

MEDICAL POLICY



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, 04/16/15, 04/21/16, 01/19/17, 12/21/17, 10/18/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

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: May be determined by PET or MRS. Only one technique should be performed, unless the initial study is inconclusive.

 1. Low grade gliomas(World Health Organization (WHO) histologic grade I and II):
 - a. To determine need for biopsy when transformation to high grade glioma is suspected based on clinical symptoms or recent MRI findings in high grade gliomas; or
 2. Evaluate a brain lesion of indeterminate nature when the PET findings will be used to determine whether biopsy/resection can be safely postponed; (PET metabolic (CPT: 78608)
 2. High grade gliomas(WHO) histologic grade III and IV):
 - a. For differentiation of radiation necrosis from brain tumor recurrence (post treatment); or
 - b. Evaluate a brain lesion of indeterminate nature when the PET findings will be used to determine whether biopsy/resection can be safely postponed. (PET metabolic: CPT 78608); or
 - c. Evaluate inconclusive MRI findings when the PET findings will be used to determine need for biopsy or change in therapy, including a change from active therapy to surveillance
 3. PET Brain is not indicated in gliomas occurring in the brain stem due to poor uptake and lack of impact on patient outcomes
 4. PET is not indicated in the evaluation or management of primary central nervous system (CNS) tumors.
 - B. **Breast Carcinoma**
 1. Initial Staging; CT and bone scan inconclusive (please refer to#3 listed below);
 2. Subsequent Treatment Strategies:
 - a. Inconclusive CT, MRI, and/or bone scan for suspected recurrence, and further characterization is needed to make treatment decisions,
 - b. Suspicion of recurrence,
 - i. changes on other imaging when conventional imaging is inconclusive; or

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- ii. bone metastasis as the only site of stage IV disease (excluding brain metastasis) and a prior bone scan has not been performed for serial comparison
- 3. There is insufficient evidence for PET in breast cancer for:
 - a. Primary diagnosis or detection; or
 - b. Non-invasive breast cancers; or
 - c. Staging of Stage I, II or operable IIIA-B breast cancer prior to lymph node sampling; or
 - d. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease; or
 - e. Obvious multi-organ metastatic disease is present on CT or MRI

C. Thyroid Cancer

- 1. Initial staging:
 - a. Individuals diagnosed with anaplastic or medullary thyroid cancer when conventional imaging inconclusive;
 - b. Investigational for all other indications, including prior to thyroidectomy; PET for initial staging for anaplastic thyroid cancer is currently not recommended before conventional imaging since recommendations for PET are derived from observational studies and clinical trials with other methodological limitations.
- 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); negative radioiodine scan and rising thyroglobulin level;
 - b. Re-staging and suspected recurrence of anaplastic or medullary carcinoma - when conventional imaging inconclusive;
 - c. Surveillance: Not routinely indicated for 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; For any of the following:
 - a. Known stage III or IV disease; or
 - b. Nasopharyngeal primary site; or
 - c. Inconclusive findings on conventional imaging (CT, MRI); or
 - d. Prior to start of primary chemoradiotherapy and have not undergone definitive surgical resection; or
 - e. In order to direct laryngoscopy/exam under anesthesia for biopsy; or
 - f. Pulmonary nodule(s) greater than or equal to 8 mm in size; or
 - g. Cervical lymph node biopsy positive for squamous cell carcinoma and no primary site identified on CT or MRI; or
 - h. Prior to biopsy in order to determine a more favorable site for biopsy when a prior biopsy was nondiagnostic or a relatively inaccessible site is contemplated which would require invasive surgical intervention for biopsy attempt; or
 - i. Inconclusive findings suggestive of disease outside the head and neck area
- 2. Subsequent Treatment Strategies:
 - a. Restaging after therapy: stage III-IV disease; radiation therapy: no sooner than 12 weeks after completion of treatment when:
 - i. evaluating the need for salvage surgery/radical neck dissection in patients with measurable residual disease on physical exam or recent CT or MRI; or
 - ii. distinguishing active tumor from radiation fibrosis; or
 - b. Inconclusive conventional imaging (CT or MRI) or biopsy proven local recurrence.

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Monitoring for recurrence - altered clinical situation.

- c. 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 less than 3cm (30 mm) and not calcified;
 - b. Prior to biopsy of pulmonary mass greater than 3.1 cm (31 mm) seen on CT or MRI when:
 - i. resection would be performed instead of biopsy if PET confirms limited disease; or
 - ii. multiple possible biopsy options are present within the chest and PET findings will be used to determine the most favorable biopsy site
 - c. When chest x-ray and CT fail to distinguish benign from malignant disease;
 - d. When the results of the test could change clinical management;
 - e. 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; stage I-IIIB and stage IV disease confined to the chest region;
 - a. PET for initial staging is not generally indicated for metastatic disease, pleural/pericardial effusion, or for multiple sites that are located outside the chest cavity, when found on conventional imaging (i.e., liver, bone and adrenal metastasis, etc).
 - b. PET may be considered to confirm solitary focus of metastatic disease (i.e., brain or adrenal) if being considered for an aggressive surgical management.
2. Subsequent Treatment Strategies:
 - a. New or indeterminate findings localized to chest cavity on standard imaging suggestive of suspicion of recurrence; or
 - b. PET/CT is not indicated if new findings are obviously metastatic disease
 - c. 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 as confined to the ipsilateral hemithorax)
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. Isolated metastatic lesion(s) on other imaging and patient is a candidate for aggressive surgical resection, or other localized treatment to metastasis for curative intent.
2. Subsequent Treatment Strategies
 - a. Suspicion of recurrence: rising CEA (greater than 2.5 in nonsmoker and greater than 5.0 in a smoker); or Liver Function Tests (LFTs) with negative recent conventional imaging; or
 - b. Isolated metastatic lesion(s) on other imaging and patient is a candidate for aggressive surgical resection, or other localized treatment to metastasis for curative intent; or
 - c. To differentiate local tumor recurrence from postoperative and/or post-radiation scarring

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- d. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

H. Lymphoma, including Non-Hodgkin disease

Diffuse Large B Cell:

1. Initial Staging: PET may be used as the initial imaging technique for staging;
2. Subsequent Treatment Strategies:
 - a. Monitoring response to therapy; may be approved at the end of chemotherapy and again at the end of radiation;
 - b. Not routinely indicated for surveillance.

Follicular Cell:

1. Initial Staging: Stage I or II disease when XRT being considered
2. Subsequent Treatment Strategies:
 - a. Monitoring response to therapy; end of therapy evaluation;
 - b. Suspicion of progression; Suspected transformation (Richter's) from a low grade lymphoma to a more aggressive type based on one or more of the following:
 - i. new B symptoms; or
 - ii. rapidly growing lymph nodes; or
 - iii. extranodal disease develops; or
 - iv. significant recent rise in LDH above normal range.
 - c. Not routinely indicated for surveillance.

Marginal Zone:

1. Initial Staging: Stage I or II disease when XRT being considered;
2. Subsequent Treatment Strategies:
 - a. Monitoring response to therapy; end of therapy evaluation;
 - b. Not routinely indicated for surveillance.

Mantle Cell:

1. Initial Staging: Stage I or II disease when XRT being considered;
2. Subsequent Treatment Strategies:
 - a. Monitoring response to therapy; end of therapy evaluation;
 - b. Not routinely indicated for surveillance.

Burkitt's:

1. Initial Staging: PET may be used as the initial imaging technique for staging;
2. Subsequent Treatment Strategies:
 - a. Monitoring response to therapy; may be approved at the end of chemotherapy and again at the end of radiation;
 - b. Not routinely indicated for surveillance.

Cutaneous (includes Primary Cutaneous B Cell Lymphomas, Peripheral T-Cell Lymphomas, Mycosis Fungoides/Sézary Syndrome, Primary Cutaneous CD30+T Cell Lymphoproliferative Disorders):

1. Initial Staging: PET may be used as the initial imaging technique for staging;
2. Subsequent Treatment Strategies:
 - a. Monitoring response to therapy; may be approved at the end of chemotherapy and again at the end of radiation;
 - b. Not routinely indicated for surveillance.

I. Lymphoma, Hodgkin disease:

1. Initial Staging: PET may be used as the initial imaging technique for staging;
2. Subsequent Treatment Strategies:
 - a. Monitoring response to therapy; as frequently as every 2 cycles;

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- b. End of therapy evaluation; greater than 12 weeks after the end of RT;
- c. Suspected recurrence: nodular lymphocyte – predominant Hodgkin lymphoma; Suspected transformation (Richter’s) from a low grade lymphoma to a more aggressive type based on one or more of the following:
 - i. new B symptoms; or
 - ii. rapidly growing lymph nodes; or
 - iii. extranodal disease develops; or
 - iv. significant recent rise in LDH above normal range.
- d. Surveillance. Hodgkin lymphoma: A single follow-up PET/CT may be approved greater than 12 weeks after the end of radiation therapy if end of therapy PET/CT report documents Deauville 4 or 5 FDG avidity.

J. Esophageal Carcinoma

- 1. Initial Staging of known esophageal cancer; Prior to start of neoadjuvant therapy in preparation for surgery and no evidence of metastatic disease by conventional imaging.
- 2. Subsequent Treatment Strategies:
 - a. Restaging after therapy:
 - i. if conventional imaging inconclusive; or
 - ii. re-evaluation following radiation therapy – as early as 6 weeks after radiation therapy if recent CT findings are inconclusive and PET findings will alter immediate care decision making; or
 - iii. if a salvage surgical candidate with recurrence and no metastatic disease documented by conventional imaging
 - b. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

K. Cervical Cancer

- 1. Initial Staging;
 - a. Stage IB1 or less: less than 4 cm confined to the cervix – to explain inconclusive findings on other imaging studies; or
 - b. Stage IB2 or higher;
 - c. Any size cervical cancer incidentally found in a hysterectomy specimen – if conventional imaging inconclusive.
- 2. Subsequent Treatment Strategies:
 - a. Restaging: If primary therapy radiation therapy with or without chemotherapy (not adjuvant therapy) only when surgical salvage is an option (one time only); or
 - b. Evaluate for recurrence in an individual with new signs and symptoms, elevated LFTs, difficult or abnormal examination AND conventional imaging inconclusive; or
 - c. Not routinely indicated for surveillance

L. Ovarian Carcinoma

- 1. Initial Staging of:
 - a. Primary peritoneal disease with biopsy-proven malignancy consistent with ovarian carcinoma; or
 - b. Elevated tumor markers with negative or inconclusive CT imaging.
- 2. Subsequent Treatment Strategies:
 - a. Evaluation of recurrence: elevated tumor markers (eg, CA-125 greater than 35U/ml or elevated LFTs) and CT negative or inconclusive; or
 - b. Conventional imaging failed to demonstrate tumor or if persistent radiographic mass with rising tumor markers.

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- c. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

M. Pancreatic Carcinoma

1. Initial Staging; No evidence of metastatic disease on CT or MRI;
2. Subsequent Treatment Strategies:
 - a. Post chemoradiation (if given as definitive/curative therapy) when conventional imaging inconclusive;
 - b. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

N. Gastric Carcinoma

1. Initial Staging: gastric cancer greater than or equal to T2 or higher with no metastatic disease by conventional imaging;
2. Subsequent Treatment Strategies:
 - a. Restaging/recurrence: inconclusive findings on conventional imaging.
 - b. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

O. Testicular Carcinoma (seminoma or non-seminomatous germ cell tumor)

1. Initial Staging: considered **investigational**;
2. Subsequent Treatment Strategies:
 - a. Monitoring response to therapy - Seminoma with residual mass >3 cm - single scan 6 or more weeks post-chemotherapy or post-radiation therapy if recent CT findings are inconclusive and PET findings will alter immediate care decision making ; or
 - b. Surveillance: Not routinely indicated for surveillance

P. Soft Tissue Sarcoma

1. Initial Staging:
 - a. Grade of tumor is in doubt following biopsy; or
 - b. Planning neoadjuvant therapy; or
 - c. Prior to surgical resection for tumors > 3cm; or
 - d. Conventional imaging suggests solitary metastasis amenable to surgical resection.
2. Subsequent Treatment Strategies – Restaging:
 - a. Determine response to neoadjuvant therapy; or
 - b. Differentiate tumor from radiation or surgical fibrosis; or
 - c. Confirm oligometastatic disease prior to curative intent surgical resection.
3. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Q. Multiple Myeloma and Plasmacytomas

1. Initial Staging:
 - a. Determine if plasmacytoma is truly solitary; or
 - b. Suspected extraosseous plasmacytomas; or
 - c. Ensure patient has Stage I or “smoldering” myeloma (SMM) and does not have “full-blown” myeloma; or
 - d. Progression of monoclonal gammopathy of unknown significance (MGUS) or SMM to a more malignant form and CT/MRI imaging are negative; or
 - e. Inconclusive radiographic imaging.
2. Subsequent Treatment Strategies when any of the following:
 - a. Negative PET will allow change in management from active to maintenance treatment or surveillance.

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R. **Melanoma**

1. Initial Staging - Primary site is unknown and CT chest and abdomen/pelvis are negative
2. Subsequent Treatment Strategies:
 - a. Suspicion of recurrence;
 - i. When conventional imaging is inconclusive or isolated metastatic based on results of conventional imaging, initially; or
 - b. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease;

S. **Thymoma**

1. Initial Staging: inconclusive findings on CT;
2. Subsequent Treatment Strategies:
 - a. Inconclusive findings on CT;
 - b. Extensive disease on chemotherapy: following induction chemotherapy prior to surgical resection if no evidence of metastatic disease
 - b. Surveillance is considered **investigational**.

T. **PET for Radiation Therapy Planning**

1. Orders accepted from radiation oncologists only;
2. Patient must be proven to have one of the cancers listed above;
3. Approvable once per patient, prior to initiation of therapy.

U. **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 indicated for surveillance.

V. **GIST Tumor (Gastrointestinal Stromal Tumor)**

1. Initial Staging: for evaluation of inconclusive findings on conventional imaging.
2. Subsequent Treatment Strategies:
 - a. Monitoring response to therapy; for evaluation of inconclusive findings on conventional imaging;
 - b. Restaging/recurrence; for evaluation of inconclusive findings on conventional imaging.

W. **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.

X. **Prostate**

1. Initial staging – **investigational**;
2. Subsequent Treatment strategies – investigational *except* positron emission tomography (PET) imaging using the isotopes ¹¹C-Choline or Fluciclovine-F18 for restaging previously treated prostate cancer with suspicion of recurrence (rising PSA) and negative conventional imaging.

Y. **Hepatocellular(HCC)/Biliary**

1. Initial staging: For primary biliary carcinoma (no HCC) *if* no evidence of metastatic disease by conventional imaging, and determining if patient is a surgical candidate.
2. Not indicated for surveillance.

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Z. **Transitional Cell; Bladder/Ureters/Urethra/Renal Pelvis**

1. Initial staging: To determine neoadjuvant therapy versus surgery as initial treatment (if conventional imaging negative or inconclusive)
2. Not indicated for surveillance.

AA. **Anal Cancer**

1. Initial staging: Stage II-IV squamous cell carcinoma of the anal canal (not anal margin such as Bowen's disease or Paget's disease)
2. Restaging/recurrence: inconclusive findings on conventional imaging

BB. **Metastatic (lung, liver, brain, adrenal, and bone)**

1. Lung – lung nodules greater than or equal to 8 mm; or to confirm solitary metastasis amenable to resection on conventional imaging;
2. Liver – to confirm solitary metastasis amenable to resection on conventional imaging; or LFT's and/or tumor markers continue to rise and CT and MRI are negative;
3. Brain metastases and no known primary tumor - inconclusive conventional imaging; or to confirm either stable systemic disease or absence of other metastatic disease ;
4. Solitary adrenal metastasis *and* primary tumor site controlled and surgical resection or radiotherapy of an adrenal metastasis is potentially curative -to confirm isolated lesion if conventional imaging does not reveal other metastatic disease.

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 endometrial carcinoma, liver, musculoskeletal extremities, renal and parathyroid.

IV. Based upon our criteria and assessment of the peer-reviewed literature positron emission tomography (PET) imaging using isotopes other than 18F-FDG, including-¹⁸F-NaF, is considered **investigational**.

V. Based upon our criteria and assessment of the peer-reviewed literature positron emission tomography (PET) imaging using the isotopes ¹¹C-Choline or Fluciclovine-F18 for restaging previously treated prostate cancer with suspicion of recurrence (rising PSA) and negative conventional imaging is considered **medically appropriate**.

VI. Based upon our criteria and assessment of the peer-reviewed literature positron emission tomography (PET) imaging using the isotope ⁶⁸Ga-DOTATE is **medically appropriate** for low grade neuroendocrine tumors during initial staging or for restaging at follow-up.

VII. Based on upon our criteria and assessment of the peer-reviewed literature, PET positron emission tomography (PET) scans should be delayed at least 12 weeks after completion of radiation treatment, unless required sooner for imminent surgical resection.

VIII. **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#6.01.19 regarding Low-dose Computed Tomography (LDCT) for Lung Cancer Screening.

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

Refer to Corporate Medical Policy#6.01.41 regarding Positron Emission Tomography (PET) Cardiac Applications.

Refer to Corporate Medical Policy #11.01.10 regarding Clinical Trials.

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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).
- III. Except for the indications listed in the Policy Statement section, PET is **NOT** indicated for
 - A. Concomitantly, with separate diagnostic CT studies; or
 - B. Surveillance; or
 - C. Distant or diffuse metastatic disease; or
 - D. Metastatic disease in the central nervous system (CNS); or
 - E. Lesions less than 8 mm in size; or
 - F. Follow-up after localized therapy (e.g., rf ablation, embolization, or stereotactic radiation).
- IV. PET has not been shown to be diagnostically useful in all forms of cancer. PET is supported for malignancies with significant published evidence regarding its diagnostic accuracy and importance in accurately directing patient care decisions.
- V. PET imaging is not specific to cancer, and has a high rate of false positivity. Inflammation, infection (especially granulomatous), trauma, and post-operative healing may show high levels of FDG uptake and be false-positive for malignant lesions.
- VI. PET may be considered prior to biopsy in order to determine a more favorable site for biopsy when a prior biopsy was nondiagnostic or a relatively inaccessible site is contemplated which would require invasive surgical intervention for biopsy attempt.

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;

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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.

PET has not been shown to be diagnostically useful in all forms of cancer. PET imaging is not specific to cancer and has a high rate of false positivity. Inflammation, infection (especially granulomatous), trauma and post-operative healing may show high levels of FDG uptake and be false-positive for malignant lesions.

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.

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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.

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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).

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<u>CPT:</u>	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

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<u>HCPCS:</u>	A9515	Choline C-11, diagnostic, per study dose up to 20 millicuries
	A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries
	A9580	Sodium fluoride F-18, diagnostic, per study dose, up to 30 millicuries
	A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie
	A9588	Fluciclovine f-18, diagnostic, 1 millicurie
	A9597 (E/I)	Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified
	G0219 (E/I)	PET imaging whole body; melanoma, non-covered indications
	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)

ICD10: Numerous

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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:

<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=331&ncdver=4&bc=AgAAgAAAAAAAAAA%3d%3d&>

There is currently a National Coverage Determination (NCD) for Positron Emission Tomography (FDG) for (NaF-18) to Identify Bone Metastasis of Cancer. Please refer to the following NCD website for Medicare Members:

<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=336&ncdver=1&bc=AgAAgAAAAAAAAAA%3d%3d&>

There is currently a National Coverage Determination (NCD) for Positron Emission Tomography (FDG) scans. Please refer to the following NCD website for Medicare Members:

<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=211&ncdver=5&bc=AgAAgAAAAAAAAAA%3d%3d&>

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>