

04-78000-17

Original Effective Date: 06/15/01

Reviewed: 10/25/18

Revised: 11/25/18

Subject: Positron Emission Tomography (PET) for Oncologic Applications

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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 all other applications, including but not limited to 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)

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
- Evaluation of response to treatment.

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 and fluorine 18 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 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 **experiment or investigational** in prostate cancer.

PET imaging for 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 **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** 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.

Thyroid Cancer

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

- Restaging of members with differentiated thyroid cancer when thyroglobulin levels are elevated (greater than 10ng/ml) and whole-body iodine-131 imaging is negative
- Restaging and monitoring 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
 - Current serum thyroglobulin > 10ng/ml; AND
 - Current whole body I-131 scan is negative.
- Medullary thyroid cancer when calcitonin levels are elevated post-operatively.

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 the effects of PET imaging on 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:

- 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.

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
- Neuroendocrine tumors of unknown primary

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 with recent chest/abdominal (for example, if lung or thymus) or abdominal/pelvic (for example, if GI tract, pancreatic, MEN-1, MEN-2) multiphasic CT or MRI having 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 (asymptomatic surveillance does not meet the definition of medical necessity).

Note: Gallium-68 Dotatate PET/CT scans should be performed only if other imaging (CT, MRI) is inconclusive/insufficient **AND** the member has not already been evaluated with Somatostatin Receptor SPECT scanning (another form of somatostatin receptor imaging performed on standard nuclear cameras), or scanning was negative or equivocal.

Surveillance/Remission

Both somatostatin receptor imaging (Gallium-68 Dotatate PET) and FDG PET/CT are not recommended for routine surveillance.

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**.

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

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.

BILLING/CODING INFORMATION:

CPT Coding:

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 (e.g., Nitrogen -13 (as ammonia), oxygen-15 as H₂O, 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	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:

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.

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.
4. 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.
5. 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.
6. 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.

7. 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.
8. 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.
9. Blue Cross Blue Shield Association Oncologic Applications of PET Scanning Medical Policy 6.01.26, 09/18.
10. Blue Cross Blue Shield Association Interim PET Scanning in Oncology to Detect Early Response During Treatment Medical Policy 6.01.51, 09/18.
11. Blue Cross Blue Shield Association Positron Emission Mammography (PEM) 6.01.52, 09/18.
12. 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.
13. 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.
14. 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.
15. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer 220.6.19, 02/26/10.
16. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for Positron Emission Tomography (FDG) for Oncologic Conditions 220.6.17, 06/11/13.
17. 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.
18. 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.
19. 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.
20. 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.
21. Frangioni JV. New Technologies for Human Cancer Imaging. *Journal of Clinical Oncology* 2008; 26(24): 4012-4021.
22. 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.
23. Gutzeit a, Antoch G, Kuhl H et al. Unknown primary tumors: detection with dual-modality PET/CT-Initial Experience. *Radiology* 2005; 234: 227-234.
24. Havrilesky LJ, Kulasingam SL, Matchar DB et al. FDG-PET for Management of Cervical and Ovarian Cancer. *Gynecologic Oncology* 2005; 97(1): 183-191.
25. 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.
26. Hersh MR, Knapp EL, Choi J. Newer Imaging Modalities to Assess Tumor in the Prostate. *Cancer Control* 2004; 11(6): 353-357.

27. 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.
28. 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.
29. Jadvar H, Pinski JK, Conti PS. FDG PET in suspected recurrent and metastatic prostate cancer. *Oncology Reports* 2003; 10: 1485-1488.
30. Kumar R, Shuang H, Alavi A. PET in the Management of Urologic Malignancies. *Radiologic Clinics of North America*. 2004; 42(6): 1141-1153.
31. 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.
32. 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.
33. National Imaging Associates, Inc. PET Scan Clinical Guideline, 2018.
34. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer. Version 5.2018.
35. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Bone Cancer. Version 1.2019.
36. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 1.2018.
37. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer. Version 1.2019.
38. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Version 1.2019.
39. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Colon Cancer. Version 3. 2018.
40. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers. Version 2. 2018.
41. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer. Version 2. 2018.
42. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers. Version 2. 2018.
43. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma. Version 3. 2018.
44. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Melanoma. Version 3.2018.
45. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma. Version 1.2019.
46. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors. Version 3.2018.
47. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 2. 2018.
48. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 2.2018.

49. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma. Version 2.2018.
50. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Penile Cancer. Version 2.2018.
51. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 4.2018.
52. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer. Version 3. 2018.
53. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer. Version 2.2019.
54. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer. Version 2. 2018.
55. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma. Version 2.2018.
56. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer. Version 2.2018.
57. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. Version 1.2018.
58. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms. Version 2. 2018.
59. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer (Squamous Cell Carcinoma). Version 1.2019-August 30, 2018.
60. 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.
61. 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.
62. 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.
63. 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.
64. 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.
65. 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.
66. Shvarts O, Han K, Seltzer M et al. Positron Emission Tomography in Urological Oncology. *Cancer Control* 2002; 9(4): 335-342.
67. 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.
68. Tamm EP, Silverman PM, Charnsangavej C et al. Diagnosis, staging, and surveillance of pancreatic cancer. *American Journal of Roentgenology* 2003; 180: 1311-1323.

69. 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.
70. Townsend DW, Carney JPJ, Yap JT et al. PET/CT today and tomorrow. *The Journal of Nuclear Medicine* 2004; 45(1): 4S-14S.
71. 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.
72. 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.
73. 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.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the BCBSF Medical Policy & Coverage Committee on 11/15/18.

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 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.
11/15/13	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).
06/15/15	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.
02/20/17	Update; Deleted code A9552.
10/15/18	Revision; revised position statements. Added indications for an oncological gallium 68 dotatate PET/CT scan. Updated references.
11/15/18	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.