MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Positron Emission Tomography (PET) Oncologic Applications**
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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 imaging integrated with computed tomography (FDG PET/CT), is considered **medically appropriate** in a small subset of patients with a high likelihood of cancer, when **BOTH** of the following are met:
   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, PET, and PET/CT imaging are considered **medically appropriate** when cancer-specific criteria are met:

Links to the cancer-specific criteria:

Anal Cancer

Breast Cancer

Cervical Cancer

Colorectal and Small Bowel Cancer: Colorectal and Appendiceal Adenocarcinoma, (including pseudomyxoma peritoneal, follows colorectal cancer imaging guidelines.)

Esophageal and Gastroesophageal (GE) Junction Cancer

Leukemia: Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

Lung Cancer: Non-Small Cell (NSCLC) and Small Cell Lung Cancer (SCLC)

Lymphoma: Hodgkin Lymphoma (Classical or Nodular Lymphocyte-predominant)

Melanoma

Metastatic Cancer, Carcinoma of Unknown Primary Site: Lung, Liver, Brain, Adrenal, and Unknown Primary Site

Multiple Myeloma and Plasmacytomas

Neuroendocrine Cancers and Adrenal Tumors: Adrenal tumors, Adrenocortical Carcinoma, Bronchopulmonary/Thymic Carcinoids, and Gastrointestinal/Pancreatic Neuroendocrine Cancer

Non-Hodgkin Lymphomas: Non-Hodgkin Lymphomas (General Criteria), Diffuse Large B Cell Lymphoma (DLBCL), Follicular Lymphoma, Marginal Zone Lymphoma, Mantle Cell and Burkitt's, and T-Cell Lymphomas.

Ovarian Cancer

Pancreatic Cancer

Primary Central Nervous System Tumors: Brain Tumors, Gliomas (Low- and High-Grade)

Prostate Cancer

Sarcomas: Ewing Sarcoma Family of Tumors (ESFT), and Gastrointestinal Stromal Tumor (GIST), Osteogenic Sarcoma, and Soft Tissue Sarcoma.

Squamous Cell Carcinomas of the head and Neck

Testicular, and Extragonadal Germ Cell Tumors: Seminoma or Non-Seminomatous

Thoracic Cancers: Malignant Pleural Mesothelioma and Thymoma and Thymic Carcinomas

Thyroid Cancers: Follicular, Papillary and Hurthle Cell Carcinomas, Medullary, Anaplastic

Transitional Cell Cancers: Tumors of the Bladder/Ureters/Urethra/Renal Pelvis

Upper Gastrointestinal (GI) Cancers: Hepatocellular (HCC)/Gallbladder/Biliary and Gastric Cancer

Uterine Cancers

Anal Cancer

A. **Anal Cancers**
   1. Initial Work-up/Staging:
      a. PET/CT imaging is appropriate for initial work-up/staging for **either** of the following indications:
         i. 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**
         ii. inconclusive findings on conventional imaging; **or**
   2. Restaging/Recurrence:
      a. PET/CT is appropriate when there are inconclusive findings on conventional imaging; **or**
   3. Surveillance:
      a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Breast Cancer

B. **Breast Cancer (applies to invasive and pre-invasive [lobular and ductal carcinomas in-situ] histologies of breast cancer)**
   1. Initial Work-up/Staging:
      a. PET/CT imaging is appropriate for initial work-up/staging when CT and bone scan are inconclusive; **or**
   2. Restaging/Recurrence:
      a. F-FDG PET/CT may be used for **either** of the following indications:
         i. Inconclusive CT, MRI, and/or bone scan for suspected recurrence, and further characterization is needed to make treatment decisions; **or**

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; **or**

b. ^{18}F-FES (fluoroestradiol) PET/CT scan may be used to determine the ER-status of suspected/known metastatic recurrence noted on CT/bone scan and **either** of the following:
   i. Biopsy of metastatic site is non-diagnostic/inconclusive; **or**
   ii. Biopsy of metastatic site is risky and cannot be performed (metastatic sites in the brain, spine or near vascular structures; **or**

c. PET is **NOT** indicated for systemic restaging after neoadjuvant chemotherapy or after surgery; **or**

3. Surveillance:
   a. PET/CT is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease; **or**
4. Advanced imaging to evaluate for distant metastases is **NOT** indicated for asymptomatic individuals with invasive or pre-invasive or in-situ breast cancer (histology such as DCIS and LCIS).

Cervical Cancer

C. **Cervical Cancer**
1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for initial work-up/staging for **either** of the following indications:
      i. Stage IB1 or higher stages; **or**
      ii. inconclusive findings on conventional imaging; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for restaging after therapy for **either** of the following indications:
      i. Stage I-III treated with primary radiation therapy with or without chemotherapy (no surgery), at least 12 weeks after completion of treatment; **or**
      ii. suspected or biopsy proven recurrence; **or**
3. Surveillance:
   a. PET imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Colorectal and Small Bowel Cancer

D. **Colorectal Cancer (appendiceal adenocarcinoma, including pseudomyxoma peritoneal, follows colorectal cancer imaging guidelines)**
1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for initial work-up/staging for **either** of the following indications:
      i. 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**
      ii. inconclusive findings on conventional imaging; **or**
   b. PET/CT imaging is **NOT** indicated for initial staging for small bowel cancer; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for **ANY** of the following indications:
      i. 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;
      ii. to differentiate local tumor recurrence from postoperative and/or post-radiation scarring;
      iii. postoperative elevated or rising carcinoembryonic antigen (CEA) or Liver Function Tests (LFTs) with negative recent conventional imaging; **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging for colorectal and small bowel cancers.

Esophageal and Gastroesophageal (GE) Junction Cancer

E. **Esophageal and GE Junction Cancer**

1. Initial Workup/Staging:
   a. PET/CT imaging is appropriate for initial work-up/staging if there is no evidence of metastatic disease by conventional imaging; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for restaging after therapy for **ANY** of the following indications:
      i. If conventional imaging inconclusive;
      ii. decision making after primary chemoradiation therapy prior to surgery (no sooner than eight (8) weeks post completion of radiation therapy);
      iii. if a salvage surgical candidate with recurrence and no metastatic disease documented by conventional imaging; **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Leukemia

F. **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**
1. Initial Work-up/Staging:
   a. PET imaging is **NOT** indicated in the evaluation of CLL/SLL, with the exception of suspected Richter's transformation; **or**
2. Suspected Transformation:
   a. PET/CT imaging is appropriate for suspected transformation (Richter's) from a low-grade lymphoma to a more aggressive type based on **ANY** of the following:
      i. New B symptoms;
      ii. Rapidly growing lymph nodes;
      iii. Extranodal disease develops;
      iv. Significant recent rise in LDH above normal range; **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Lung Cancer

G. **Non-Small Cell (NSCLC) includes adenocarcinoma, squamous cell carcinoma, adenosquamous and large cell tumors.**
1. Suspected/Diagnosis:
   a. PET/CT imaging is generally **NOT** indicated for initial staging or restaging of NSCLC when multiple sites of extra-pulmonary metastases are found on conventional imaging (i.e., liver, bone and adrenal metastases, etc.); **or**
   b. PET/CT imaging 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; **or**
   c. PET/CT imaging is appropriate with **either** of the following indications:
      i. 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**
      ii. Pulmonary mass 31 mm (3.1 cm) or greater seen on CT or MRI, PET/CT is appropriate prior to biopsy if **either** of the following applies:
         (a) Definitive treatment with resection or radiation will be utilized instead of biopsy if PET confirms limited disease;
         (b) Multiple possible biopsy options are present within the chest and PET findings will be used to determine the most favorable biopsy site; **or**
2. Initial Work-up/Staging (after tissue diagnosis):

a. PET/CT imaging is indicated for **ANY** of the following indications: (If not already completed prior to histological diagnosis):
   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; **or**

3. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for **ANY** of the following indications:
      i. Suspected/biopsy-proven recurrence localized to the chest cavity;
      ii. Inconclusive findings on conventional imaging;
      iii. To differentiate tumor from radiation scar/fibrosis;
      iv. 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; **or**
4. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

H. **Small Cell Lung Cancer (SCLC)**
1. Suspected /Diagnosis:
   a. PET imaging is appropriate for suspected/diagnosis when there is 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**
2. Initial Work-up/Staging:
   a. PET /CT imaging is appropriate for initial staging to confirm the extent of disease when initial CT and MRI indicate limited stage disease (confirmed to one side of the chest); **or**
3. Restaging/Recurrence:
   a. PET imaging is **NOT** indicated for evaluation of recurrent SCLC but can be considered on a case-by-case basis; **or**
4. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

<u>Lymphoma</u>

I. **Hodgkin Lymphoma (Classical or Nodular Lymphocyte-predominant)**
1. Initial Work-up/Staging:
   a. PET/CT imaging may be used for initial staging in both Classical and Nodular Hodgkin Lymphoma for **ANY** of the following indications:
      i. As the initial imaging technique for staging;
      ii. Determine a more favorable site for biopsy when a relatively inaccessible site is contemplated;
      iii. CAR-T cell therapy: Once before treatment and once 30-60 days after completion of treatment; **or**
   b. PET/CT is **not medically necessary** for all other indications prior to histological confirmation of lymphoma; **or**
2. Restaging/Recurrence:
   a. **Classical Hodgkin Lymphoma:** PET/CT imaging for is appropriate for **ANY** of the following indications:
      i. Monitoring response to therapy as frequently as every two (2) cycles;
      ii. At end of chemotherapy and again at end of radiation (at least 12 weeks after radiation therapy completion);
      iii. Biopsy proven recurrence; **or**

b. **Nodular Lymphocyte – Predominant Hodgkin Lymphoma:** PET/CT imaging for is appropriate for **any** of the following indications:
   i. At end of chemotherapy and again at end of radiation (at least 12 weeks after radiation therapy completion);
   ii. Biopsy proven recurrence; **or**

3. Suspected Recurrence:
   a. **Nodular Lymphocyte – Predominant Hodgkin Lymphoma**: Suspected transformation (Richter's) from a low-grade lymphoma to a more aggressive type based on **ANY** of the following:
      i. New B symptoms;
      ii. Rapidly growing lymph nodes;
      iii. Extranodal disease develops;
      iv. Significant recent rise in LDH above normal range; **or**
4. Surveillance:
   a. **Classical and Nodular Lymphocyte – Predominant Hodgkin Lymphoma:** A single follow-up PET/CT may be approved at three (3) months if the end of therapy PET/CT shows Deauville 4 or 5 FDG avidity.

Melanoma

J. **Melanoma**
1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for initial staging for **ANY** of the following indications:
      i. Stage III (sentinel node positive and palpable regional nodes);
      ii. Stage IV (metastatic);
      iii. primary site is unknown and CT chest and abdomen/pelvis are negative; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for restaging/recurrence for **either** of the following indications:
      i. Inconclusive findings on conventional imaging;
      ii. isolated metastatic site found on conventional imaging; **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Metastatic Cancer, Carcinoma of Unknown Primary Site

K. **Metastatic (Lung, Liver, Brain, Adrenal, and Unknown Primary Site)**
1. The following criteria should only be used for individuals with metastatic cancer in **either** of the following circumstances:
   a. The primary diagnosis section does not address a particular metastatic site that is addressed in these sections;
   b. The cancer type is rare and does not have its own diagnosis-specific imaging guidelines; **AND**
2. PET/CT imaging is appropriate for **ANY** of the following metastatic cancer indications:
   a. **Adrenal**
      i. Biopsy is not feasible or is non-diagnostic;
      ii. isolated metastasis on conventional imaging and patient is a candidate for aggressive surgical management; **or**
   b. **Brain**
      i. Solidary brain metastasis suspected in individual with prior diagnosis of cancer;
      ii. brain metastases and no known primary tumor;
      iii. inconclusive conventional imaging;
      iv. to confirm either stable systemic disease or absence of other metastatic disease;

v. brain metastases treated with radiation therapy, with recent MRI Brain and MR Perfusion studies both unable to distinguish radiation necrosis versus tumor progression; **or**

c. **Liver**
   i. To confirm solitary metastasis amenable to resection on conventional imaging;
   ii. Liver function tests (LFT's) and/or tumor markers continue to rise, and CT and MRI are negative; **or**
   iii. PET imaging of the liver is **NOT** indicated for **either** of the following indications:
      (a) Assessing the response to ablation therapy regardless of the modality of ablation;
      (b) For routine surveillance of asymptomatic individuals after treatment completion; **or**

d. **Lung**
   i. Lung nodules greater than or equal to 8 mm;
   ii. to confirm solitary metastasis amenable to resection on conventional imaging; **or**

e. **Unknown (Occult) Primary Site**
   i. Primary cancer site cannot be determined by prior CT, MRI, bone scan or diagnostic mammogram and full pelvic exam;
   ii. CT imaging reveal isolated metastatic disease for which definitive curative therapy is planned.

Multiple Myeloma and Plasmacytomas

L. **Multiple Myeloma and Plasmacytomas**

1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for initial staging after completion of CT and MRI scans, and with **ANY** of the following indications:
      i. Determine if plasmacytoma is truly solitary;
      ii. suspected extraosseous plasmacytomas;
      iii. suspected progression of monoclonal gammopathy of unknown significance (MGUS) or Smoldering Multiple Myeloma (SMM) to a more malignant form and CT/MRI imaging are negative;
      iv. whole body skeletal CT and MRI bone marrow are negative, inconclusive or not feasible; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for restaging/recurrence for **ANY** of the following indications:
      i. CAR-T cell therapy: Once before treatment and once 30-60 days after completion of treatment.
      ii. when a negative PET will allow change in management from active treatment to maintenance or surveillance;
      iii. inconclusive findings on conventional imaging; **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Neuroendocrine Cancers and Adrenal Tumors

M. **Adrenal Tumors:**

1. Initial Work-up/Staging **and** Restaging/Recurrence:
   a. PET/CT imaging is appropriate for initial work-up/staging and restaging/recurrence for continued suspicion with negative/inconclusive CT scan or MRI;
      With one of the following SSR radiotracers:
      - ^{68}Gallium DOTATATE;
      - ^{68}Ga-DOTATOC;
      - ^{64}Cu-DOTATATE; **or**
   b. FDG PET/CT imaging is appropriate initial staging and restaging/recurrence if prior CT scans and MRI are negative and/or inconclusive; **or**
2. Surveillance:

a. PET imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

N. **Adrenocortical Carcinoma:**
1. Suspected Recurrence:
   a. FDG PET/CT imaging is appropriate for suspected recurrence for **either** of the following indications:
      i. Solitary adrenal mass is greater than 4 cm on conventional imaging with plans for aggressive surgical resection;
      ii. inconclusive findings on conventional imaging.

O. **Bronchopulmonary/Thymic Carcinoids**
1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for initial work-up/staging when there are inconclusive findings on CT or MRI scans;
      With one of the following SSR radiotracers:
      - ^{68}Gallium DOTATATE;
      - ^{68}Ga-DOTATOC;
      - ^{64}Cu-DOTATATE; **or**
   b. FDG PET/CT imaging is appropriate for initial staging when CT/MRI imaging and somatostatin-receptor based study are negative and **either** of the following:
      i. Markers fail to normalize after complete surgical resection;
      ii. biopsy proven neuroendocrine tumor of unknown primary site; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for restaging/recurrence for continued suspicion for recurrence with negative or inconclusive CT scan or MRI;
      With one of the following SSR radiotracers:
      - ^{68}Gallium DOTATATE;
      - ^{68}Ga-DOTATOC;
      - ^{64}Cu-DOTATATE; **or**
3. Surveillance:
   a. PET/CT is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

P. **Gastrointestinal/Pancreatic Neuroendocrine Cancer**
1. Suspected/Diagnosis or Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for suspected/diagnosis or initial work-up/staging when there is continued suspicion with negative or inconclusive findings on CT or MRI imaging;
      With one of the following SSR radiotracers:
      - ^{68}Gallium DOTATATE;
      - ^{68}Ga-DOTATOC;
      - ^{64}Cu-DOTATATE; **or**
   b. FDG PET/CT imaging is appropriate for suspected/diagnosis or initial staging when CT/MRI imaging and somatostatin-receptor based study are negative and **either** of the following:
      i. Markers fail to normalize after complete surgical resection;
      ii. biopsy proven neuroendocrine tumor of unknown primary site; **or**
2. Restaging/recurrence
   a. PET/CT imaging is appropriate for restaging/recurrence with **either** of the following indications:
      i. Continued suspicion for recurrence with negative or inconclusive CT scan or MRI;
      ii. to assess candidacy for peptide receptor radionuclide therapy (PRRT) with Lutetium ^{177}Lu-dotatate; **or**
      With one of the following SSR radiotracers:
      - ^{68}Gallium DOTATATE;

- ^{68}Ga-DOTATOC;
- ^{64}Cu-DOTATATE; **or**

3. Surveillance
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Non-Hodgkin Lymphomas

Q. **Non-Hodgkin Lymphomas (General Criteria)**
1. PET/CT imaging is appropriate for **either** of the following indications:
   a. To determine a more favorable site for biopsy when a relatively inaccessible site is contemplated;
   b. CAR-T cell therapy: Once before treatment and once 30-60 days after completion of treatment; **or**
2. PET/CT is **not medically necessary** for all other indications prior to histological confirmation of lymphoma.

R. **Diffuse Large B Cell Lymphoma (DLBCL) (Including Grey zone, primary mediastinal B cell, Grade 3 (high) follicular, double or triple-hit, primary cutaneous DLBCL lymphomas).**
1. Initial Staging/Diagnosis:
   a. PET/CT imaging may be used as the initial imaging technique for staging/diagnosis; **or**
2. Restaging/Recurrence:
   a. PET/CT is appropriate for restaging/recurrence for **ANY** of the following indications:
      i. Treatment response for all stages after 3-4 cycles of chemotherapy.
      ii. at the end of chemotherapy and/or again at the end of radiation therapy;
      iii. Suspected recurrence (can be considered in rare circumstances (e.g., bone involvement);
      iv. biopsy confirmed recurrence;
      v. CAR-T cell therapy: Once before treatment and once 30-60 days after completion of treatment; **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

S. **Follicular Lymphoma (Including, WHO grade 1 (low) or 2 (intermediate) and Primary Cutaneous Follicle Center Lymphomas).**
1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for initial work-up/staging for **ANY** of the following indications:
      i. If radiation therapy is being considered for Stage I or II disease;
      ii. if systemic therapy is planned;
      iii. Pediatric-type follicular lymphoma in adults; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for end of therapy evaluation; **or**
   b. PET/CT imaging is appropriate for suspected transformation (Richter's) from a low-grade lymphoma to a more aggressive type based on **ANY** of the following:
      i. New B symptoms;
      ii. Rapidly growing lymph nodes;
      iii. Extranodal disease develops;
      iv. Significant recent rise in LDH above normal range; **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

T. **Marginal Zone Lymphomas (Including mucosa associated lymphoid tissue (MALT) lymphomas in any location and primary cutaneous marginal zone lymphoma).**
1. Initial Work-up/Staging:

a. PET/CT imaging is appropriate for initial work-up/staging for **either** of the following indications:
   i. If radiation therapy is being considered for stage, I or II disease;
   ii. if systemic therapy is planned; **or**

2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for **either** of the following indications:
      i. End of therapy evaluation;
      ii. Suspected recurrence in rare circumstances (e.g., bone involvement); **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

U. **Mantle Cell and Burkitt's**
1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for initial imaging work-up/staging/diagnosis for Mantle Cell and Burkitt's; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for Mantle Cell and Burkitt's for **either** of the following indications:
      i. End of therapy evaluation (For Burkitt's Lymphoma it may be approved at the end of chemotherapy and again at the end of radiation);
      ii. Suspected recurrence in rare circumstances (e.g., bone involvement); **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

V. **T-Cell Lymphomas** (Includes Peripheral T-Cell Lymphomas, Mycosis Fungoides/Sézary Syndrome, Anaplastic Large Cell Lymphoma (ALCL) including breast implant-associated ALCL, Angioimmunoblastic lymphoma, and Primary Cutaneous CD30+T Cell Lymphoproliferative Disorders)
1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for initial work-up/staging/diagnosis of T-Cell Lymphomas; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for **ANY** of the following indications:
      i. Monitoring response to therapy following 3-4 cycles;
      ii. At the end of chemotherapy and again at the end of radiation therapy;
      iii. Suspected recurrence in rare circumstances (e.g., bone involvement); **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

<u>Ovarian Cancer</u>

W. **Ovarian Cancer**
1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for initial work-up/staging for **ANY** of the following indications:
      i. Primary peritoneal disease with biopsy-proven malignancy consistent with ovarian carcinoma;
      ii. Elevated tumor markers with negative or inconclusive CT imaging; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate for restaging/recurrence with **either** of the following indications:
      i. CT negative or inconclusive and CA-125 continues to rise or elevated LFTs;
      ii. Conventional imaging failed to demonstrate tumor or if persistent radiographic mass with rising tumor markers; **or**
3. Surveillance:

a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Pancreatic Cancer

X. **Pancreatic Cancer**
1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for initial work-up/staging when there is 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; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is **NOT** routinely indicated for response to therapy/progression imaging; **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Primary Central Nervous System Tumors

Y. **Brain Tumors (e.g., astrocytoma, oligodendroglioma)**
1. Initial Work-up/Staging:
   a. PET imaging is **NOT** indicated for initial work-up/staging of brain tumors; **or**
2. PET Brain Metabolic imaging is appropriate for individuals undergoing chemotherapy treatment with **either** of the following:
   a. **Low grade Gliomas** (defined by the World Health Organization (WHO) as I or II) with **either** of the following:
      i. Determine need for biopsy when transformation to high-grade glioma is suspected based on clinical symptoms or recent MRI findings;
      ii. evaluate a brain lesion of indeterminate nature when the study will be used to determine whether biopsy/resection can be safely postponed; **or**
   b. **High Grade Gliomas** (defined by the World Health Organization (WHO) as III or IV) with **ANY** of the following:
      i. Distinguish radiation-induced tumor necrosis from progressive disease;
      ii. 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;
      iii. evaluate a brain lesion of indeterminate nature when the study will be used to determine whether biopsy/resection can be safely postponed; **or**
3. Fusion PET/CT and full body PET imaging are **NOT** indicated for in the evaluation or management of primary CNS tumors; **or**
4. PET Brain imaging is **NOT** indicated in gliomas occurring in the brain stem due to poor uptake and lack of impact on individual outcomes.

Prostate Cancer

Z. **Prostate Cancer**
1. Initial Work-up/Staging:
   a. PSMA PET/CT imaging is appropriate for initial work-up/staging for localized prostate cancer with **ANY** of the following risk groups:
      i. Unfavorable Intermediate Risk;
      ii. High Risk;
      iii. Very High Risk;
      With one of the following radiotracers:

- ^{68}Ga PSMA-11;
- ^{18}F Piflufolastat (Pylarify);
- ^{68}Ga Gozetotide (Illuccix and Locametz);
- ^{18}F Flotufolastat (Posluma); **or**

b. PET/CT imaging is appropriate for work-up/initial staging for localized prostate cancer for **ANY** of the following indications:
   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 need further confirmation;
   With 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); **or**

2. Restaging/Recurrence:
   a. PSMA PET/CT imaging is appropriate for non-metastatic prostate cancer previously treated with prostatectomy or radiation therapy, and **ALL** of the following are met:
      i. PSA rises on two (2) consecutive measurements above post-treatment baseline; **and**
      ii. PSA ≥0.5 ng/mL; **and**
      iii. Individual is a candidate for salvage local therapy;
      With one of the following radiotracers:
      - ^{68}Ga PSMA-11;
      - ^{18}F Piflufolastat (Pylarify);
      - ^{68}Ga Gozetotide (Illuccix and Locametz);
      - ^{18}F Flotufolastat (Posluma); **or**

   b. PET/CT imaging is appropriate for non-metastatic prostate cancer previously treated with prostatectomy or radiation therapy, and **ALL** of the following are met:
      i. PSA rises on two consecutive measurements above post-treatment baseline; **and**
      ii. PSA ≥1 ng/mL; **and**
      iii. Recent CT scan and bone scan are negative for metastatic disease; **and**
      iv. Individual is a candidate for salvage local therapy;
      With 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); **or**

   c. PMSA PET/CT imaging is appropriate for previously treated metastatic cancer progressed on conventional imaging and being considered for ^{177}Lu-PSMA-617 (Pluvicto) treatment; **or**
      Using one of the following radiotracers:
      - ^{68}Ga PSMA-11;
      - ^{18}F Piflufolastat (Pylarify);
      - ^{68}Ga Gozetotide (Illuccix and Locametz);
      - ^{18}F Flotufolastat (Posluma); **or**

   d. PET/CT imaging is appropriate for **either** of the following indications:
      i. Inconclusive bone findings on both CT/MRI and bone scan; **or**

ii. conventional imaging studies (CT and bone scan) suggests oligo- or low volume metastatic disease that needs further confirmation;
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); **or**

3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease; **or**
4. PET/CT imaging using ^{18}F-FDG radiotracers are considered **investigational** for all indications for prostate cancer.

Sarcomas

AA. **Ewing Sarcoma Family of Tumors (ESFT) and Osteogenic Sarcoma**

1. Initial Work-up/Staging:
   a. PET/CT whole body imaging may be approved for initial work-up/staging after biopsy confirmed disease in addition to conventional imaging (i.e., MRI, CT, Chest CT); **or**
2. Restaging:
   a. PET/CT whole body imaging Restaging after 10-12 weeks of neoadjuvant chemotherapy prior to local control surgery; **or**
3. Treatment After Local Control Surgery:
   a. PET/CT whole body imaging following local control surgery at the end of planned chemotherapy (PET/CT whole body imaging can be used in place of bone scan, if positive for distant bone metastases at initial diagnosis); **or**
4. Metastatic disease undergoing current chemotherapy:
   a. PET/CT whole body imaging is appropriate for metastatic disease, if previously positive for boney metastases and can be done every two (2) cycles during treatment and at the end of planned chemotherapy; **or**
5. Recurrent metastatic or recurrent unresectable disease on treatment:
   a. PET imaging is generally NOT indicated during active treatment for recurrent pediatric cancer; **or**
   b. In rare circumstances PET imaging may be appropriate when results are likely to result in a treatment change for the individual, including a change from active treatment to surveillance and may be approved every two (2) cycles during treatment and at the end of planned chemotherapy; **or**
6. Suspected recurrence:
   a. PET/CT imaging is appropriate when there is a suspected recurrence, for **either** of the following:
      i. Conventional imaging reveals findings that are inconclusive or suspicious for recurrence and PET avidity will determine whether biopsy or continued observation is appropriate;
      ii. In 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**
7. Biopsy suspected recurrence:
   a. PET/CT whole body may be performed for biopsy proven recurrence; **or**
8. Surveillance:
   a. PET/CT has no established role for asymptomatic surveillance; **or**
9. PET/CT can replace bone scan and bone marrow biopsy in ESFT individuals and is indicated in the initial staging of all ESFT individuals after histologic diagnosis is established.

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

1. Initial Work-up/Staging and Known or Suspected Recurrence:
   a. PET/CT imaging is appropriate for Initial work-up/staging and for known or suspected recurrence of disease when the evaluation of findings on conventional imaging are inconclusive; **or**
2. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

CC. **Soft Tissue Sarcoma**

1. Initial Work-up/Staging:
   a. PET/CT imaging may be used for initial work-up/staging for **either** of the of the following indications:
      i. Grade of tumor in doubt following biopsy;
      ii. conventional imaging suggests solitary metastasis amenable to surgical resection; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging may be used for **ANY** of the following indications:
      i. Differentiate tumor from radiation or surgical fibrosis;
      ii. determine response to neoadjuvant therapy;
      iii. confirm oligometastatic disease prior to curative intent surgical resection; **or**
3. Surveillance
   a. PET/CT is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

<u>Squamous Cell Carcinomas of the Head and Neck</u>

DD. **Squamous Cell Carcinomas of the Head and Neck Cancers**

1. Suspected/Diagnosis:
   a. PET/CT is appropriate for suspected/diagnosis prior to biopsy in order to determine a more favorable site for biopsy with **either** of the following indications:
      i. A prior biopsy was nondiagnostic;
      ii. A relatively inaccessible site is contemplated which would require invasive surgical intervention for biopsy attempt; **or**
2. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate For **ANY** of the following indications:
      i. Known stage III or IV disease;
      ii. prior to start of primary chemoradiotherapy and have not undergone definitive surgical resection;
      iii. Nasopharyngeal (NPC) Cancer;
      iv. inconclusive findings on conventional imaging (CT, MRI);
      v. in order to direct laryngoscopy/exam under anesthesia for biopsy;
      vi. pulmonary nodule(s) greater than or equal to 8 mm in size;
      vii. cervical lymph node biopsy positive for squamous cell carcinoma and no primary site identified on CT or MRI of neck and chest;
      viii. inconclusive findings suggestive of disease outside the head and neck area; **or**
3. Restaging/Recurrence:
   a. PET/CT imaging is considered appropriate for **ANY** of the following indications;
      i. Following primary chemoradiotherapy or radiation therapy in an individual who has not undergone surgical resection of primary tumor or neck dissection;
      ii. biopsy proven local recurrence;
      iii. inconclusive conventional imaging (CT or MRI); **or**
   b. PET imaging is **NOT** indicated for **either** of the following:
      i. To assess response to induction chemotherapy;
      ii. if post-treatment PET/CT scan is negative; **or**

4. Surveillance:
    a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Testicular, and Extragonadal Germ Cell Tumors

EE. **Testicular and Germ Cell Tumor (Seminoma or Non-Seminomatous)**

1. Initial Work-up/Staging:
    a. PET/CT imaging for initial work-up/staging of testicular cancer is considered **investigational**;
    b. PET/CT imaging for evaluation of non-seminomatous germ cell tumors is considered **investigational**; **or**
2. Restaging/Recurrence:
    a. **Pure Seminoma Tumor**: PET/CT imaging is appropriate for monitoring a seminoma tumor with residual mass greater than 3 cm after completion of chemotherapy; **or**
3. Surveillance:
    a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Thoracic Tumors

FF. **Malignant Pleural Mesothelioma**

1. Initial Work-up/Staging:
    a. PET/CT imaging is appropriate for initial work up/staging when cytologically or pathologically proven and **either** of the following:
        ii. If no evidence of metastatic disease;
        iii. imaging is inconclusive; **or**
2. Restaging/Recurrence:
    a. PET/CT imaging is appropriate following induction of chemotherapy prior to surgical resection if there is no evidence of metastatic disease; **or**
3. Surveillance:
    a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

GG. **Thymoma and Thymic Carcinomas**

1. Initial Work-up/Staging:
    a. PET/CT imaging is appropriate for initial work-up/staging when there are inconclusive findings on CT imaging; **or**
2. Restaging/Recurrence:
    a. PET/CT imaging is appropriate for **either** of the following indications:
        i. following induction chemotherapy prior to surgical resection if no evidence of metastatic disease;
        ii. inconclusive findings on CT imaging; **or**
3. Surveillance:
    a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Thyroid Cancers

HH. **Follicular, Papillary and Hurthle Cell Carcinomas**

1. Initial Staging:
    a. Routine preoperative advanced imaging is not indicated for initial work-up/staging; **or**
2. Restaging/Recurrence:
    a. FDG PET/CT imaging is appropriate for **ANY** of the following indications:
        i. Rising thyroglobulin level with negative CT scans and radioiodine scans;
        ii. Inconclusive findings on conventional imaging (CT scans and radioiodine scans);

iii. Known radioiodine-refractory disease and CT scans are negative or inconclusive; **or**

3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

II. **Medullary Thyroid Cancer**

1. Initial Work-up/Staging:
   a. ^{68}Gallium DOTATATE PET/CT imaging is appropriate to evaluate findings on conventional imaging are inconclusive; **or**
2. Restaging/Recurrence:
   a. ^{68}Gallium DOTATATE PET/CT imaging is appropriate to evaluate inconclusive conventional imaging with calcitonin greater than or equal to 150 pg per mL; **or**
3. Surveillance:
   a. PET/CT is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

JJ. **Anaplastic Thyroid Cancer**

1. Initial Work-up/Staging:
   a. FDG PET/CT imaging is appropriate for all anaplastic thyroid carcinomas; **or**
2. Restaging/Recurrence:
   a. FDG PET/CT imaging is appropriate for signs or symptoms of recurrence; **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Transitional Cell Cancers

KK. **Tumors of the Bladder/Ureters/Urethra/Renal Pelvis**

1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate to evaluate inconclusive findings on conventional imaging; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate to evaluate inconclusive findings on conventional imaging; **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Upper GI Cancers

LL. **Hepatocellular (HCC)/Gallbladder/Biliary**

1. Initial Work-up/Staging:
   a. **Hepatocellular carcinoma:** PET/CT imaging is considered **investigational** for diagnosis or staging;
   b. **Gallbladder and Biliary cancer:** PET/CT imaging is appropriate for evaluation of inconclusive findings on conventional imaging; **or**
2. Restaging/Recurrence:
   a. **Gallbladder and Biliary cancer:** PET/CT imaging is appropriate for evaluation of inconclusive findings on conventional imaging; **or**
3. Surveillance:
   a. PET/CT imaging is **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

MM. **Gastric Cancer**

1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate for gastric cancer greater than or equal to T2 or higher with no metastatic disease by conventional imaging; **or**
2. Restaging/Recurrence

a. PET/CT imaging is appropriate when findings are inconclusive on conventional imaging; **or**

3. Surveillance:
   a. PET/CT imaging **NOT** routinely indicated for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Uterine Cancer

NN. **Uterine Cancer**

1. Initial Work-up/Staging:
   a. PET/CT imaging is appropriate to evaluate inconclusive findings on conventional imaging; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is appropriate to evaluate inconclusive findings on conventional imaging; **or**
3. Surveillance:
   a. PET/CT is **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, 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;
C. ^{68}Ga-DOTA-TOC (HCPCS C9067) for low-grade neuroendocrine tumors;
D. ^{11}C Choline for prostate cancer;
E. ^{18}F-Fluciclovine (AXUMIN) for prostate cancer;
F. ^{68}Ga PSMA-11 (HCPCS A9593 and A9594) for prostate cancer;
G. ^{18}F Piflufolastat PSMA (Pylarify) (HCPCS A9595) for prostate cancer;
H. ^{68}Ga Gozetotide (Illuccix (HCPCS A9596) and Locametz (HCPCS A9800) for prostate cancer;
I. ^{18}F Flotufolastat (Posluma) (HCPCS A9608) for prostate cancer;
J. ^{18}F Fluoroestradiol (cerianna) (HCPCS A9591) for breast cancer.

IV. Based upon our criteria and assessment of the peer-reviewed literature, unless specified in the diagnosis-specific statement criteria, PET/CT imaging is considered **not medically appropriate** for the following indications:
A. Infection, inflammation, trauma, postoperative healing, granulomatous disease or rheumatological conditions;
B. Concomitantly, with separate diagnostic CT studies;
C. Conclusive evidence of distant or diffuse metastatic disease on recent conventional imaging studies;
D. Metastatic disease in the central nervous system (CNS);
E. For lesions less than 8 mm in size;
F. For follow-up after localized therapy (e.g., radiofrequency ablation, embolization, or stereotactic radiation).
G. Rare malignancies, due to lack of available evidence regarding the diagnostic accuracy of PET in rare cancers;
H. For surveillance for any of the following;
   1. Serial monitoring of individuals who are not currently receiving anti-tumor treatment or are receiving maintenance treatment;
   2. Serial monitoring of FDG avidity until resolution;
   3. PET/CT avidity in a residual mass at the end of planned therapy is not an indication for PET/CT imaging during surveillance;
   4. Residual mass that has not changed in size since the last conventional imaging does not justify PET imaging.

V. Based upon our criteria and assessment of the peer-reviewed literature, the use of PET scans is 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;
C. Acute lymphoblastic leukemia, acute myeloid leukemia, and chronic myeloid leukemia.

VI. Based upon our criteria and assessment of the peer-reviewed literature, PET/CT imaging using isotopes other than those specified in the above statement are considered **investigational**.

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. PET scans should be delayed at least twelve (12) weeks after completion of radiation treatment, unless required sooner for imminent surgical resection.

II. 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.

III. Unless otherwise specified for a specific cancer type, once PET has been documented to be negative for a given individual's cancer or all PET-avid disease has been surgically resected, PET should not be used for continued disease monitoring or surveillance.

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

V. 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.

VI. 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.

VII. 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.

DESCRIPTION

Phases of Oncology Imaging	**Definition**
Screening	Imaging requested for individuals at increased risk for a particular cancer in the absence of known clinical signs or symptoms.
Suspected Diagnosis	Imaging requested to evaluate a suspicion of cancer, prior to histological confirmation.
Initial work-up and Staging	Imaging requested after biopsy confirmation and prior to starting specific treatment.
Treatment response or Interim Restaging	Imaging performed during active treatment with chemotherapy, targeted therapy, immunotherapy, or endocrine therapy.
Restaging of locally treated lesions	Imaging performed to evaluate primary or metastatic lesions with ablation using cryoablation, radiofrequency, radioactive isotope, microwave or chemotherapy.

Restaging / Suspected Recurrence	Imaging requested when there is suspicion for progression or recurrence of known cancer based on clinical signs/symptoms, laboratory tests or basic imaging studies.
Surveillance	Imaging performed in individuals who: • Are asymptomatic or have chronic stable symptoms, and • Have no clinical suspicion of change in disease status, and • Are not receiving active anti-tumor treatment or are receiving maintenance treatment.

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.

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

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.

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.

Anal Cancer

National Comprehensive Cancer Network (NCCN) guidelines for Anal Carcinoma version 1.2024 recommend:

- Consider FDG-PET/CT or FDG-PET/MRI if available when doing a workup for anal and perianal cancer with a biopsy confirming squamous cell carcinoma, but FDG-PET/CT scan does not replace a diagnostic CT.
- For surveillance FDG-PET is not indicated.

Breast Cancer

NCCN guidelines for Breast Cancer version 2.2024 recommend:

- Consider imaging for systemic staging, including chest/abdomen ± pelvis diagnostic CT with contrast, bone scan, and optional FDG-PET/CT.
- FDG-PET/CT is most beneficial and accurate for advanced disease (stage III) and invasive ductal (compared to lobular) histology but may be useful in selected circumstances of earlier stage disease (stage IIA disease: T1N1, T2N0) such as: equivocal CT+ bone scan results; suspicion of undetected nodal and/or distant disease; and treatment response assessment.
- An FDG-PET/CT may be utilized as an adjunct to, or in lieu of, initial standard staging and may be performed simultaneously with diagnostic CT. Conversely, a bone scan or sodium fluoride PET/CT may not be needed if an upfront FDG-PET/CT clearly indicates consistent findings on both PET and CT components.

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

NCCN guidelines for Cervical Cancer version 3.2024 recommend:

Initial workup:

- Neck/chest/abdomen/pelvis/groin FDG-PET/CT (preferred) or chest/abdomen/pelvis CT or FDG-PET/MRI for FIGO stage IB1–IB3.
- For patients who underwent TH with incidental finding of cervical cancer, consider neck/chest/abdomen/pelvis/groin FDG-PET/CT.

Fertility Sparing:

- Neck/chest/abdomen/pelvis/groin FDG-PET/CT (preferred) or chest/abdomen/pelvis CT in FIGO stage IB1–IB3.

Stage II-IVA:

- Neck/chest/abdomen/pelvis/groin FDG-PET/CT (preferred) or chest/abdomen/pelvis CT to evaluate for metastatic disease.
- For patients who underwent TH with incidental finding of cervical cancer, consider neck/chest/abdomen/pelvis/groin FDG-PET/CT or chest/abdomen/pelvis CT to evaluate for metastatic disease.
- If first post-treatment FDG-PET/CT is indeterminate, then consider repeating in 3 months.

Esophageal Esophagogastric Junction Cancer

NCCN guidelines for Esophageal and Esophagogastric Junction Cancers version 3.2024 recommend:

- FDG-PET/CT evaluation (skull base to mid-thigh) if no evidence of M1 disease.
- FDG-PET/CT for preoperative and definitive chemoradiation for the assessment ≥5 to 8 weeks after completion of preoperative therapy.

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.

Hepatocellular Carcinoma

NCCN guidelines for Hepatocellular Carcinoma version 1.2024 recommend:

- FDG-PET/CT has limited sensitivity but high specificity and may be considered when there is an equivocal finding. When HCC is detected by CT or MRI and has increased metabolic activity on FDG-PET/CT, higher intralesional standardized uptake value is a marker of biologic aggressiveness and might predict less optimal response to locoregional therapies.

Lung Cancer

NCCN guidelines for Small Cell Lung Cancer version 2.2024 recommend:

- FDG-PET/CT scan (skull base to mid-thigh) for initial workup, if needed to clarify extent of disease is appropriate for SCLC or combined SCLC/ NSCLC confirmed on biopsy or cytology of primary or metastatic site. If FDG-PET/CT is not available, bone scan may be used to identify metastases.
- FDG-PET/CT is not recommended for routine follow-up unless contrast CT (chest/abdomen/pelvis) is contraindicated.
- FDG-PET/CT is recommended, preferably within 4 weeks and no more than 8 weeks, before treatment. Ideally, FDG-PET/CT should be obtained in the treatment position.

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

NCCN guidelines for Melanoma Cutaneous version 2.2024 recommend:

- Baseline metastatic workup with imaging (CT chest/abdomen/pelvis or FDG-PET/CT) may be warranted to exclude stage III/IV disease at the outset.
- Cross-sectional imaging studies that include chest/abdomen/pelvis (and neck if clinically indicated) CT with intravenous (IV) contrast and/or whole-body FDG-PET/CT.

- Nodal ultrasound surveillance is preferred if institutional expertise is available. Alternative imaging modalities (eg, CT, MRI, FDG-PET/CT) are acceptable.
- Although not recommended at baseline, in the absence of firm data, the panel acknowledged that surveillance chest x-ray, CT, brain MRI, and/or PET/CT every three (3) to 12 months (unless otherwise mandated by clinical trial participation) could be considered to screen for recurrent disease at the discretion of the physician (category 2B). Because most recurrences manifest within the first 3 years (depending on stage and other risk factors), routine imaging to screen for asymptomatic recurrence is not recommended beyond 3 to 5 years.
- Baseline imaging (CT and/or PET/CT or MRI) is recommended for staging and to evaluate specific signs or symptoms of recurrence (category 2B).

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 and Adrenal Tumors

NCCN guidelines for Neuroendocrine Tumors and Adrenal Tumors version 1.2023 recommend:

- Somatostatin receptor (SSTR)-based imaging with PET/CT or PET/MRI, using SSTR PET tracers, ^{68}Ga-dotatate, ^{68}Ga-dotatoc, or ^{64}Cu-dotatate to assess receptor status and presence of distant disease. SSTR imaging can assist in determining if a patient would benefit from receiving a SSTR-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), SSTR-based imaging with PET/CT or PET/MRI or FDG-PET/CT scans for surveillance are recommended as clinically indicated.
- SSTR-based imaging and fluorodeoxyglucose (FDG)-PET/CT scan are not recommended for routine surveillance.

Occult Primary Cancer

NCCN guidelines for Occult Primary version 2.2024 recommend:

- CT should be performed with contrast and MRI should be performed with and without IV contrast unless contraindicated. FDG-PET/CT is an alternative in patients with a contraindication to contrast enhancement.

Ovarian Cancer

NCCN guidelines for Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal cancer version 2.2024 recommend:

- PET/CT, MRI, or PET/MRI may be indicated for indeterminate lesions if results will alter management.
- Newly diagnosed ovarian cancer after a surgical procedure- Imaging as clinically indicated (eg, chest/abdomen/pelvis [C/A/P] CT/MRI, PET/CT, and/or ultrasound).
- Patients receiving primary chemotherapy- chest/abdomen/pelvis (C/A/P) CT or MRI with contrast, PET/CT (skull base to mid-thigh), or PET as indicated.
- Stage II-IV (post primary treatment)- Imaging as clinically indicated: C/A/P CT, MRI, PET/CT, or PET (skull base to mid-thigh).
- Stage I-IV (post primary treatment)- C/A/P CT, MRI, PET/CT, or PET as clinically indicated for monitoring and recurrent disease (Recurrent disease may be identified clinically (e.g., pelvic pain, weight loss), biochemically (i.e., elevated CA-125 levels), and/or with imaging).
- For assessing advanced disease, FDG-PET/CT may also be useful if CT results are indeterminate.

Pancreatic Cancer

NCCN guidelines for Pancreatic Adenocarcinoma version 2.2024 recommend:

- PET/CT or PET/MRI scan may be considered after formal pancreatic CT protocol in patients with high risk to detect extra-pancreatic metastases. It is not a substitute for high-quality, contrast-enhanced CT.
- For neoadjuvant therapy, consider PET/CT scan before and after initiation to assess response to systemic therapy and for restaging.

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

NCCN guidelines for Prostate Cancer version 4.2024 recommend:

- Currently FDA-approved PSMA agents: F-18 piflufolastat PSMA (also known as F-18 DCFPyL), F-18 flotufolastat PSMA (also known as rh-PSMA-7.3), and Ga-68 PSMA-11. “PSMA-PET” refers to and of these FDA approved PSMA ligands.
- PSMA-PET/CT or PET/MRI can be considered as an alternative to standard imaging of bone and soft tissue for initial staging, the detection of biochemically recurrent disease, and as workup for progression.

CT, MRI, PSMA-PET/CT or PSMA-PET/MRI, or PET/CT or PET/ MRI with F-18 sodium fluoride, C-11 choline, or F-18 fluciclovine can be considered for equivocal results on initial bone imaging. Alternatively, PSMA-PET/CT or PSMA-PET/ MRI can be considered for bone and soft tissue (full body) imaging.

Because of the increased sensitivity and specificity of PSMA-PET tracers for detecting micrometastatic disease compared to conventional imaging (eg, CT, bone scan) at both initial staging and BCR, the panel does not feel that conventional imaging is a necessary prerequisite to PSMA-PET and that PSMA-PET/CT or PSMA-PET/ MRI can serve as an equally effective, if not more effective frontline imaging tool for these patients.

PSMA-PET/CT or PSMA-PET/MRI are preferred for bone and soft tissue (full body) imaging. Alternatively, bone imaging can be achieved by conventional technetium-99m-MDP bone scan. CT, MRI, PSMA-PET/CT or PSMA-PET/MRI, or PET/CT or PET/MRI with F-18 sodium fluoride, C-11 choline, or F-18 fluciclovine can be considered for equivocal results on initial bone imaging. Soft tissue imaging of the pelvis, abdomen, and chest can include chest CT and abdominal/pelvic CT or abdominal/pelvic MRI. mpMRI is preferred over CT for pelvic staging and its use is recommended in addition to PSMA-PET in the setting of RT recurrence.

For active surveillance A metastatic staging evaluation (PSMA PET, bone scan, CT scan, or whole-body MRI) should not be performed.

Soft Tissue Sarcoma

NCCN guidelines for Soft Tissue Sarcoma version 1.2024 recommend:

- Consider CT or FDG-PET/CT as part of initial workup and follow-up given propensity for soft tissue metastases (outside CT cap imaging field)
- FDG-PET/CT scan may be useful in staging, prognostication, grading, and determining response to neoadjuvant therapy.
- In certain situations, MRI and FDG-PET/CT imaging obtained prior to biopsy may allow for targeting of enhancing/metabolically active components and less necrotic regions of the tumor.

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

NCCN guidelines for Testicular Cancer version 1.2024 recommend:

Pure Seminoma:

- FDG-PET from skull base to mid-thigh may also be considered in assessing treatment response and residual masses following chemotherapy in patients with seminoma.
- Consider FDG-PET/CT scan (skull base to mid-thigh) for a residual mass >3 cm post primary chemotherapy.
- FDG-PET/CT scan should be performed at least 6 weeks following completion of chemotherapy in individuals with a residual mass greater that 3 cm and normal serum tumor marker level.
- If results are indeterminate, the PET/CT or CT scan should be repeated in 6 to 8 weeks. If the PET/CT is positive, resection or interventional radiology (IR)-guided biopsy of the residual mass should be considered.

Nonseminoma:

- FDG-PET has no role in assessing treatment response and residual masses following chemotherapy in patients with nonseminoma.

Thymoma and Thymic Carcinomas

NCCN guidelines for Thymomas and Thymic carcinomas version 1.2024 recommend:

- After induction chemotherapy, imaging is recommended (e.g., chest CT, MRI, PET/CT) as clinically indicated to determine whether resection is feasible.
- FDG-PET/CT can be used for recurrent, advanced or metastatic disease when locally advanced or solitary metastasis or ipsilateral pleural metastasis following systemic therapy.
- FDG-PET/CT scan (skull base to mid-thigh) can be used for initial evaluation of a mediastinal mass.

Thyroid Cancer

NCCN guidelines for Thyroid carcinomas version 2.2024 recommend:

- Consider Ga-68 DOTATATEPET/CT for Medullary thyroid carcinoma on FNA by cytology or molecular diagnostics.
- Consider PET scan for known or suspected distant metastatic disease 6-12 weeks post thyroidectomy and an inconclusive CT scan.
- Consider additional imaging (CT neck/ chest), PET, or RAI imaging if Tg ab is rising or new Tg ab after total thyroidectomy with or without RAI.
- Conservative surveillance with repeat measurement of the serum markers every 6 to 12 months. Additional imaging studies (e.g., FDG-PET/CT, Ga-68 DOTATATE, or MRI with contrast of the neck, chest, and abdomen with liver protocol) may be indicated depending on calcitonin/CEA doubling time.
- PET/CT or MRI scans are recommended to accurately stage the patient.

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
78608	Brain imaging, positron emission tomography, (PET); metabolic evaluation
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 **(E/I)**	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
A9591	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)

Code	Description
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 06/04/24.

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 06/04/24.

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 06/04/24.