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Subject: Positron Emission Tomography (PET) for Oncologic Applications

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Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

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 for the following: 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.

Summary of Evidence: Prostate cancer: According to the Society of Nuclear Medicine and Molecular Imaging (2024), several molecular radiotracers demonstrate the ability to diagnose and guide the treatment of prostate cancer using different pathophysiology processes that are related to prostate cancer metabolism and cell growth. These include metabolic radiotracers such as ^{18}F -Fluorodeoxyglucose (FDG), ^{18}F -Fluciclovine, and choline as well as agents that target the prostate-specific membrane antigen (PSMA). These radiotracers utilize positron emission tomography (PET) scanning in conjunction with computer-aided tomography (CT) to identify sites of disease. FDG PET scan involves the use of a PET with an ^{18}F -Fluorodeoxyglucose (FDG) radiotracer. FDG is a compound derived from a simple sugar (glucose) and a small amount of radioactive fluorine. FDG accumulates in tissues with high metabolic activity levels, such as the normal brain tissue. Many cancers, including aggressive prostate cancer (also known as high Gleason Score), accumulate high levels of FDG due to their altered metabolism and rapid cell growth. A choline PET scan uses PET and the ^{11}C -choline radiotracer, a positron-emitting radiopharmaceutical. Choline is an essential component of cell membranes and accumulates in tissues with high cellular proliferation (high rate of cell replication). Malignancies, such as prostate cancer demonstrate increased choline uptake and incorporation into their cellular membranes. ^{11}C -choline PET is used in patients with prostate cancer previously treated and now have an increase in prostate-specific antigen (PSA) blood levels suggesting recurrent prostate cancer. A ^{18}F -Fluciclovine [Axumin®] PET scan uses PET and the ^{18}F -Fluciclovine radiotracer. ^{18}F -Fluciclovine is a positron-emitting synthetic amino acid radiotracer that accumulates in prostate cancer cells. Amino acids are essential to cell metabolism and growth, and prostate cancer cells have a much higher nutrient demand compared to normal tissues. ^{18}F -Fluciclovine PET is used in patients that have previously been treated for prostate cancer and now have a clinical suspicion of recurrent disease and rising PSA blood levels.

Thyroid cancer: According to the Society of Nuclear Medicine and Molecular Imaging (2023), ^{18}F -Fluorodeoxyglucose (FDG) is used in the treatment of thyroid cancer. National Comprehensive Cancer Network (NCCN) guidelines (2024) for thyroid carcinomas supports use of FDG-PET/CT during disease monitoring for thyroid carcinomas when iodine-131 imaging is negative and stimulated thyroglobulin is greater than 2 to 5 ng/mL For medullary thyroid cancer, Ga 68 DOTATATE PET/CT may be considered as part of the diagnostic workup and recommend Ga 68 DOTATATE PET/CT or FDG-PET in certain cases for disease monitoring.

Neuroendocrine tumor: According to the Society of Nuclear Medicine and Molecular Imaging (2023), radiotracers ^{68}Ga -DOTATOC (Gallium-68) or ^{64}Cu Dotatate (Copper Cu 64 Dotatate) may be used with PET imaging. National Comprehensive Cancer Network (NCCN) guidelines (2024) for neuroendocrine and adrenal tumors, PET/CT imaging using the radiolabeled somatostatin analog gallium-68 (^{68}Ga) DOTATATE is included and note that several studies have shown the diagnostic utility, safety, specificity, and high sensitivity of ^{68}Ga -DOTATATE PET/CT.

POSITION STATEMENT:

Positron emission tomography (PET) imaging with or without combined positron emission tomography/computed tomography (PET/CT) with an FDA approved radiopharmaceutical or radiotracer **meets the definition of medical necessity** for the following when the results will influence treatment decision.

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 less than cT2). The evidence is insufficient to determine that PET imaging results in an improvement in 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 that PET imaging results in an improvement in health outcomes.

Brain Cancer

PET imaging using *Fluorodeoxyglucose (FDG) of the brain **meets the definition of medical necessity** for the following:

- Staging and restaging of brain cancer
- To differentiate radiation necrosis or post treatment change from residual/recurrent tumor on magnetic resonance imaging (MRI).

*Also known as fluorodeoxyglucose F 18, fluorodeoxyglucose ([F18] FDG, 18F-FDG or FDG.

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 for breast cancer is considered **experimental or investigational** for the following. The evidence is insufficient to determine that PET imaging results in an improvement in health outcomes.

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

Cervical Cancer

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

- Evaluation of known or suspected recurrence
- Initial staging of locally advanced cervical cancer.

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).

PET imaging for chronic lymphocytic leukemia (CLL) and small lymphocytic leukemia (SLL) **meets the definition of medical necessity** for staging for suspected high-grade transformation or to guide biopsy.

PET imaging **meets the definition of medical necessity** for restaging for accelerated chronic lymphocytic leukemia (CLL) or to guide biopsy.

Colorectal Cancer

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

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

PET imaging for colorectal cancer is considered **experimental or investigational** for the following. The evidence is insufficient to determine that PET imaging results in an improvement in 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:

- Assessment of endometrial cancer recurrence

- Detection of lymph node metastases
- Staging and restaging with prior inconclusive imaging.

Esophageal Cancer

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

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

PET imaging for esophageal cancer is considered **experimental or investigational** for other indications, including, but not limited to the detection of primary esophageal cancer. The evidence is insufficient to determine that PET imaging results in an improvement in health outcomes.

Gastric Cancer

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

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

Head and Neck Cancer

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

- Evaluation of response to treatment
- 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:

- Staging or restaging for non-small cell lung cancer
- Members with a solitary pulmonary nodule: to distinguish between benign and malignant disease when prior CT scan and chest x-ray are inconclusive or imaging results are discordant (e.g., unclearly characterized nodule)
- Staging small cell lung cancer if limited stage is suspected based on other imaging (e.g., MRI, CT).
- To determine resectability for presumed solitary metastatic lesion from lung cancer.

PET imaging is considered **experimental or investigational** in staging of small-cell lung cancer if extensive stage is established. The evidence is insufficient to determine that PET imaging results in an improvement in 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:

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

PET imaging for melanoma is considered **experimental or investigational** for the following. The evidence is insufficient to determine that PET imaging results in an improvement in health outcomes.

- Detection of regional lymph node metastases in members with clinically localized melanoma
- Managing stage 0, I, or II melanoma.

Multiple Myeloma

PET imaging for multiple myeloma **meets the definition of medical necessity** in the staging or restaging of multiple myeloma when skeletal survey is negative.

Neuroendocrine Tumors

PET imaging with Gallium-68 Dotatate and Copper-64 **meets the definition of medical necessity** for staging neuroendocrine tumors (e.g., carcinoid, pheochromocytoma) either during initial staging or for restaging at follow-up.

Ovarian Cancer

PET imaging for ovarian cancer **meets the definition of medical necessity** in the evaluation of members with signs and/or symptoms of suspected ovarian cancer recurrence (restaging) when imaging (e.g., CT) 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 that PET imaging results in an improvement in 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 modalities are inconclusive in determining a treatment plan or if unable to perform imaging modalities.

Penile Cancer

PET imaging **meets the definition of medical necessity** for staging and restaging in members with suspected inguinal lymph node positive disease.

PET imaging for penile cancer for other indications is considered **experimental or investigational**. The evidence is insufficient to determine that PET imaging results in an improvement in health outcomes.

Prostate Cancer

PET imaging using carbon 11choline and fluorine 18F-fluciclovine **meets the definition of medical necessity** for evaluating suspected or biochemically recurrent prostate cancer after primary treatment to detect small volume disease in soft tissues.

PET imaging using gallium 68-prostate-specific membrane antigen and piflufolastat fluorine-18 **meets the definition of medical necessity** for any of the following:

- Members with diagnosed prostate cancer in need of staging information and:
 - NCCN unfavorable intermediate risk group: high- or very-high-risk prostate cancer; **OR**
 - NCCN unfavorable intermediate risk group: high- or very-high-risk prostate cancer with equivocal results or oligometastatic disease on initial conventional imaging.
- Members 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; **OR**
 - Definitive radiotherapy with PSA rise above nadir.
- Members with treated prostate cancer (including active surveillance/observation) in need of imaging as part of a workup for progression.
- Members with metastatic prostate cancer for whom lutetium Lu-177 vipivotide tetraxetan PSMA-directed therapy is indicated.

PET imaging for all other indications is considered **experimental or investigational**. The evidence is insufficient to determine that PET imaging results in an improvement in health outcomes.

Renal Cell Carcinoma

PET imaging is considered **experimental or investigational** in managing renal cancer. The evidence is insufficient to determine that PET imaging results in an improvement in health outcomes.

Soft Tissue Sarcoma

PET imaging **meets the definition of medical necessity** for evaluating response to imatinib and other treatments for gastrointestinal stromal tumors.

PET imaging for restaging and monitoring of soft tissue sarcoma **meets the definition of medical necessity** if other imaging modalities (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. The evidence is insufficient to determine that PET imaging results in an improvement in health outcomes.

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

Testicular Cancer

PET imaging **meets the definition of medical necessity** in the evaluation of residual mass following chemotherapy of stage IIB and III seminomas (PET imaging should be completed no sooner than 6 weeks following chemotherapy).

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

PET imaging for testicular cancer is considered **experimental or investigational** for the following. The evidence is insufficient to determine that PET imaging results in an improvement in health outcomes.

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

Thyroid Cancer

PET imaging **meets the definition of medical necessity** in the restaging of members with differentiated thyroid cancer when thyroglobulin levels are elevated and whole-body iodine-131 imaging is negative.

PET imaging is considered **experimental or investigational** in the evaluation of known or suspected differentiated or poorly differentiated thyroid cancer. The evidence is insufficient to determine that PET imaging results in an improvement in health outcomes.

Cancer of Unknown Primary

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

- After a negative work up for an occult primary tumor; **AND**
- 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**
- 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 indications in members with cancer of unknown primary including, but not limited to the following. The evidence is insufficient to determine that PET imaging results in an improvement in health outcomes.

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

Other

Positron emission tomography (PET) imaging with or without combined positron emission tomography/computed tomography (PET/CT) with an FDA approved radiopharmaceutical or radiotracer **meets the definition of medical necessity** for the following when the results will influence treatment decision.

- Acute lymphoblastic leukemia (extramedullary suspected)
- Acute myeloid leukemia (extramedullary suspected)
- Anal cancer
- Castleman's disease
- Cholangiocarcinoma (inconclusive findings on conventional imaging)
- Chordoma
- Fallopian tube cancer
- Gallbladder cancer (inconclusive findings on conventional imaging)
- Hepatocellular carcinoma (inconclusive findings on conventional imaging)
- Kaposi sarcoma
- Merkel cell carcinoma
- Mesothelioma
- Neuroblastoma
- Post-transplant lymphoproliferative disorder
- Small bowel adenocarcinoma

- Squamous cell carcinoma
- Thymoma/thymic cancer
- Uterine cancer
- Vaginal cancer
- Vulvar cancer

PET imaging is considered **experimental or investigational** for all other indications, including but not limited to the following. The evidence is insufficient to determine that PET imaging results in an improvement in health outcomes.

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

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. The evidence is insufficient to permit conclusions on health outcomes.

Note: 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.

Interim PET Imaging

Interim fluorine 18 fluorodeoxyglucose PET imaging to determine response to tyrosine kinase inhibitor treatment in members with gastrointestinal stromal tumor **meets the definition medical necessity**.

Interim fluorine 18 fluorodeoxyglucose PET imaging performed during planned chemotherapy and/or radiotherapy to determine early response to treatment, including but not limited to treatment for gastrointestinal stromal tumors on palliative or adjuvant therapy is considered **experimental or investigational**. The evidence is insufficient to permit conclusions on health outcomes.

Radiopharmaceutical/Radiotracers

Radiopharmaceuticals or radiotracers for PET imaging **meets the definition of medical necessity** for the Food and Drug Administration (FDA) approved indication.

BILLING/CODING INFORMATION:

CPT Coding:

78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
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78609	Brain imaging, positron emission tomography (PET); perfusion evaluation
78811	Positron emission tomography (PET) imaging; limited area (e.g., chest, head/neck)
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (e.g., chest, head/neck)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

HCPCS Coding:

G0219	PET imaging whole body; melanoma for non-covered indications (non-covered)
G0235	PET imaging, any site, not otherwise specified
G0252	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)

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 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	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or

			fewer before starting date of service for the claim
Plan of treatment	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

PROGRAM EXCEPTIONS:

Federal Employee Plan (FEP): 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.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

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)

REFERENCES:

1. ACR-ACNM-SNMMI-SPR Practice Parameter for Performing FDG-PET/CT in Oncology, Revised 2021.
2. 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.
3. Albano D, Bonacina M, Savelli G et al. Clinical and prognostic 18F-FDG PET/CT role in recurrent vulvar cancer: a multicentric experience. *Jpn J Radiol*. 2022 Jan;40(1):66-74.
4. Albert RH, Russell JJ. Evaluation of the solitary pulmonary nodule. *Am Fam Physician*. 2009 Oct 15;80(8): 827-31.
5. American College of Radiology (ACR) Guideline for the Performance of FDG-PET Scintigraphy in Oncology, 01/01/01.
6. Antoch G, Saoudi N, Kuehl H et al. Accuracy of whole-body dual-modality fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography and computed tomography (FDG-PET/CT) for tumor staging in solid tumors: comparison with CT and PET. *Journal of Clinical Oncology* 2004; 22(21): 4357-4368.
7. Antoch G, Vogt FM, Freudenberg LS et al. Whole-Body Dual-Modality PET/CT and Whole-Body MRI for Tumor Staging in Oncology. *The Journal of the American Medical Association (JAMA)* 2003; 290(24): 3199-3206.
8. Becherer A, De Santis M, Karanikas G et al. FDG PET is superior to CT in the prediction of viable tumour in post-chemotherapy seminoma residuals. *European Journal of Radiology* 2005; 54(2): 284-288.
9. Benz MR, Czerni J, Allen-Auerbach MS et al. FDG-PET/CT imaging predicts histopathologic treatment responses after the initial cycle of neoadjuvant chemotherapy in high-grade soft-tissue sarcomas. *Clinical Cancer Research* 2009; 15(8): 2856-63.
10. Binderup T, Knigge U, Loft A, et al. Functional imaging of neuroendocrine tumors: a head-to-head comparison of somatostatin receptor scintigraphy, 123I-MIBG scintigraphy, and 18F-FDG PET. *Journal of Nuclear Medicine* 2010; 51(5): 704-712.
11. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.26 Oncologic Applications of Positron Emission Tomography Scanning (Genitourinary), 10/24.
12. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.51 Interim Positron Emission Tomography Scanning in Oncology to Detect Early Response During Treatment, 10/24.
13. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.52 Positron Emission Mammography Archived, 11/20.
14. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.61 Oncologic Applications of Positron Emission Tomography Scanning (Gastrointestinal and Pancreatic), 12/24.
15. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.62 Oncologic Applications of Positron Emission Tomography Scanning (Breast and Gynecologic), 12/23.

16. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.63 Oncologic Applications of Positron Emission Tomography Scanning (Bone and Sarcoma), 12/24.
17. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.64 Oncologic Applications of Positron Emission Tomography Scanning (Hematologic), 12/24.
18. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.65 Oncologic Applications of Positron Emission Tomography Scanning (Lung), 12/24.
19. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.66 Oncologic Applications of Positron Emission Tomography Scanning (Thyroid, Neuroendocrine, head and Neck), 12/24.
20. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.67 Oncologic Applications of Positron Emission Tomography Scanning (Brain, Melanoma, Unknown Primary), 12/24.
21. Bredella MA, Steinbach L, Caputo G et al. Value of FDG PET in the assessment of patients with multiple myeloma. *American Journal of Roentgenology* 2005; 184: 1199-1204.
22. Bristow RE del Carmen MG, Pannu HK et al. Positron emission tomography for detecting clinically occult surgically resectable metastatic ovarian cancer. *Gynecologic Oncology* 2003; 85(1): 196-200.
23. Bristow RE, Simpkins F, Pannu HK et al. Clinically occult recurrent ovarian cancer: patient selection for secondary cytoreductive surgery using combined PET/CT. *Gynecologic Oncology* 2003; 90(3): 519-528.
24. Cohn DE, Dehadashti F, Gibb RK et al. Prospective Evaluation of Positron Emission Tomography for the Detection of Groin Node Metastases from Vulvar Cancer. *Gynecologic Oncology*. 2002; 85(1): 179-184.
25. Delbeke D, Coleman RE, Guiberteau MJ et al. Society of Nuclear Medicine-Procedure Guidelines for Tumor Imaging with F-FDG PET/CT 1.0, 03/10/06.
26. Delgado-Bolton RC, Fernandez-Perez C, Gonzalez-Mate A et al. Meta-analysis of the performance of 18F-FDG PET in primary tumor detection in unknown primary tumors. *The Journal of Nuclear Medicine* 2003; 44(8): 1301-1314.
27. Durie BG, Waxman AD, D'Agnolo A et al. Whole-body (18)F-FDG PET identifies high-risk myeloma. *The Journal of Nuclear Medicine* 2002; 43(11): 1457-1463.
28. Frangioni JV. New Technologies for Human Cancer Imaging. *Journal of Clinical Oncology* 2008; 26(24): 4012-4021.
29. Ghidini M, Vuozzo M, Galassi B et al. The Role of Positron Emission Tomography/Computed Tomography (PET/CT) for Staging and Disease Response Assessment in Localized and Locally Advanced Pancreatic Cancer. *Cancers (Basel)*. 2021 Aug 18;13(16):4155.
30. Gould MK, Donington J, Lynch WR, et al. Evaluation of individuals with pulmonary nodules: when is it lung cancer? Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest*. 2013 May;143(5 Suppl): e93S-e120S.
31. Grisaru D, Almong B, Levine C et al. The Diagnostic Accuracy of F-Fluorodeoxyglucose PET/CT in Patients with Gynecological Malignancies. *Gynecologic Oncology* 2004; 94(3): 680-684.
32. Gutzeit a, Antoch G, Kuhl H et al. Unknown primary tumors: detection with dual-modality PET/CT- Initial Experience. *Radiology* 2005; 234: 227-234.

33. Havrilesky LJ, Kulasingam SL, Matchar DB et al. FDG-PET for Management of Cervical and Ovarian Cancer. *Gynecologic Oncology* 2005; 97(1): 183-191.
34. Heinrich S, Goerres GW, Schafer M et al. Positron emission tomography/computed tomography influences on the management of resectable pancreatic cancer and its cost-effectiveness. *Annals of Surgery* 2005; 242(2): 235-243.
35. Hersh MR, Knapp EL, Choi J. Newer Imaging Modalities to Assess Tumor in the Prostate. *Cancer Control* 2004; 11(6): 353-357.
36. Hillner BE, Tunuguntla R, Melvin Fratkin. Clinical Decisions Associated with Positron Emission Tomography in a Prospective Cohort of Patients with Suspected or Known Cancer at One United States Center. *Journal of Clinical Oncology* 2004; 22(20): 4147-4156.
37. Jadvar H, Kherbache HM, Pinski JK et al. Diagnostic Role of [F-18]-FDG Positron Emission Tomography in Restaging Renal Cell Carcinoma. *Clinical Nephrology* 2003; 60 (6): 395-400.
38. Jadvar H, Pinski JK, Conti PS. FDG PET in suspected recurrent and metastatic prostate cancer. *Oncology Reports* 2003; 10: 1485-1488.
39. Kalemaki MS, Karantanis AH, Exarchos D et al. PET/CT and PET/MRI in ophthalmic oncology (Review). *Int J Oncol*. 2020 Feb;56(2):417-429.
40. Kang SY, Rahim MK, Kim YI et al. Clinical Significance of Pretreatment FDG PET/CT in MIBG-Avid Pediatric Neuroblastoma. *Nucl Med Mol Imaging*. 2017 Jun;51(2):154-160.
41. Kumar R, Shuang H, Alavi A. PET in the Management of Urologic Malignancies. *Radiologic Clinics of North America*. 2004; 42(6): 1141-1153.
42. Lim JS, Yun MJ, Kum MJ et al. CT and PET in stomach cancer: preoperative staging and monitoring of response to therapy. *Radiographics* 2006; 26(1): 143-156.
43. Lu RC, She B, Gao WT et al. Positron-emission tomography for hepatocellular carcinoma: Current status and future prospects. *World J Gastroenterol*. 2019 Aug 28;25(32):4682-4695.
44. Mahajan S, Barker CA, Singh B et al. . Clinical value of 18F-FDG-PET/CT in staging cutaneous squamous cell carcinoma. *Nucl Med Commun*. 2019 Jul;40(7):744-751.
45. Mapelli P, Mangili G, Picchio M et al. Role of 18F-FDG PET in the management of gestational trophoblastic neoplasia. *Eur J Nucl Med Mol Imaging*. 2013 Apr;40(4):505-13. [Abstract]
46. Miller FR, Hussey D, Beeram M, Eng T et al. Positron Emission Tomography in the Management of Unknown Primary Head and Neck Carcinoma. *Archives of Otolaryngology Head and Neck Surgery* 2005; 131 (7): 626-629.
47. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology; accessed at nccn.org.
48. Pesqué L, Delyon J, Lheure C et al. Yield of FDG PET/CT for Defining the Extent of Disease in Patients with Kaposi Sarcoma. *Cancers (Basel)*. 2022 Apr 27;14(9):2189.
49. Piccardo A, Lopci E, Conte M et al. PET/CT imaging in neuroblastoma. *Q J Nucl Med Mol Imaging*. 2013 Mar;57(1):29-39. [Abstract]
50. Podoloff DA, Advani RH, Allred C et al. NCCN Task Force Report: Positron Emission Tomography (PET)/Computed Tomography (CT) Scanning in Cancer. *Journal of the National Comprehensive Cancer Network*; 5 (Suppl 1): S-1-S-22, 05/07.

51. Podoloff DA, Ball DW, Ben-Josef E et al. NCCN task force: clinical utility of PET in a variety of tumor types. *Journal of the National Comprehensive Cancer Network* 2009 Jun;7 Suppl 2: S1-26.
52. Rose DM, Delbeke D, Beaucham RD et al. 18Fluorodeoxyglucose-Positron Emission Tomography in the Management of Patients with Suspected Pancreatic Cancer. *Annals of Surgery* 1999; 229 (5): 729-737.
53. Safaei A, Figlin R, Hoh CK et al. The Usefulness of F-18 Deoxyglucose Whole-Body Positron Emission Tomography (PET) for Re-staging of Renal Cell Cancer. *Clinical Nephrology* 2002; 57 (1): 56-62.
54. Schick V, Franzius C, Beyna T et al. Diagnostic impact of 18F-FDG PET-CT evaluating solid pancreatic lesions versus endosonography, endoscopic retrograde cholangio-pancreatography with intraductal ultrasonography and abdominal ultrasound. *European Journal of Nuclear Medicine and Molecular Imaging* 2008 Oct; 35(10): 1775-1785.
55. 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.
56. Shvarts O, Han K, Seltzer M et al. Positron Emission Tomography in Urological Oncology. *Cancer Control* 2002; 9(4): 335-342.
57. Society of Nuclear Medicine & Molecular Imaging (SNMMI) Neuroendocrine Tumors, 2023.
58. Society of Nuclear Medicine & Molecular Imaging (SNMMI) Prostate Cancer, 2024.
59. Society of Nuclear Medicine & Molecular Imaging (SNMMI) Thyroid Cancer, 2023.
60. Sun L, Zhang B, Peng R. Diagnostic Performance of 18F-FDG PET(CT) in Bone-Bone Marrow Involvement in Pediatric Neuroblastoma: A Systemic Review and Meta-Analysis. *Contrast Media Mol Imaging*. 2021 Jun 16; 2021:8125373.
61. Takahashi N, Inoue T, Lee J et al. The roles of PET and PET/CT in the diagnosis and management of prostate cancer. *Oncology* 2007; 72 (3-4): 226-233.
62. Tamm EP, Silverman PM, Charnsangavej C et al. Diagnosis, staging, and surveillance of pancreatic cancer. *American Journal of Roentgenology* 2003; 180: 1311-1323.
63. Tateishi U, Yamaguchi U, Seki K et al. Bone and soft-tissue sarcoma: preoperative staging with fluorine 18 fluorodeoxyglucose PET/CT and conventional imaging. *Radiology* 2007; 245-3:839-847.
64. Townsend DW, Carney JPJ, Yap JT et al. PET/CT today and tomorrow. *The Journal of Nuclear Medicine* 2004; 45(1): 4S-14S.
65. Van den Abbeele AD. The lessons of GIST—PET and PET/CT: a new paradigm for imaging. *The Oncologist* 2008; 13 Suppl 2:8-13.
66. Wakabayashi H, Nishiyama Y, Otani T et al. Role of 18F-fluorodeoxyglucose positron emission tomography imaging in surgery for pancreatic cancer. *World Journal of Gastroenterology* 2008; 14(1):64-69.
67. Wells SA, Asa SL, Dralle H et al. Revised American Thyroid Association Guidelines for the Management of Medullary Thyroid Carcinoma the American Thyroid Association Guidelines Task Force on Medullary Thyroid Carcinoma. *Thyroid* 2015; 25(6): 567-653.
68. Zhao M, Ma Y, Yang B et al. A meta-analysis to evaluate the diagnostic value of dual-time-point F-fluorodeoxyglucose positron emission tomography/computed tomography for diagnosis of pulmonary nodules. *J Cancer Res Ther*. 2016 Dec;12(Supplement):C304-C308.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 02/12/25.

GUIDELINE UPDATE INFORMATION:

10/15/03	Annual review. Developed separate policy for PET Scans Oncologic Applications.
04/23/04	Added coverage statement for G0296. Deleted Medicare & More program exception for G0296.
11/15/04	Annual Review. No change in coverage statements. Revised NIA statements under Program Exceptions. Updated references.
01/01/05	HCPCS update. Deleted 78810. Added 78811, 78812, 78813, 78814, and 78815.
02/15/05	HCPCS update. Added G0330 and G0331. Deleted 78814 and 78815, separate MCG to be developed.
05/15/05	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.
02/15/06	HCPCS update, deleted G0253 and G0254. Updated references.
03/15/06	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.
06/15/06	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.
12/28/06	Added ICD-9 diagnoses codes.
04/01/07	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.
07/01/07	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.
01/01/08	HCPCS update. Revised 78811, 78812, 78813, 78814, 78815, and the descriptor for code 78816.
01/21/08	Updated Program Exceptions.
07/15/08	Scheduled review. No change in position statement. Updated references.
05/21/09	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.
07/01/09	Updated BCBSF Radiology Management program exception; added BlueSelect.

11/15/09	Annual review. Added renal/kidney cancer to experimental or investigational position statement. Added program exception for Medicare. Updated references.
01/01/10	Revised BCBSF Radiology Management program exception section.
05/15/10	Added coverage criteria for NaF-18 PET imaging for bone metastasis cancer to program exception for Medicare Care Advantage products.
11/15/10	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.
10/01/11	Revision; related ICD-9 code 793.11 added and formatting changes.
11/15/11	Annual review; maintain position statements. Updated Medicare Advantage program exception. Updated references.
04/01/12	Update; added related ICD-10 codes.
08/15/13	Removed “scan” from guideline subject. Updated description section; revised radiotracer (radiopharmaceutical) statement. Moved indications considered experimental or investigational from the “Other” section to the corresponding indications that meet the definition of medical necessity. Added heading: “Initial Treatment Management” for (diagnosis and staging) and “Subsequent Treatment Management” for (restaging and monitoring). Added indication for bone cancer; PET scanning meets the definition of medical necessity in the staging of Ewing sarcoma and osteosarcoma. Added investigational statement for bone cancer; PET scanning is considered experimental or investigation in the staging of chondrosarcoma. Added investigational statement for breast cancer; predicting pathologic response to neoadjuvant therapy for locally advanced disease. Added indication for cervical cancer: in the evaluation of known or suspected recurrence of cervical cancer. Added indication for multiple myeloma: diagnosis, initial staging, restaging after completion of treatment and monitoring response to treatment. Add indication for pancreatic cancer; subsequent (post-treatment) if imaging (e.g., ultrasound, CT, or MRI) is inconclusive in determining a treatment plan or if unable to perform imaging modalities. Added indication for soft

	<p>tissue sarcoma; subsequent (post-treatment) if imaging (e.g., ultrasound, CT, or MRI) is inconclusive in determining a treatment plan or if unable to perform imaging modalities. Add indication for testicular cancer; initial staging. Add investigational statement for colorectal cancer; radiotherapy treatment planning. Add indications for head and neck cancer: diagnosis of suspected cancer, initial staging of disease and deleted “For detection and evaluation”; added “Restaging” to residual or recurrent disease after treatment. Added investigational statement for ovarian cancer; PET scanning is considered experimental or investigational in the initial evaluation of known or suspected ovarian cancer. Revised investigational statement for thyroid cancer; added “or poorly differentiated” in the evaluation of known or suspected thyroid cancer. Added investigational applications: determining early response to treatment, diagnosis of brain cancer, restaging of gastric cancer, evaluation of neuroendocrine tumors and staging inguinal lymph nodes in patients with squamous cell carcinoma of the penis. Added PET magnetic resonance imaging (PET/MR, PET/MRI); experimental or investigational. Deleted indication for ovarian cancer: for localization of recurrent ovarian cancer with rising CA-125 levels, and negative, equivocal, or inconclusive CT imaging and monitoring of ovarian cancer for response to treatment. Deleted PET bone scanning. Deleted diagnoses codes. Updated program exception and references.</p>
11/15/13	<p>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).</p>
06/15/15	<p>Revision; added chronic lymphocytic leukemia (CLL), prostate cancer, lung cancer (small cell), neuroendocrine cancer (e.g., carcinoid pheochromocytoma), and medullary thyroid cancer. Deletes the indication (brain and criteria). Updated references.</p>
02/20/17	<p>Update; Deleted code A9552.</p>
10/15/18	<p>Revision; revised position statements. Added indications for an oncological gallium 68 dotatate PET/CT scan. Updated references.</p>
11/15/18	<p>Revision; revised position statements. Added position statement for cancers (bladder, endometrial, gastric and renal cell carcinoma). Added position statement for interim fluorine 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.</p>
03/15/20	<p>Review/Revision. Revised: position statement and expand indications and criteria. Added indications and criteria for an oncological F¹⁸ FDG, GA⁶⁸ DOTATATE, F¹⁸ FLUCICLOVINE PET scan. Revised and expand indications for an oncological GALLIUM 68</p>

	DOTATATE PET/CT scan. Added indications for an oncological ¹⁸ F-Fluciclovine (Axumin) PET/CT scan. Added indications and criteria for F ¹⁸ FDG, Ga ⁶⁸ Dotatate, F ¹⁸ Fluciclovine. Added position statement for breast cancer (initial diagnosis and/or surgical planning). Added position statement for whole body melanoma. Updated references.
07/15/21	Review/Revision. Revised: position statement indications and criteria for: (cancer: endometrial, colorectal, chronic lymphocytic leukemia, soft tissue sarcoma, neuroendocrine tumors, GA ⁶⁸ (Gallium 68) Dotatate, ¹⁸ F-Fluciclovine (Axumin). Added indication and criteria for: brain and thyroid cancer and lung nodule. Repositioned subsequent treatment management. Deleted surveillance/remission. Updated references.
12/15/21	Review/Revision. Added cholangiocarcinoma, fallopian tube cancer, leukemia, neuroblastoma, post-transplant lymphoproliferative disorder (PTLD). Revised restaging statement. Revised and expanded criteria for other (non-FDG) PET tracers; GA 68-Dotate, GA 68-Dotatoc and CU 64-Dotatate. Added indication and criteria for F18 Fluciclovine (Axumin), prostate-specific membrane antigen (PSMA) tracers (such as F18 piflufolastat (Pylarify) and GA 68) and C11 Choline. Updated references.
07/01/22	Revision to Program Exceptions section.
07/08/23	Review: position statements and references updated. Added 78608 and 78609.
07/15/24	Review; no change in position statement. Updated references.
03/15/25	Review; no change in position statement. Updated references.