td>
<td>Update; added related ICD-10 codes.</td>
</tr>
<tr>
<td>08/15/13</td>
<td>Removed “scan” from guideline subject. Updated description section; revised radiotracer.</td>
</tr>
</tbody>
</table>
**Updated references.** (Initial diagnosis and/or staging and criteria for F-18 FDG, Ga-68 DOTATATE, F-18 Fluorodeoxyglucose PET scan. Added indications for an oncological GALLIUM 68 DOTATATE PET/CT scan. Added indications for an oncological 18F-Fluciclovine (Axumin) PET/CT scan. Added indications and criteria for F-18 FDG, Ga-68 Dotate, F-18 Fluuciclovine. Added position statement for breast cancer (initial diagnosis and/or surgical planning). Added position statement for whole body melanoma. Updated references.

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<tr>
<td>11/15/13</td>
<td>Revision; brain: added initial study to experimental or investigational statement; esophageal cancer: deleted diagnosis of esophageal cancer, evaluation of esophageal tumor; and added detection of primary to experimental or investigational statement; lung: added non-small cell; ovarian cancer: added diagnostic to experimental or investigational statement; soft tissue sarcoma: deleted distinguishing between benign lesions and malignant soft tissue sarcoma, detecting locoregional recurrence and detecting distant metastasis; deleted whole body tumor imaging; other: deleted renal/kidney cancer (diagnosis, staging, restaging, monitoring), diagnosis and management of known or suspected prostate cancer, determining early response to treatment (PET performed during a planned course of chemotherapy and/or radiation therapy), and gastric cancer (staging).</td>
</tr>
<tr>
<td>06/15/15</td>
<td>Revision; added chronic lymphocytic leukemia (CLL), prostate cancer, lung cancer (small cell), neuroendocrine cancer (e.g., carcinoid phenochromocytoma), and medullary thyroid cancer. Deletes the indication (brain and criteria). Updated references.</td>
</tr>
<tr>
<td>02/20/17</td>
<td>Update; Deleted code A9552.</td>
</tr>
<tr>
<td>10/15/18</td>
<td>Revision; revised position statements. Added indications for an oncological gallium 68 dotate PET/CT scan. Updated references.</td>
</tr>
<tr>
<td>11/15/18</td>
<td>Revision; revised position statements. Added position statement for cancers (bladder, endometrial, gastric and renal cell carcinoma). Added position statement for interim fluorne 18 Fluorodeoxyglucose PET scans to determine response to tyrosine kinase inhibitor treatment for gastrointestinal stromal tumors. Added position statement for PET scans to determine early response to treatment. Add penile to other section. Updated references.</td>
</tr>
<tr>
<td>03/15/20</td>
<td>Review/Revision. Revised position statement and expand indications and criteria. Added indications and criteria for an oncological F-18 FDG, Ga-68 DOTATATE, F-18 FLUCICLOVINE PET scan. Revisited and expand indications for an oncological GALLIUM 68 DOTATATE PET/CT scan. Added indications for an oncological 18F-Fluciclovine (Axumin) PET/CT scan. Added indications and criteria for F-18 FDG, Ga-68 Dotate, F-18 Fluuciclovine. Added position statement for breast cancer (initial diagnosis and/or surgical planning). Added position statement for whole body melanoma. Updated references.</td>
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