MEDICAL POLICY

Excellus

SUBJECT: POSITRON EMISSION TOMOGRAPHY (PET) ONCOLOGIC APPLICATIONS	**EFFECTIVE DATE: 11/18/99** **REVISED DATE: 04/19/00, 04/19/01, 01/17/02, 10/16/02, 01/16/03, 08/21/03, 05/19/04, 08/18/05, 03/16/06, 04/19/07, 09/20/07, 08/21/08, 11/19/09, 04/22/10, 04/21/11, 09/20/12, 08/15/13, 04/17/14**
POLICY NUMBER: 6.01.29 **CATEGORY: Technology Assessment**	**PAGE: 1 OF: 13**

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of peer reviewed literature, FDG positron emission tomography (PET) or FDG PET/CT is considered **medically appropriate** in a small subset of patients where the likelihood of cancer is high when:
   A. Conventional studies are non-diagnostic; and
   B. Used to determine the optimal site for biopsy.

II. Based upon our criteria and assessment of peer reviewed literature, FDG positron emission tomography (PET) or FDG PET/CT is considered **medically appropriate** for the following tumor specific indications when conventional imaging techniques such as, but not limited to ultrasound, computed tomography (CT) and/or magnetic resonance imaging (MRI) are inconclusive and clinical management of the patient would differ depending on the stage of the cancer identified:

   A. **Brain tumors (e.g., astrocytoma, oligodendroglioma)**
   Subsequent Treatment Strategies - Suspicion of recurrence: differentiation of radiation necrosis from brain tumor recurrence (post treatment). May be determined by PET or MRS. Only one technique should be performed, unless the initial study is inconclusive.

   B. **Breast Carcinoma**
      1. Initial Staging; must have tissue diagnosis of breast cancer (Please refer to 3);
      2. Subsequent Treatment Strategies:
         a. Monitoring response to therapy when a change in therapy is planned,
         b. Suspicion of recurrence,
            i. new palpable lesion in axilla or adjacent area; or
            ii. rising tumor markers; or
            iii. changes on other imaging when conventional imaging is inconclusive.
         c. Restaging after completion of therapy in a member with known metastases.
      3. There is **insufficient** evidence for PET in breast cancer for:
         a. Primary diagnosis or detection; or
         b. Staging of Stage I, IIA-B breast cancer; or
         c. Staging or evaluation of axillary lymph nodes; or
         d. Not indicated for routine surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

   C. **Thyroid Cancer**
      1. Initial staging:
         a. Individuals diagnosed with anaplastic thyroid cancer;
         b. Investigational for all other indications, including prior to thyroidectomy.
      2. Subsequent treatment strategies after cancer has been previously treated by thyroidectomy and radioiodine ablation:

a. Re-staging and suspected recurrence of differentiated thyroid cancer (e.g., papillary, follicular, hurthle cell) with:
   i. elevated or rising serum thyroglobin (Tg) level; thyroglobulin level detectable on hormone replacement therapy OR thyroglobulin greater than 2 micro grams/liter after Thyrogen stimulation; or
   ii. negative I-131 WBS; or
   iii. negative thallium 201 scan;
b. Re-staging and suspected recurrence of medullary carcinoma - elevated or rising calcitonin level.
c. Surveillance: Not for routine surveillance imaging in a stable asymptomatic individual with no change in signs, symptoms or laboratory results such as thyroglobulin level.

D. **Head and Neck Cancer**
1. Initial Staging;
   a. Identification of unknown primary tumor suspected to be head and neck cancer;
   b. Initial staging known primary of pathologically documented head and neck cancer;
2. Subsequent Treatment Strategies:
   a. Monitoring response to therapy - chemotherapy no sooner than 12 weeks after completion of first cycle;
   b. Restaging after therapy:
      i. radiation therapy: no sooner than 12 weeks after completion of treatment;
      ii. surgery: no sooner than 6 weeks after surgery;
      iii. evaluation for possible recurrence based on physical examination or conventional imaging
   c. Monitoring for recurrence - altered clinical situation.
   d. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

E. **Solitary Pulmonary Nodule**
1. Initial Strategy:
   a. Evaluation of newly discovered SPN with a size greater than or equal to 0.8 cm (8 mm) and not calcified;
   b. When chest x-ray and CT fail to distinguish benign from malignant disease;
   c. When the results of the test could change clinical management;
   d. Multiple nodules are not covered by these criteria, unless one is significantly larger than the others or is new since a prior chest x-ray. Such a lesion should be treated as a solitary nodule.

F. **Lung Cancer**

Non Small-Cell Lung Cancer
1. Initial Staging after tissue diagnosis is established
2. Subsequent Treatment Strategies:
   a. Restaging after completion of chemotherapy or no sooner than 12 weeks after completion of radiation therapy unless there is a change in clinical or imaging findings suggestive of recurrence or progression;
   b. Monitoring response to therapy when a change in therapy is considered;
   c. New or indeterminate finding on standard imaging suggestive of suspicion of recurrence;
   d. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Small-cell Lung Cancer
1. Initial Staging; in limited stage disease (defined confined to the ipsilateral hemithorax) and PET is being used to assess for distant metastasis
2. Surveillance: Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

G. **Colorectal Cancer**
1. Initial Staging:
   a. For staging and prognosis if conventional imaging (CT, MRI) is equivocal for metastases; or
   b. Preoperative assessment of liver metastasis prior to surgical resection
2. Subsequent Treatment Strategies
   a. Evaluation of radiofrequency ablation (or similar procedure) of metastases:
      i. after procedure to evaluate effect and confirm adequate margins,
      ii. may be repeated after each such procedure;
   b. Suspicion of recurrence: rising CEA (greater than 2.5 in nonsmoker and greater than 5.0 in a smoker);
   c. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

H. **Lymphoma, including Hodgkin disease**
1. Initial Staging; after tissue diagnosis is established or lymphoma is strongly suspected based on other diagnostic testing in addition to standard imaging; PET may be used as the initial imaging technique for staging, either during initial staging or follow-up;
2. Subsequent Treatment Strategies:
   a. Monitoring response to therapy:
      i. assessment during chemotherapy,
      ii. not more frequently than after 2 cycles,
   b. Restaging after therapy completed. PET is best done at least 3 weeks after completion of chemotherapy and 8-12 weeks after completion of radiation therapy or chemoradiation therapy;
   c. Diffuse large B-cell lymphoma wait at least 8 weeks after radiation therapy is completed before restaging;
   d. Suspicion of recurrence - new symptoms or findings:
      i. night sweats
      ii. weight loss
      iii. ESR greater than 30 mm/hr
      iv. Fever greater than 100.4 (unknown etiology) greater than 1 week;
   e. Suspicion of progression of CLL or SLL for transformation to Follicular Lymphoma
   f. Large B-Cell Lymphoma:
      i. completion of chemotherapy and prior to radiation therapy if planned,
      ii. completion of radiation therapy but no sooner than 8 weeks after completion of radiation;
   g. Surveillance - Hodgkin lymphoma - PET is not routinely indicated for Hodgkin lymphoma.

I. **Esophageal Carcinoma**
1. Initial Staging of known esophageal cancer;
2. Subsequent Treatment Strategies:
   a. Restaging after therapy:
      i. re-evaluation following chemotherapy; or
      ii. re-evaluation following radiation therapy;
      iii. re-evaluation following surgery;
   b. Reevaluation for suspicion of recurrence:
      i. changed findings on endoscopy or imaging; or
      ii inability to perform endoscopy; or
      iv. lymphadenopathy.
   c. Monitoring response to treatment if a change in therapy is anticipated;
   d. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

J. **Cervical Cancer**
1. Initial Staging;
2. Subsequent Treatment Strategies:
   a. Monitoring response to therapy if a change in therapy is indicated; or
   b. Evaluate for recurrence in an individual with new signs and symptoms; or
   c. Not routinely indicated for surveillance during remission in asymptomatic individual with no clinical or laboratory evidence of disease.

K. **Ovarian Carcinoma**
1. Initial Staging of indeterminate lesions if results will alter management;
2. Subsequent Treatment Strategies:
   a. Restaging after completion of therapy;
   b. Evaluation of recurrence:
      i. elevated tumor markers (eg, CA-125 greater than 35U/ml); or
      ii. change in clinical status;
   c. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

L. **Pancreatic Carcinoma**
1. Initial Strategy:
   a. Pancreatic mass undiagnosed by conventional testing, abnormal ERCP, and/or unexplained jaundice,
   b. Initial Staging;
   c. Subsequent Treatment Strategies: Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

M. **Gastric Carcinoma**
1. Initial Staging: must have established tissue diagnosis of gastric cancer or gastric cancer is strongly suspected based on other diagnostic testing prior to surgery;
2. Subsequent Treatment Strategies:
   a. Restaging after completion of therapy.
   b. Not for routine surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

N. **Testicular Carcinoma (seminoma or non-seminomatous germ cell tumor)**
1. Initial Staging: considered **investigational**;
2. Subsequent Treatment Strategies:
   a. Monitoring response to therapy - single scan 6 or more weeks post-chemotherapy; or
   b. Suspicion of recurrence:
      i. abnormal lab values; or
      ii. residual mass seen on CT;
   c. Surveillance: Not for routine surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

O. **Soft Tissue Sarcoma**
1. Initial Staging – intermediate or high-grade sarcoma;
2. Subsequent Treatment Strategies – Restaging: evaluation of recurrence after completion of therapy;
3. Not for routine surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

P. **Multiple Myeloma**
1. Initial Staging;
2. Subsequent Treatment Strategies:

a. Restaging after completion of therapy;
b. Surveillance after completion of therapy annually.

Q. **Melanoma**
1. Initial Staging - Must have an established diagnosis of stage greater than I; PET may be used as the initial imaging technique for detection of extranodal metastases either during initial staging or follow-up
2. Subsequent Treatment Strategies:
   a. Restaging after completion of therapy;
   b. Suspicion of recurrence;
   c. Not for routine surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease;
   d. Stage IIB-IV every 4-12 months for 5 years and if negative at 5 years no further imaging.

R. **Thymoma**
1. Initial Staging: must have established tissue diagnosis of thymoma or thymoma is strongly suspected based on other diagnostic testing;
2. Subsequent Treatment Strategies:
   a. Restaging after completion of therapy (one time only);
   b. Surveillance is considered **investigational**.

S. **PET for Radiation Therapy Planning**
1. Orders accepted from radiation oncologists only;
2. Patient must be proven to have one of the cancer listed above;
3. Approvable once per patient, prior to initiation of therapy.

T. **Ewing's Sarcoma and Osteogenic Sarcoma**
1. Initial Staging: must have an established diagnosis of Ewing's Sarcoma or osteogenic sarcoma is strongly suspected based on other diagnostic testing;
2. Subsequent Treatment Strategies: Restaging after completion of therapy;
3. Not allowed for surveillance.

U. **GIST Tumor (Gastrointestinal Stromal Tumor)**
Initial Staging must have established tissue diagnosis of GIST tumor when conventional studies are inconclusive.

V. **Unknown (Occult) Primary**
1. Initial staging when:
   a. There is an established diagnosis of malignancy of unknown primary site; or
   b. Indeterminate histology on biopsy;
   c. Primary site cannot be determined by endoscopy, prior CT, or prior MRI
2. Not used for restaging carcinoma of unknown primary.

W. **Prostate**
1. Initial staging – **investigational**,
2. Subsequent Treatment strategies; Suspicion of recurrence.

III. Based upon our criteria and assessment of the peer-reviewed literature, the use of positron emission tomography (PET) scans are considered **investigational** for all other indications, including, but not limited to:
A. **Lymphadenopathy**: evaluation of enlarged lymph node(s) when there is no diagnosis of cancer;
B. Other **neoplasms**, such as adrenal, bladder, endometrial carcinoma, liver, musculoskeletal extremities, neuroendocrine tumors, renal and parathyroid.

IV. **MOLECULAR COINCIDENCE DETECTION** is considered **investigational** as an alternative to PET.

Refer to Corporate Medical Policy #6.01.07 regarding Positron Emission Tomography Non-oncologic Applications.

Refer to Corporate Medical Policy #6.01.35 regarding Magnetic Resonance Imaging (MRI) of the Breast.

Refer to Corporate Medical Policy #11.01.10 regarding Clinical Trials.

POLICY GUIDELINES:

I. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

II. Requests for suspected recurrence should include changes in the clinical status of patient leading to the suspicion (e.g., new symptoms or elevated tumor markers or other laboratory changes).

DESCRIPTION:

The indications for PET for neoplasms are usually divided into either initial strategy or subsequent treatment strategies. For the purpose of this policy, the initial strategy and subsequent treatment strategy may include any of the following components:

I. Initial Strategy (e.g., diagnosis and staging):
   A. A known diagnosis of malignancy to determine the optimal anatomic site for additional biopsy or other invasive diagnostic procedure;
   B. Initial Staging; Must have established tissue diagnosis;
   C. To establish the diagnosis of malignancy in a patient where the findings on other imaging modalities are inconclusive; AND
   D. The PET results may assist in avoiding an invasive diagnostic procedure:
      1. In patients without established malignancy in select circumstances where the likelihood of malignancy is high; or
      2. In patients with known malignancy and tumor characteristics are unique (related to specific tumor detail below; e.g., pancreatic and solitary pulmonary nodule)

II. Subsequent treatment strategies; staging and restaging:
   A. Routine monitoring of tumor response during treatment when a change in therapy is planned;
   B. Staging after completion of therapy to detect residual disease;
   C. Suspicion of recurrence and/or to determine extent of recurrence; (e.g., new symptoms, elevated tumor markers or other laboratory changes and changes on other imaging). Requests for suspected recurrence should include changes in the clinical status of the patient leading to the suspicion;
   D. Surveillance which is defined as: a study performed beyond the completion of treatment, in the absence of signs or symptoms of cancer, recurrence or progression, for the purpose of detecting recurrence or progression or predicting outcome. Surveillance may or may not be indicated depending on the tumor type.

Positron emission tomography (PET) is an imaging technology that can reveal both metabolic and anatomical information in various tissue sites. The metabolic information is what distinguishes it from other imaging modalities such as magnetic resonance imaging (MRI) and computed tomography (CT) that provide primarily anatomic information. PET scans measure concentrations of radioactive chemicals that are partially metabolized in the body region of interest. PET scans are based on the use of positron emitting radionuclide tracers coupled to organic molecules, such as glucose, ammonia, or water. The clinical value of PET scans is related both to the ability to image the relative metabolic activity of target tissues and the resolution associated with PET scanners. Dedicated PET scanners consist of multiple detectors arranged in a full or partial ring around the patient, permitting the simultaneous detection of the high-energy paired photons that are emitted at 180 degrees from one another.

A variety of tracers, intravenously injected or inhaled, are used for PET scanning, including oxygen-15, nitrogen-13, carbon-11, rubidium-82 and fluorine-18. 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 potentially useful in cancer imaging, since tumor cells show increased metabolism of glucose. The most common malignancies studied have been melanoma, lymphoma, lung, and colorectal.

Molecular Coincidence Detection (MCD). PET using a gamma camera is a general term describing imaging techniques in which a SPECT gamma camera is used to detect photons emitted from decaying positrons associated with the metabolism of radiolabeled FDG. It produces images similar to those produced by a PET scanner. This technique is also referred to as FDG-SPECT, metabolic SPECT, FDG-collimated SPECT or dual-head-coincidence SPECT (FDG-DHC-SPECT). Researchers have begun to investigate whether the more readily available SPECT cameras, routinely used to detect low-energy photons, could be adapted for use to detect higher energy photons.

FDG-collimated-SPECT screens out lower energy photons, thus only detecting the high-energy photons, however this approach decreases sensitivity and resolution compared to that associated with PET scanners. FDG-dual head coincidence-SPECT, operated in the "coincidence mode," (the camera will only count those photons that are simultaneously detected at 180 degrees from one another) more closely resembles a PET scanner. However, the lower number of detectors in the SPECT approach compared detectors used in PET imaging will result in a relative loss of sensitivity and resolution.

PET/CT (combined positron emission tomography and computed tomography). PET/CT is a form of PET scanning that has similar clinical applications.

RATIONALE:

The U.S. Food and Drug Administration (FDA) has approved the scanner and imaging hardware for PET as being substantially equivalent to x-ray computed tomography (CT). The FDA requires PET radiotracers to be approved through a new drug approval (NDA) process. Because PET radiotracers have an extremely short half-life, they must be produced in the clinical setting; the FDA also intends to regulate drug manufacturing processes in PET facilities.

Published clinical trials do not provide evidence to support the diagnostic performance and improvement of health outcomes of FDG PET scans for the indications listed as investigational in this policy including brain, ovarian, pancreatic, small cell lung, and testicular cancers, primary diagnosis and staging of esophageal cancer, and as part of the initial work-up for occult primary tumor or for patients with multiple sites of metastasis.

Breast cancer. Clinical evidence does not support FDG PET imaging for differential diagnosis in patients with suspicious breast lesions or an indeterminate/low suspicion finding on mammography. Patients with positive PET scans would presumably undergo biopsy confirmation; thus there would be no change in the net health outcome from using PET compared with not using PET prior to biopsy. Among patients who have been referred for biopsy, a false-negative PET finding could result in delayed or missed diagnosis and treatment.

Clinical evidence does not support FDG PET imaging for staging axillary lymph nodes in patients with an initial diagnosis of primary breast cancer. If the PET scan correctly suggested no spread of tumor to the axillary lymph nodes, the patient could avoid the pain and other complications associated with axillary lymph node dissection. A false-negative PET scan result could lead to harm if a patient with undetected axillary involvement chose to forego adjuvant systemic therapy.

Brain cancer. Clinical evidence for the use of FDG PET in brain cancer to distinguish tumor from radiation necrosis in recurrent brain lesions indicates that PET has similar operating characteristics to imaging technology such as MRS (magnetic resonance spectroscopy).

Cervical cancer. Clinical evidence including sensitivity and specificity suggests that the addition of FDG PET after a negative CT or MRI that is negative for extra-pelvic metastasis can improve clinical decision-making. The literature indicates improved sensitivity for FDG PET compared to conventional imaging in detecting nodal metastases, and specifically para-aortic nodal metastases, in patients with newly diagnosed cervical cancer.

Esophageal carcinoma. Studies have shown that FDG-PET provides information that may improve health outcomes *for initial staging to determine resectability* following neoadjuvant chemotherapy for reduction of tumor volume in esophageal carcinoma patients to assess respectability, *and for suspected recurrence*. For diagnosis, a diagnostic tissue sample is usually obtainable without FDG-PET localization.

Ewing's Sarcoma and Osteogenic Sarcoma: Clinical evidence supports the use of FDG PET for initial staging and restaging when there is an established tissue diagnosis.

Lung Cancer. In patients with known *non-small cell lung cancer*, the clinical value of PET scanning relates to improved staging information regarding the involvement of mediastinal lymph nodes, which generally excludes patients from surgical excision. Some studies of patients with *small cell lung cancer* (SCLC) reported evidence suggesting that for non-brain metastases PET added to conventional staging is more sensitive in detecting disease than conventional staging alone. PET may correctly upstage and downstage disease and studies reported very high occurrence of patient management changes that were attributed to PET. However, available studies have methodological flaws and it is difficult to determine whether the use of PET adds value relative to conventional staging tests for SCLC.

Melanoma. Prospective studies have found that PET was much more sensitive and specific than conventional imaging for detection of extranodal metastases as an aid in selecting treatment appropriate to the patient's extent of disease.

Molecular Coincidence Detection: There are no data to suggest that the combination of FDG-SPECT with PET scans improves diagnostic performance, and no data regarding the use of FDG-SPECT in the evaluation of coronary perfusion defects. Available literature suggests molecular coincidence detection cannot be considered an equivalent diagnostic modality compared to conventional PET scanning, particularly for small lesions. There are inadequate data regarding the diagnostic performance of molecular coincidence detection compared to other anatomic imaging techniques, such as CT or MRI scan.

Occult cancer. Clinical evidence demonstrates adequate diagnostic performance for use of FDG PET to detect metastatic sites in patients eligible for local or regional therapy of one to several metastases from an occult carcinoma. Detecting new sites of metastasis improves health outcomes for patients thought to have an isolated metastatic site, by sparing them from attempted definitive local or regional therapy that is unlikely to be effective. Conversely, if no new sites of disease are identified, clinicians can administer the planned local or regional treatments with greater confidence.

Ovarian cancer. Clinical evidence for ovarian cancer is only fair indicating no improvement in diagnostic results for recurrence by using FDG PET as an adjunct to conventional imaging and CA-125 levels. For patients with rising CA-125 titer and negative conventional imaging, there may be improved outcomes with the additional of FDG PET to the standard work-up.

Pancreatic cancer. Studies regarding pancreatic cancer demonstrated a trend toward greater sensitivity for FDG PET compared to conventional imaging techniques, however diabetes and abnormal glucose metabolism in this patient population affect FDG PET results.

Prostate cancer. On June 11, 2013 CMS issued a Decision Memo which included the use of FDG PET for prostate cancer. CMS found little evidence about effects of FDG PET on outcomes for patients whose initial therapy for prostate cancer had been completed. After review of the public comments and therapeutic studies of the evidence base, CMS agrees that a significant benefit of FDG PET scans is their use to determine effect of treatment, especially at certain types of progressive prostate disease. CMS notes that FDG PET/CT imaging's selective use in assessing progression of prostate cancer does provide valuable additional information for managing treatment decisions, and therefore its use for subsequent treatment strategy planning was considered to be reasonable and necessary. In many of the studies, a rising PSA level was key to the clinical suspicion of progressive or recurrent prostate cancer.

Soft Tissue Sarcoma. Prospective and retrospective studies support that FDG-PET is more accurate than size-based criteria at assessing histopathologic response to neoadjuvant therapy, and is accurate in preoperative staging of soft-tissue sarcoma.

Solitary pulmonary nodule. Numerous case series support that FDG-PET may be effective in patients with solitary pulmonary lung nodules in whom the diagnosis is uncertain after prior CT scan and chest x-ray. Patients who are relatively young and have no smoking history are at a relatively low risk for lung cancer, and in this setting the negative predictive value of a PET scan is relatively high. If presented with a negative PET scan and information about the very low probability of undetected malignancy, it is quite likely that some patients would choose to avoid the harms of an invasive sampling procedure (e.g., biopsy).

Testicular cancer. Literature suggests a possible role for FDG PET in staging testicular cancer.

Thymoma: Clinical evidence supports the use of FDG PET in predicting the grade of malignancy in thymic epithelial tumors, in differentiating thymoma from hyperplasia in myasthenia gravis, and in differentiating subgroups of thymic epithelial tumors and for staging the extent of disease.

Thyroid cancer. Clinical evidence supports the effectiveness of FDG PET in the staging of thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation with an elevated or rising serum Tg greater than 10 ng/ml and negative I-131 WBS. Medullary thyroid cancer is a relatively rare disease composing only 3-10% of all malignant thyroid cancers. Metastasis to locoregional lymph nodes is common and can be seen in 71-80% of cases. Distant metastases can be found in about 20% of patients. Following surgical treatment, elevation of serum calcitonin and CEA levels suggest persistent or recurrent disease. In these patients FDG PET can identify more than twice as many sites of disease than conventional imaging modalities (CT, MRI). FDG PET is less sensitive for detection of pulmonary and hepatic metastases compared to CT and MR, respectively.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

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

HCPCS:	A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries
	G0219 **(E/I)**	PET imaging whole body; melanoma, non-covered indications (replaces G0165)
	G0235	PET imaging any site not otherwise specified
	G0252 **(E/I)**	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)

S8085 **(E/I)** Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual -head coincidence detection system (non-dedicated PET scan)

ICD9: Numerous

ICD10: Numerous

REFERENCES:

Barger RLJ and Nandalur KR. Diagnostic performance of dual-time 18F-FDG PET in the diagnosis of pulmonary nodules: a meta-analysis. Acad Radiol 2012;19(2):153-8.

Bartoletti R, et al. Fluorodeoxyglucose positron emission tomography may aid the diagnosis of aggressive primary prostate cancer: A case series study. Oncol Lett 2014 Feb;7(2):381-6.

*Bastinaannet E, et al. The value of FDG-PET in the detection, grading and response to therapy of soft tissue and bone sarcomas: a systematic review and meta-analysis. Cancer Treatment Reviews 2004;30:83-101.

BlueCross BlueShield Association. FDG using camera-based imaging (FDG-SPECT). Medical Policy Reference Manual. Policy #6.01.27. 2009 Dec 10.

BlueCross BlueShield Association. Oncologic applications of PET scanning. Medical Policy Reference Manual. Policy #6.01.26. 2013 Feb 14.

*BlueCross BlueShield Association, Technology Evaluation Center. FDG positron emission tomography for evaluating breast cancer. 2001 Aug.

*BlueCross BlueShield Association, Technology Evaluation Center. FDG positron emission tomography for evaluating breast cancer. 2003 Nov.

*BlueCross BlueShield Association, Technology Evaluation Center. FDG positron emission tomography for evaluating esophageal cancer. 2002 Apr.

*BlueCross BlueShield Association, Technology Evaluation Center. FDG positron emission tomography to manage patients with an occult primary carcinoma and metastasis outside the cervical lymph nodes. 2002 Jun.

*BlueCross BlueShield Association, Technology Evaluation Center. FDG positron emission tomography for the detection of ovarian cancer. 2002 Jun.

*Cerfolio RJ, et al. The role of FDG-PET scan in staging patients with non small cell carcinoma. Ann Thorac Surg 2003 Sep;76(3):861-6.

Chae BJ, et al. Positron emission tomography-computed tomography in the detection of axillary lymph node metastasis in patients with early stage breast cancer. Jpn J Clin Oncol 2009;39(5):284-9.

*Chao ST, et al. The sensitivity and specificity of FDG PET in distinguishing recurrent brain tumor from radionecrosis in patients treated with stereotactic radiosurgery. Int J Cancer 2001 Jun 20:96(3):191-7.

Cheng X, et al. 18F-FDG PET/CT and PET for evaluation of pathological response to neoadjuvant chemotherapy in breast cancer: a meta-analysis. Acta Radiol 2012; 53(6):615-27.

Cheng X, et al. (1)(8)F-FDG-PET and (1)(8)F-FDG-PET/CT in the detection of recurrent or metastatic medullary thyroid carcinoma: a systematic review and meta-analysis. J Med Imaging Radiat Oncol 2012;56(2):136-42.

*Choi JY, et al. 18F-FDG PET in patients with esophageal squamous cell carcinoma undergoing curative surgery: prognostic implications. J Nucl Med 2004 Nov;45(11):1843-50.

*Choi H, et al. CT evaluation of the response of gastrointestinal stromal tumors after imatinib mesylate treatment: a quantitative analysis correlated with FDG-PET findings. AJR 2004;183:1619-28.

*Desai DC, et al. Positron emission tomography affects surgical management in recurrent colorectal cancer patients. Ann Surg Oncol 2003 Jan-Feb;10(1):59-64.

Dunet V, et al. Performance of 18F-fluoro-ethyl-tyrosine (18F-FET) PET for the differential diagnosis of primary brain tumor: a systematic review and metaanalysis. J Nucl Med 2012;53(2):207-14.

*Eubank WB, et al. Impact of FDG PET on defining the extent of disease and on the treatment of patients with recurrent or metastatic breast cancer. AJR 2004;183:479-86.

*Evan-Sapir E, et al. Detection of recurrence in patients with rectal cancer: PET/CT after abdominoperineal or anterior resection. Radiology 2004;232:815-22.

*Grigsby PW, et al. Posttherapy (18F) fluorodeoxyglucose positron emission tomography in carcinoma of the cervix: response and outcome. J Clin Oncol 2004 Jun 1;22(11):2167-71.

Gwynne S, et al. Imaging for target volume delineation in rectal cancer radiotherapy--a systematic review. Clin Oncol (R Coll Radiol) 2012; 24(1):52-63.

*Heeren PA, et al. Detection of distant metastases in esophageal cancer with (18)F-FDG PET. J Nucl Med 2004 Jun;45(6):980-7.

Hillner BE, et al. The impact of positron emission tomography (PET) on expected management during cancer treatment. Cancer 2009;115(2):410-8.

*Ioannidis JPA, et al. FDG-PET for the diagnosis and management of soft tissue sarcoma. Technology Assessment. Agency for Healthcare Research and Quality (AHRQ). 2002 Apr.

*Israel O, et al. Is 18F-FDG PET/CT useful for imaging and management of patients with suspected occult recurrence of cancer. J Nucl Med 2004;45:2045-51.

*Kelly RF, et al. Accuracy and cost-effectiveness of (18F)-2-fluoro-deoxy-D-glucose-positron emission tomography scan in potentially resectable non-small cell lung cancer. Chest 2004 Apr;125(4):1413-23.

*Kneist W, et al. Prospective evaluation of positron emission tomography in the preoperative staging of esophageal carcinoma. Arch Surg 2004 Oct;139(10):1043-9.

*Kushner BH, et al. Extending positron emission tomography scan utility to high-risk neuroblastoma: fluorine-18 fluorodeoxyglucose positron emission tomography as sole imaging modality in follow-up of patients. J Clin Oncol 2001 Jul 15;19(14):3397-405.

*Lai CH, et al. Restaging of recurrent cervical carcinoma with dual-phase [18F]fluoro-2-deoxy-D-glucose positron emission tomography. Cancer 2004 Feb 1:100(3):544-52.

*Liu IJ, et al. Fluorodeoxyglucose positron emission tomography studies in diagnosis and staging of clinically organ-confined prostate cancer. Urol 2001 Jan;57(1):108-11.

*Lonneux M, et al. FDG-PET improves the staging and selection of patients with recurrent colorectal cancer. Eur J Nucl Med Mol Imag 2002 Jul;29(7):915-21.

Lu YY, et al. FDG PET or PET/CT for detecting intramedullary and extramedullary lesions in multiple myeloma: a systematic review and meta-analysis. Clin Nucl Med 2012;37(9):833-7.

*Matchar DB, et al. Positron emission testing for six cancers (brain, cervical, small cell lung, ovarian, pancreatic and testicular. Technology Assessment. Agency for Healthcare Research and Quality (AHRQ). 2004 Feb.

Prakash P, et al. Role of PET/CT in ovarian cancer. AJR Am J Roentgenol 2010 Jun;194(6):W464-70.

Roh JL, et al. Utility of combined 18F-fluorodeoxyglucose-positron emission tomography and computed tomography in patients with cervical metastases from unknown primary tumors. Oral Oncology 2009;45:218–24.

*Rohren EM, et al. The role of F-18 FDG positron emission tomography in preoperative assessment of the liver in patients being considered for curative resection of hepatic metastases from colorectal cancer. Clin Nucl Med 2002 Aug;27(8):550-5.

Ruben JD and Ball DL. The efficacy of PET staging for small-cell lung cancer: a systematic review and cost analysis in the Australian setting. J Thorac Oncol 2012;7(6):1015-20.

Sadeghi R, et al. Accuracy of 18F-FDG PET/CT for diagnosing inguinal lymph node involvement in penile squamous cell carcinoma: systematic review and meta-analysis of the literature. Clin Nucl Med 2012;37(5):436-41.

*Schaefer NG, et al. Non-Hodgkin lymphoma and Hodgkin disease: co-registered FDGPET and CT at staging and restaging – do we need contrast-enhanced CT. Radiology 2004;232:823-9.

*Seidenfeld J, et al. Management of small cell lung cancer. Evidence Report. Agency for Healthcare Research and Quality (AHRQ) Publ No. 06-E016; 2006 Jul.

*Sihvo EI, et al. Adenocarcinoma of the esophagus and the esophagogastric junction: positron emission tomography improves staging and prediction of survival in distant but not in locoregional disease. J Gastrointest Surg 2004 Dec;8(8):988-96.

*Swetter SM, et al. Positron emission tomography is superior to computed tomography for metastatic detection in melanoma patients. Ann Surg Oncol 2002 Aug;9(7):646-53.

Treglia G, et al. Diagnostic performance of Gallium-68 somatostatin receptor PET and PET/CT in patients with thoracic and gastroenteropancreatic neuroendocrine tumours: a meta-analysis. Endocrine 2012;42(1):80-7.

Treglia G, et al. 18F-Fluorodeoxyglucose positron emission tomography in evaluating treatment response to imatinib or other drugs in gastrointestinal stromal tumors: a systematic review. Clin Imaging 2012; 36(3):167-75.

Treglia G, et al. Diagnostic accuracy of (18)?F-FDG-PET and PET/CT in patients with Ewing sarcoma family tumours: a systematic review and a meta-analysis. Skeletal Radiol 2012; 41(3):249-56.

van Lammeren-Venema D, et al. (1)(8)F-fluoro-deoxyglucose positron emission tomography in assessment of myeloma-related bone disease: a systematic review. Cancer 2012; 118(8):1971-81.

*van Tinteren, et al. Effectiveness of positron emission tomography in the preoperative assessment of patients with suspected non small cell lung cancer: the PLUS multicentre randomized trial. Lancet 2002 Apr 20;359(9315):1361-2.

Wang Y, et al. Is 18F-FDG PET accurate to predict neoadjuvant therapy response in breast cancer? A meta-analysis. Breast Cancer Res Treat 2012;131(2):357-69.

Wu LM, et al. 18 F-fluorodeoxyglucose positron emission tomography to evaluate recurrent gastric cancer: a systematic review and meta-analysis. J Gastroenterol Hepatol 2012;27(3):472-80.

Yang Z, et al. Prevalence and risk of cancer of incidental uptake in prostate identified by fluorine-18 fluorodeoxyglucose positron emission tomography/computed tomography. Clin Imaging 2014 Feb 11 [Epub ahead of print].

KEY WORDS:

FDG PET, FDG SPECT, Gamma Camera, PET, Positron emission tomography.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Positron Emission Tomography (FDG) for Oncologic Conditions. Please refer to the following NCD website for Medicare Members:
http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=331&ncdver=3&bc=BAABAAAAAAAA&

There is currently a Final Decision Memo for Positron Emission Tomography (FDG) for Solid Tumors. Please refer to the following CMS website for Medicare Members:
http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=263