MEDICAL POLICY

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MEDICAL POLICY DETAILS	
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

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

II. Based upon our criteria and assessment of the peer-reviewed literature, 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:

INDICATIONS		
A. <u>Adrenal Tumors</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance

a. PET/CT scan with any one of the following SSR radiotracers: ^{68}Gallium DOTATATE, ^{68}Ga-DOTATOC or ^{64}Cu-DOTATATE for continued suspicion with negative/inconclusive CT scan or MRI. **OR** b. FDG PET/CT scan if prior CT scans and MRI are negative and/or inconclusive.	Restaging/Recurrence: a. PET/CT scan with any one of the following SSR radiotracers: ^{68}Gallium DOTATATE, ^{68}Ga-DOTATOC or ^{64}Cu-DOTATATE for continued suspicion for recurrence with negative or inconclusive CT scan or MRI. **OR** b. FDG PET/CT scan if prior CT scans and MRI are negative and/or inconclusive.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
Adrenocortical Carcinoma: FDG PET/CT scan if the isolated adrenal mass is greater than 4 cm on conventional imaging with plans for aggressive surgical resection or inconclusive findings on conventional imaging.		
B. <u>Anal Cancer</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. Stage II- III squamous cell carcinoma of the anal canal (not anal margin such as Bowen's disease or Paget's disease), and no evidence of metastatic disease by conventional imaging. **OR** b. Inconclusive findings on conventional imaging.	a. Inconclusive findings on conventional imaging.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
C. <u>Brain Tumors (e.g., astrocytoma, oligodendroglioma)</u>		
1. PET/CT scan is generally not indicated for initial staging.		
2. Subsequent Treatment Strategies – Response to therapy/progression		
a. Suspicion of recurrence: May be determined by PET or MRS. Only one technique should be performed unless the initial study is inconclusive.		
Low grade gliomas (World Health Organization (WHO) histologic grade I and II) High grade gliomas (WHO) histologic grade III and IV)	i. To determine need for biopsy when transformation to high grade glioma is suspected based on clinical symptoms or recent MRI findings; or ii. To differentiate recurrent tumor from treatment effects such as radiation necrosis and following radiotherapy; **OR** iii. To 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** iv. To evaluate inconclusive MRI findings, when the PET findings will be used to determine the need for biopsy or change in therapy, including a change from active therapy to surveillance.	
PET perfusion imaging of the brain is not indicated in gliomas occurring in the brain stem, due to poor uptake and lack of impact on patient outcomes.		
PET perfusion imaging of the brain is not indicated in the evaluation or management of primary central nervous system (CNS) tumors.		

D. Breast Carcinoma		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. CT and bone scan inconclusive (please refer to insufficient evidence for PET listed below).	Restaging/Recurrence a. Inconclusive CT, MRI, and/or bone scan for suspected recurrence, and further characterization is needed to make treatment decisions; **OR** b. 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.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
There is insufficient evidence for PET in breast cancer: a. For primary diagnosis or detection; **OR** b. For non-invasive breast cancers; **OR** c. For staging of Stage I, II or operable IIIA 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. Where obvious multi-organ metastatic disease is present on CT or MRI; **OR** f. To evaluate for distant metastases for preinvasive or in-situ breast cancer (histology such as DCIS and LCIS).		
E. Bronchopulmonary / Thymic Carcinoids		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance

a. PET/CT scan with any one of the following SSR radiotracers: ^{68}Gallium DOTATATE, ^{68}Ga-DOTATOC or ^{64}Cu-DOTATATE for inconclusive findings on CT or MRI scans. **OR** b. FDG PET/CT scan for the following indications: i. Markers fail to normalize after complete surgical resection **AND** CT/MRI and somatostatin-receptor based study are negative; **OR** ii. Biopsy proven neuroendocrine tumor of unknown primary site **AND** CT/MRI and somatostatin-receptor based study are negative.	a. <u>Restaging/Recurrence</u>: PET/CT scan with any one of the following SSR radiotracers: ^{68}Gallium DOTATATE, ^{68}Ga-DOTATOC or ^{64}Cu-DOTATATE for continued suspicion for recurrence with negative or inconclusive CT scan or MRI.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
F. <u>Cervical Cancer</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. Stage IB1 or higher stages; **OR** b. Inconclusive findings on conventional imaging.	Restaging after therapy: a. If primary therapy is radiation therapy with or without chemotherapy (no surgery), restage at least 12 weeks after completion of treatment; **OR** b. Suspected or biopsy proven recurrence.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
G. <u>Colorectal Cancer</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. 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** b. Inconclusive findings on conventional imaging.	a. 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** b. To differentiate local tumor recurrence from postoperative and/or post-radiation scarring. **OR**	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

	c. Postoperative elevated or rising CEA or LFTs with negative recent conventional imaging.	
Appendiceal adenocarcinoma (including pseudomyxoma peritonei) follows imaging guidelines for colorectal cancer.		
H. Esophageal and Gastroesophageal Junction Carcinoma		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. If no evidence of metastatic disease by conventional imaging.	Restaging after therapy: a. If conventional imaging inconclusive; **OR** b. Decision making after primary chemoradiation therapy prior to surgery (no sooner than 8 weeks post completion of radiation therapy); **OR** c. If a salvage surgical candidate with recurrence and no metastatic disease documented by conventional imaging.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
I. Ewing Sarcoma and Osteogenic Sarcoma		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. Must have an established diagnosis of Ewing's sarcoma or osteogenic sarcoma is strongly suspected based on other diagnostic testing. **OR** b. PET/CT can replace bone scan and bone marrow biopsy in Ewing Sarcoma Family of Tumors (ESFT) and is indicated in the initial staging of ESFT patients after histological diagnosis is established.	a. Restaging after completion of therapy. **OR** b. Restaging after biopsy-confirmed recurrence. **OR** c. Restaging after 10-12 weeks of neoadjuvant chemotherapy prior to local control surgery. **OR** d. Treatment response following local control surgery at the end of planned chemotherapy. **OR** e. Metastatic disease does not routinely undergo local control surgery unless metastatic disease has resolved with chemotherapy every two cycles during treatment and at the end of planned chemotherapy. **OR** For suspected recurrence, any of the following:	a. PET/CT has no established role for asymptomatic surveillance.

	a. Conventional imaging reveals findings that are inconclusive or suspicious for recurrence and PET avidity will determine whether biopsy or continued observation is appropriate. **OR** b. Rare circumstances where obvious clinical symptoms show strong evidence suggesting recurrence and PET imaging could result in a treatment change for the patient, including a change from active treatment to surveillance. **OR** c. For biopsy proven recurrence, PET/CT may be performed.	
J. Gastric Carcinoma		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. Gastric cancer greater than or equal to T2 or higher with no metastatic disease by conventional imaging.	a. Restaging/recurrence: For evaluation of inconclusive findings on conventional imaging.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
K. GIST Tumor (Gastrointestinal Stromal Tumor)		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. For evaluation of inconclusive findings on conventional imaging.	a. Monitoring response to therapy: For evaluation of inconclusive findings on conventional imaging. **OR** b. Restaging/recurrence: For evaluation of inconclusive findings on conventional imaging.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
L. Hepatocellular (HCC)/Gallbladder/Biliary		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. PET/CT scan is not indicated for diagnosis or staging of Hepatocellular carcinoma. **OR**	Restaging/recurrence for gallbladder and biliary carcinoma:	a. Not routinely indicated for surveillance imaging for HCC/Gallbladder/Biliary Carcinoma in an asymptomatic

b. For gallbladder and biliary carcinoma: For evaluation of inconclusive findings on conventional imaging.	a. For evaluation of inconclusive findings on conventional imaging.	individual with no clinical or laboratory evidence of disease.
M. <u>Head and Neck Cancers (Squamous Cell Carcinomas)</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
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 of neck and chest; **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.	a. Stage III-IV disease: Following primary radiochemotherapy or radiation therapy in an individual who has not undergone surgical resection of primary tumor or neck dissection: no sooner than 10 weeks when the clinical indicates an aggressive form of cancer; otherwise, 12 weeks after completion of treatment, as recommended by NCCN 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** iii. Inconclusive conventional imaging (CT or MRI) or biopsy proven local recurrence.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
N. <u>Lung Cancers</u>		
<u>Non-Small Cell Lung Cancer</u>		

1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. Pulmonary nodule 8 mm (0.8 cm) to 30 mm (3 cm) seen on CT Chest or MRI Chest (If PET is positive: qualifies as initial staging PET/CT). **OR** b. Pulmonary mass 31 mm (3.1 cm) or greater seen on CT or MRI (PET/CT prior to biopsy if one or more of the following applies: i. Definitive treatment with resection or radiation will be utilized instead of biopsy if PET confirms limited disease. ii. Multiple possible biopsy options are present within the chest and PET findings will be used to determine the most favorable biopsy site. c. After tissue diagnosis is established: i. Stage I-IIIB. ii. Stage IV confined to the chest region (including pleural/pericardial effusion). iii. Stage IV with oligometastatic disease on conventional imaging and patient is a candidate for aggressive surgical resection or other localized treatment of metastases with a curative intent. iv. Conventional imaging is inconclusive. d. PET is not generally indicated for initial staging or restaging of NSCLC with distant metastatic disease, pleural/pericardial effusion, or for multiple sites that are located outside the chest cavity, when found on conventional imaging (i.e.,	a. To differentiate tumor from radiation scar/fibrosis. **OR** b. Suspected/biopsy-proven recurrence localized to the chest cavity. **OR** c. Inconclusive findings on conventional imaging. **OR** d. Stage IV with oligometastatic disease on conventional imaging and patient is a candidate for aggressive surgical resection or other localized treatment of metastases with a curative intent.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

liver, bone and adrenal metastasis, etc.). **OR** e. PET may be considered to confirm solitary focus of extra-pulmonary metastatic disease (i.e., brain or adrenal) if the individual is being considered for an aggressive oligometastatic disease.		
<u>Small Cell Lung Cancer</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. Confirm limited stage (nonmetastatic) disease if initial staging imaging (CT and MRI) shows disease limited to the thorax. b. Pulmonary nodule 8 mm (0.8 cm) to 30 mm (3 cm) seen on CT Chest or MRI Chest (If PET is positive: qualifies as initial staging PET/CT).	Response to Therapy/Restaging: a. PET is not indicated for evaluation of recurrent SCLC.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
O. <u>Lymphoma, Hodgkin Disease</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. PET may be used as the initial imaging technique for staging. **OR** b. Determine a more favorable site for biopsy when a relatively inaccessible site is contemplated. **OR** c. PET/CT is medically unnecessary for all other indications prior to histological confirmation of lymphoma. **OR**	a. Monitoring response to therapy as frequently as every two cycles. **OR** b. At end of chemotherapy and again at end of radiation (at least 12 weeks after radiation therapy completion). **OR** c. Biopsy proven recurrence. **OR** d. 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.	a. A single follow-up PET/CT may be approved if end of therapy PET/CT shows Deauville 4 or 5 FDG avidity.

P. <u>Lymphoma, including Non-Hodgkin Disease</u>		
<u>Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)</u> PET imaging is not indicated in the evaluation of CLL/SLL, with the exception of suspected Richter's transformation.		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. Not routinely indicated for initial staging.	a. 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.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
<u>Diffuse Large B Cell</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. PET may be used as the initial imaging technique for staging/diagnosis.	a. Treatment response **for all stages** after 3-4 cycles of chemotherapy. c. At the end of chemotherapy and/or again at the end of radiation therapy. **OR** d. Suspected recurrence or biopsy confirmed recurrence. **OR** e. CAR-T cell therapy: Once before treatment and once 30-60 days after completion of treatment.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
<u>Follicular Lymphoma with WHO grade of 1 (low) or 2 (intermediate)</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
For any of the following: a. Stage I or II disease when radiation therapy is being considered; **OR** b. If systemic therapy is planned; **OR**	a. Monitoring response to therapy; End of therapy evaluation. **OR** b. Suspicion of progression; suspected transformation (Richter's) from a low-grade lymphoma to a more aggressive	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

c. Pediatric-type follicular lymphoma in adults.	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.	
<u>Marginal Zone</u>		
1. Initial Staging/Diagnosis	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
PET/CT for either of the following: a. If radiation therapy is being considered for stage, I or II disease; **OR** **b.** If systemic therapy is planned.	a. End of therapy evaluation. **OR** b. Suspected recurrence in rare circumstances such as bone involvement.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
<u>Mantle Cell</u>		
1. Initial Staging/Diagnosis	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. PET/CT may be used as the initial imaging technique for staging.	a. PET/CT can be considered for end of therapy evaluation. **OR** b. PET/CT can be considered in rare circumstances such as bone involvement.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
<u>Burkitt's</u>		
1. Initial Staging/Diagnosis	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
b. PET may be used as the initial imaging technique for staging.	a. End of chemotherapy and again at the end of radiation therapy. **OR** b. Suspected recurrence in rare circumstances such as bone involvement.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
<u>Cutaneous and T-Cell Lymphomas</u> (includes Primary Cutaneous B Cell Lymphomas, Peripheral T-Cell Lymphomas, Mycosis Fungoides/Sézary Syndrome, Anaplastic Large Cell Lymphoma, Angioimmunoblastic lymphoma, and Primary Cutaneous CD30+T Cell Lymphoproliferative Disorders)		
1. Initial Staging/Diagnosis	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. PET may be used as the initial imaging technique for staging.	a. Monitoring response to therapy: i. After 3-4 cycles. **OR**	a. Not routinely indicated for surveillance imaging in an

	ii. At the end of chemotherapy and again at the end of radiation therapy. **OR** iii. Suspected recurrence in rare circumstances such as bone involvement.	asymptomatic individual with no clinical or laboratory evidence of disease.
Q. <u>Melanoma</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. Primary site is unknown and CT chest and abdomen/pelvis are negative. **OR** b. Any of the following: Stage III (sentinel node positive and palpable regional nodes or Stage IV (metastatic).	a. When conventional imaging is inconclusive or isolated metastatic based on results of conventional imaging, initially.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
R. <u>Metastatic (Lung, Liver, Brain and Adrenal)</u>		
When primary cancer is known, PET scan imaging should follow the primary cancer guideline. 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. PET scan is not indicated for assessing the response to ablation therapy regardless of the modality of ablation. 3. Brain - metastases and no known primary tumor; inconclusive conventional imaging; or to confirm either stable systemic disease or absence of other metastatic disease. Brain metastases treated with radiation therapy, with recent MRI Brain and MR Perfusion studies both unable to distinguish radiation necrosis versus tumor progression. 4. Adrenal - biopsy is not feasible or is non-diagnostic; isolated metastasis on conventional imaging and patient is a candidate for aggressive surgical management.		
S. <u>Multiple Myeloma and Plasmacytomas</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance

After completion of skeletal CT and MRI scans, PET/CT for: a. Determine if plasmacytoma is truly solitary. **OR** b. Suspected extraosseous plasmacytomas. **OR** c. Suspected progression of monoclonal gammopathy of unknown significance (MGUS) or SMM to a more malignant form and CT/MRI imaging are negative; **OR** d. Whole body skeletal CT and MRI bone marrow are negative, inconclusive or not feasible.	a. When a negative PET will allow change in management from active treatment to maintenance or surveillance. **OR** b. Inconclusive findings on conventional imaging.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
T. <u>Neuroendocrine Cancers – Gastrointestinal/Pancreatic</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/progression	3. Surveillance
a. PET/CT scan with any one of the following SSR radiotracers: ^{68}Gallium DOTATATE, ^{68}Ga-DOTATOC or ^{64}Cu-DOTATATE for continued suspicion with negative/inconclusive findings on CT scan or MRI. **OR** b. FDG PET/CT scan for the following indications: i. Markers fail to normalize after complete surgical resection AND CT/MRI and somatostatin-receptor based study are negative; **OR** ii. Biopsy-proven neuroendocrine tumor of unknown primary site AND CT/MRI and somatostatin-receptor based study are negative.	<u>Restaging/Recurrence</u>: a. PET/CT scan with any one of the following SSR radiotracers: ^{68}Gallium DOTATATE, ^{68}Ga-DOTATOC or ^{64}Cu-DOTATATE for: i. Continued suspicion for recurrence with negative or inconclusive CT scan or MRI; **OR** ii. To assess candidacy for peptide receptor radionuclide therapy (PRRT) with Lutetium ^{177}Lu-dotatate.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
U. <u>Ovarian Carcinoma</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance

a. Primary peritoneal disease with biopsy-proven malignancy consistent with ovarian carcinoma. **OR** b. Elevated tumor markers with negative or inconclusive CT imaging.	<u>Restaging/Recurrence</u>: a. CT negative or inconclusive and CA-125 continues to rise or elevated LFTs. **OR** b. Conventional imaging failed to demonstrate tumor or if persistent radiographic mass with rising tumor markers.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
V. <u>Pancreatic Carcinoma</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. No evidence of metastatic disease on CT or MRI and any of the following high- risk features: i. Borderline resectable disease ii. Markedly elevated CA19-9 iii. Large primary tumor(s) iv. Enlarged regional lymph nodes	a. Not routinely indicated for response to therapy/progression imaging.	b. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
W. <u>Prostate Cancer</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. PET/CT scan using any **ONE** of the following radiotracers: • ^{68}Ga PSMA-11 • ^{18}F Piflufolastat (Pylarify) • ^{68}Ga Gozetotide (Illuccix and Locametz) • ^{18}F Flotufolastat (Posluma) For: Localized prostate cancer with any of the following NCCN Risk Groups: Unfavorable Intermediate Risk, High Risk or Very High Risk. b. PET/CT scan using any **ONE** of the following radiotracers: • ^{18}F-Fluciclovine • ^{11}C Choline • ^{68}Ga PSMA-11 • ^{18}F Piflufolastat (Pylarify)	a. PET/CT scan using any one of the following radiotracers: • ^{68}Ga PSMA-11 • ^{18}F Piflufolastat (Pylarify) • ^{68}Ga Gozetotide (Illuccix and Locametz) • ^{18}F Flotufolastat (Posluma) For: Non-metastatic prostate cancer previously treated with prostatectomy or radiation therapy, and **ALL** of the following are met: • PSA rises on two (2) consecutive measurements above post-treatment baseline **AND** • PSA ≥0.5 ng/mL **AND** • Individual is a candidate for salvage local therapy.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

• ^{68}Ga Gozetotide (Illuccix and Locametz) • ^{18}F Flotufolastat (Posluma) For: • Inconclusive bone findings on both CT/MRI and bone scan. • Conventional imaging studies (CT and bone scan) suggests oligo- or low volume metastatic disease that need further confirmation.	b. PET/CT scan using any one of the following radiotracers: • ^{18}F-Fluciclovine • ^{11}C Choline • ^{68}Ga PSMA-11 • ^{18}F Piflufolastat (Pylarify) • ^{68}Ga Gozetotide (Illuccix and Locametz) • ^{18}F Flotufolastat (Posluma) For: Non-metastatic prostate cancer previously treated with prostatectomy or radiation therapy, and **ALL** of the following are met: • PSA rises on two consecutive measurements above post-treatment baseline; **AND** • PSA ≥1 ng/mL; **AND** • Recent CT scan and bone scan are negative for metastatic disease; **AND** • Individual is a candidate for salvage local therapy. c. PSMA PET scan using **ONE** of the following radiotracers: • ^{68}Ga PSMA-11 • ^{18}F Piflufolastat (Pylarify) • ^{68}Ga Gozetotide (Illuccix and Locametz) • ^{18}F Flotufolastat (Posluma) For: Previously treated metastatic cancer progressed on conventional imaging and being considered for ^{177}Lu-PSMA-617 (Pluvicto) treatment. d. PET/CT scan using any one of the following radiotracers: • ^{18}F-Fluciclovine • ^{11}C Choline • ^{68}Ga PSMA-11 • ^{18}F Piflufolastat (Pylarify) • ^{68}Ga Gozetotide (Illuccix and Locametz) • ^{18}F Flotufolastat (Posluma) For: i. Inconclusive bone findings on both CT/MRI and bone scan.	

	ii. Conventional imaging studies (CT and bone scan) suggests oligo- or low volume metastatic disease that needs further confirmation.	
PET/CT scans using ^{18}F-FDG radiotracers are considered **investigational** for all indications for prostate cancer.		
X. <u>Soft Tissue Sarcoma</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. PET/CT may be used for **either** of the following: i. Grade of tumor in doubt following biopsy. **OR** ii. Conventional imaging suggests solitary metastasis amenable to surgical resection.	<u>Restaging/Recurrence</u> a. PET/CT may be used for **ANY** of the following: i. Differentiate tumor from radiation or surgical fibrosis. **OR** ii. Determine response to neoadjuvant therapy. **OR** iii. Confirm oligometastatic disease prior to curative intent surgical resection.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
Y. <u>Solitary Pulmonary Nodule</u>		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. Pulmonary nodule 8 mm (0.8 cm) to 30 mm (3 cm) seen on CT Chest or MRI Chest. **OR** b. If PET is positive: qualifies as initial staging PET/CT. **OR** c. Prior to biopsy of pulmonary mass greater than 3.1 cm (31 mm) seen on CT or MRI when: i. Definitive treatment with resection or radiation 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.	a. Not routinely indicated for response to therapy/ progression imaging.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

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.		
Z. Testicular Carcinoma (Seminoma or Non-Seminomatous Germ Cell Tumor)		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. Investigational	a. Monitoring response to therapy - Seminoma with residual mass greater than 3 cm after completion of chemotherapy.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
PET/CT scan is not indicated for evaluation of non-seminomatous germ cell tumors.		
AA. Thoracic Tumors		
Malignant Pleural Mesothelioma		
1. Initial Workup/Staging	2. Subsequent Treatment Strategies – Restaging	3. Surveillance
a. Cytologically **OR** pathologically proven. i. if no evidence of metastatic disease; **OR** ii. inconclusive conventional imaging.	a. Following induction chemotherapy prior to surgical resection if no evidence of metastatic disease.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
Thymoma		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. To evaluate inconclusive findings on CT.	b. To evaluate inconclusive findings on CT. **OR** c. Following induction chemotherapy prior to surgical resection if no evidence of metastatic disease.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
BB. Thyroid Cancers		
Follicular, Papillary and Hurthle Cell Carcinomas		
1. Initial Staging	2. Subsequent Treatment Strategies – Restaging/Recurrence	3. Surveillance
a. Routine preoperative advanced imaging is not indicated.	a. Negative CT scan and radioiodine scan and rising thyroglobulin level and radioiodine scan; **OR**	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

	b. Known radioiodine-refractory disease and CT scans are negative or inconclusive.	
Medullary Thyroid Carcinoma		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. ^{68}Gallium DOTATATE PET/CT scan: i. To evaluate inconclusive finding on conventional imaging.	a. ^{68}Gallium DOTATATE PET/CT scan: i. To evaluate inconclusive conventional imaging with calcitonin greater than or equal to 150 pg per mL.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
Anaplastic Thyroid Carcinoma		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. To evaluate inconclusive finding on conventional imaging.	a. Signs and symptoms of recurrence.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
CC. Transitional Cell: Bladder/Ureters/Urethra/Renal Pelvis		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. To evaluate inconclusive findings on conventional imaging.	Restaging/Recurrence: a. To evaluate inconclusive findings on conventional imaging.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
DD. Unknown (Occult) Primary Site		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. Primary site cannot be determined by prior CT or MRI, bone scan or diagnostic mammogram and full pelvic exam. **OR** b. CT scans reveal isolated metastatic disease for which definitive curative therapy is planned.	a. Not routinely indicated for response to therapy/ progression imaging.	b. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

EE. Uterine Cancer		
1. Initial Staging	2. Subsequent Treatment Strategies – Response to therapy/ progression	3. Surveillance
a. To evaluate inconclusive findings on conventional imaging.	a. To evaluate inconclusive findings on conventional imaging.	a. Not routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

III. Based upon our criteria and assessment of the peer-reviewed literature, the use of 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, musculoskeletal extremities, renal, and parathyroid; and
   C. Acute lymphoblastic leukemia, acute myeloid leukemia, and chronic myeloid leukemia.

IV. Based upon our criteria and assessment of the peer-reviewed literature, PET imaging using ^{18}F-FDG isotope is considered **medically appropriate**, as are the following radiotracers with indications listed:
   A. ^{68}Gallium DOTATATE (NETSPOT) for low-grade neuroendocrine tumors and medullary thyroid cancer;
   B. ^{64}Cu-DOTATATE (DETECTNET) (HCPCS A9592) for low-grade neuroendocrine tumors; or
   C. ^{68}Ga-DOTA-TOC (HCPCS C9067) for low-grade neuroendocrine tumors; or
   D. ^{11}C Choline for prostate cancer; or
   E. ^{18}F-Fluciclovine (AXUMIN) for prostate cancer; or
   F. ^{68}Ga PSMA-11 (HCPCS A9593 and A9594) for prostate cancer; or
   G. ^{18}F Piflufolastat PSMA (Pylarify) (HCPCS A9595) for prostate cancer; or
   H. ^{68}Ga Gozetotide (Illuccix (HCPCS A9596) and Locametz (HCPCS A9800) for prostate cancer.
   I. ^{18}F Flotufolastat (Posluma) (HCPCS A9608) for prostate cancer.

V. Based upon our criteria and assessment of the peer-reviewed literature, PET/CT scans using the following listed radiotracer is considered **investigational**:
   A. ^{18}F Fluoroestradiol (HCPCS A9591)

VI. Based upon our criteria and assessment of the peer-reviewed literature, PET scans should be delayed at least twelve weeks after completion of radiation treatment, unless required sooner for imminent surgical resection.

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

Refer to Corporate Medical Policy #6.01.07 Positron Emission Tomography Non-Oncologic Applications

Refer to Corporate Medical Policy #6.01.19 Low-dose Computed Tomography (LDCT) for Lung Cancer Screening

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

Refer to Corporate Medical Policy #11.01.10 Clinical Trials

POLICY GUIDELINES

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

II. Except for the indications listed in the Policy Statement section, PET is **NOT** indicated:
   A. Concomitantly, with separate diagnostic CT studies; or
   B. For surveillance; or
   C. For distant or diffuse metastatic disease; or
   D. For metastatic disease in the central nervous system (CNS); or
   E. For lesions less than 8 mm in size; or

F. For follow-up after localized therapy (e.g., radiofrequency ablation, embolization, or stereotactic radiation).

III. 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.

IV. 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.

V. PET may be considered prior to biopsy to determine a more favorable site for biopsy when a prior biopsy was nondiagnostic or when a relatively inaccessible site is contemplated that would require invasive surgical intervention for biopsy attempt.

VI. PET for Radiation Therapy Planning may be considered when ordered by a radiation oncologist prior to initiation of treatment for one of the cancers listed in Policy Statement II: Indications Grid.

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 progression, 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; or
   D. Surveillance, which is defined as a study performed beyond the completion of treatment, for asymptomatic or chronic stable symptoms with no clinical suspicion of change in disease status and not receiving active treatment 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), which 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 radiotracers, intravenously injected or inhaled, are used for PET scanning, including oxygen-15, nitrogen-13, carbon-11, rubidium-82 and fluorine-18. The radiotracer most 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, as tumor cells show increased metabolism of glucose. The most common malignancies studied have been melanoma, lymphoma, lung, and colorectal. Researchers continue to develop and investigate new radiotracers for PET scan imaging. Somatostatin receptors (SSRs or SSTRs) are present on the cell surface of neuroendocrine cells, providing a unique and specific molecular target for imaging. Prostate-specific membrane antigen (PSMA) is a transmembrane protein present in all prostatic tissues and almost all prostate adenocarcinomas show PSMA expression in both primary and metastatic lesions. PSMA-targeted PET imaging is being utilized for the detection of prostate cancer. SSR PET radiotracers as well as PSMA PET radiotracers are now receiving FDA approval as well as National Comprehensive Cancer Network (NCCN) recommendations. The most recent radiotracer approved by the FDA is F-18 flotufolastat PSMA is a PET imaging agent that is part of a novel class of tracers referred to as radio hybrid (rh) ligands. These rh ligands have the unique advantage of offering two binding sites for radionuclides (i.e., F-18 or Ga-68) which increases its flexibility in imaging. In addition, the presence of a chelator in these rh ligands also allows for chelation of Lu-177 for its use as a theranostic as well as imaging agent.

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.

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 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 regulates 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 magnetic resonance spectroscopy (MRS).

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. 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.

Neuroendocrine Tumors

Clinical evidence supports the use of PET or PET/CT in the management of patients with neuroendocrine tumors. Current NCCN guidelines for neuroendocrine tumors (v.1.2023) have recommended somatostatin receptor-based imaging with

PET/CT or PET/MRI, using somatostatin receptor PET tracers, ^{68}Ga-dotatate, ^{68}Ga-dotatoc, or ^{64}Cu-dotatate to assess receptor status and presence of distant disease. Somatostatin receptor imaging can assist in determining if a patient would benefit from receiving a somatostatin receptor-directed therapy. Use of FDG-PET may be considered to identify high-grade active disease in selected patients when high-grade neuroendocrine tumors or poorly differentiated carcinomas are documented or suspected or when disease is growing rapidly. For certain types of neuroendocrine tumors (e.g., well-differentiated, grade 3), somatostatin receptor-based imaging with PET/CT or PET/MRI or FDG-PET/CT scans for surveillance are recommended as clinically indicated.

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 that addressed the use of FDG PET for prostate cancer. CMS found little evidence concerning the 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 agreed 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 noted 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, considered its use for subsequent treatment strategy planning 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. Prostate-specific membrane antigen (PSMA) is a transmembrane protein present in all prostatic tissues and almost all prostate adenocarcinomas show PSMA expression in both primary and metastatic lesions. PSMA-targeted PET imaging is now being utilized for the detection of prostate cancer. NCCN guidelines for Prostate Cancer state, although the FDA has approved Ga-68 PSMA-11 for use with Lu-177–Prostate-specific membrane antigen (PSMA)-617, the panel believes that F-18 piflufolastat PSMA and F-18 flotufolastat PSMA can also be used in the same space due to multiple reports describing the equivalency of these imaging agents in: PSMA molecular recognition motifs, normal organ biodistribution, and detection accuracy of prostate cancer lesions.

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 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, 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

- *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 Codes

Code	Description
78811	Positron emission tomography (PET) imaging; limited area (e.g., 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 imaging; limited area (e.g., chest, head/neck)
78815	skull base to mid-thigh
78816	whole body

HCPCS Codes

Code	Description
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

Code	Description
A9587	Gallium Ga-68, dotatate, diagnostic, 0.1 millicurie
A9588	Fluciclovine f-18, diagnostic, 1 millicurie
A9591 **(E/I)**	Fluoroestradiol f 18, diagnostic, 1 millicurie
A9592	Copper cu-64, dotatate, diagnostic, 1 millicurie
A9593	Gallium Ga-68 PSMA-11, diagnostic, 1 millicurie (UCSF)
A9594	Gallium Ga-68 PSMA-11, diagnostic, 1 millicurie (UCLA)
A9595	Piflufolastat f-18, diagnostic, 1 millicurie
A9596	Gallium GA-68 gozetotide, diagnostic, (illuccix), 1 millicurie
A9597	Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified
A9608	Flotufolastat f 18, diagnostic, 1 millicurie (Posluma) *(Effective 01/01/2024)*
A9800	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie
C9067	Gallium Ga-68, dotatoc, diagnostic, 0.01 millicurie
G0219 **(E/I)**	PET imaging whole body; melanoma for 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 Codes

Code	Description
Numerous codes	

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*Key Article

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 (220.6.17). 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=AgAAgAAAAAAAAA%3d%3d&] accessed 10/26/23.

There is currently a National Coverage Determination (NCD) for Positron Emission Tomography (FDG) for (NaF-18) to Identify Bone Metastasis of Cancer (22.6.19). 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=AgAAgAAAAAAAAA%3d%3d&] accessed 10/26/23.

There is currently a National Coverage Determination (NCD) for Positron Emission Tomography (FDG) scans (220.6). 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=AgAAgAAAAAAAAA%3d%3d&] accessed 10/26/23.

There is currently a Final Decision Memo for Positron Emission Tomography (FDG) for Solid Tumors (CAG-00181R4). Please refer to the following CMS website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=263] accessed 10/26/23.