MEDICAL POLICY

Excellus
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Medical Policy Title	**Positron Emission Tomography (PET) Oncologic Applications**
Policy Number	**6.01.29**
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Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. 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;

   B. It is used to determine the optimal site for biopsy.

II. PET imaging is 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 and Non-Melanoma Skin Cancers

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

Salivary Gland Cancers

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 **medically necessary** 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 **medically necessary** when there are inconclusive findings on conventional imaging.
    3. Surveillance:
        a. PET/CT imaging is **not routinely medically necessary** 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] histology of breast cancer)

1. Initial Work-up/Staging:
    a. FDG PET/CT imaging is **medically necessary** for **any** of the following:
        i. Stage III N2 disease;
        ii. T4 disease;
        iii. Inflammatory breast cancer (stage T4d);
        iv. Inconclusive CT and/or bone scan; **or**
    b. Bone pain-PET/CT with Sodium Fluoride radiotracer may be obtained if CT, MRI, Bone scan and FDG PET/CT scan are inconclusive for bone metastases; **or**
2. Restaging/Recurrence:
    a. ^{18}F-FDG PET/CT may be used for **either** of the following indications:
        i. Inconclusive CT, MRI, and/or bone scan; **or**
        ii. Treatment response assessment for bone-only metastases and a prior bone scan has not been performed for serial comparison.
    b. ^{18}F Sodium Fluoride PET/CT is appropriate for individuals with known or suspected bone metastases **and** inconclusive bone findings on **all** of the following:
        i. CT;
        ii. MRI;
        iii. Bone scan; **and**
        iv. FDG PET/CT scan.
    c. ^{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.
    d. PET is **not medically necessary** for systemic restaging after neoadjuvant chemotherapy or after surgery.
3. Surveillance:
    a. PET/CT is **not routinely medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
4. Advanced imaging to evaluate for distant metastases is **not medically necessary** 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 or PET/MRI imaging is **medically necessary** for initial work-up/staging for **any** of the following indications:
        i. Stage IB1-IB3, non-fertility sparing treatment;
        ii. IB1-IB3, fertility sparing treatment;
        iii. Stage II-IVA;
        iv. Any size cervical cancer incidentally found in a hysterectomy specimen;
        v. Small cell neuroendocrine carcinoma of the cervix (NECC); **or**
        vi. Inconclusive findings on conventional imaging; **or**
2. Restaging/Recurrence:
    a. PET/CT imaging is **medically necessary** for restaging after therapy for **any** of the following indications:
        i. Three (3) to six (six) months post-completion of therapy for **either**:
            a) Stage IB3; **or**
            b) Stage I treated with post-operative adjuvant radiation or chemoradiation due to positive nodes, positive parametria, positive margins, or local cervical factors;
        ii. Following within three (3) to six (six) months of completion of therapy for:
            a) Stage II-IV;
        iii. After completion of therapy:
            a) Small cell NECC, treated with primary chemoradiation;
        iv. Inconclusive conventional imaging; **or**
        v. Suspected or biopsy proven recurrence; **or**
3. Surveillance:
    a. PET/CT imaging is **medically necessary** for surveillance when **all** of the following are met:
        i. Once, 3-6 months after completion of therapy; **and**
        ii. Small Cell NECC.

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 **medically necessary** 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**
2. Restaging/Recurrence:
    a. PET/CT imaging is **medically necessary** 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; **or**
        iii. Postoperative elevated or rising carcinoembryonic antigen (CEA) or Liver Function Tests (LFTs) with negative recent conventional imaging.
3. Surveillance:
    a. PET/CT imaging is **not medically necessary** for surveillance imaging for colorectal and colorectal cancers.

E. Small Bowel Cancer

1. Initial Work-up/Staging:
    a. PET/CT imaging is **not medically necessary** for initial staging for small bowel cancer.
2. Restaging/Recurrence:
    a. PET/CT imaging is **medically necessary** for **any** of the following indications:
        i. Postoperative elevated or rising carcinoembryonic antigen (CEA) or Liver Function Tests (LFTs) with negative recent conventional imaging; **or**
        ii. 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.
3. Surveillance/Follow-up:
    a. PET/CT imaging is **not routinely medically necessary** for surveillance imaging for colorectal and small bowel cancers.

Esophageal and Gastroesophageal (GE) Junction Cancer

F. Esophageal and GE Junction Cancer

1. Initial Workup/Staging:
    a. PET/CT imaging is **medically necessary** 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 **medically necessary** for restaging after therapy for **any** of the following indications:
        i. If conventional imaging is inconclusive;
        ii. Decision making after primary chemoradiation therapy prior to surgery (no sooner than five (5) weeks post completion of radiation therapy); **or**
        iii. A salvage surgical candidate with recurrence and no metastatic disease documented by conventional imaging.
3. Surveillance:
    a. PET/CT imaging is **not routinely medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Leukemia

G. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

1. Initial Work-up/Staging:
    a. PET imaging is **not medically necessary** in the evaluation of CLL/SLL, with the exception of suspected Richter's transformation.
2. Suspected Transformation:
    a. PET/CT imaging is **medically necessary** 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; **or**
        iv. Significant recent rise in LDH above normal range.
3. Surveillance:
    a. PET/CT imaging is **not routinely medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Lung Cancer

H. Non-Small Cell (NSCLC) includes adenocarcinoma, squamous cell carcinoma, adenosquamous and large cell tumors

1. Suspected/Diagnosis:

a. 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**

b. PET/CT imaging is **medically necessary** 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:

b) Definitive treatment with resection or radiation will be utilized instead of biopsy if PET confirms limited disease; **or**

c) 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 **medically necessary** for all individuals (if not already completed prior to histological diagnosis); **or**

3. Restaging/Recurrence:

a. PET/CT imaging is **medically necessary** 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; **or**

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.

4. Surveillance:

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

I. Small Cell Lung Cancer (SCLC)

1. Suspected /Diagnosis:

a. PET imaging is **medically necessary** 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**

b. 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:

i. Definitive treatment with resection or radiation will be utilized 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; **or**

2. Initial Work-up/Staging:

a. PET /CT imaging is **medically necessary** for initial staging:

i. To confirm the extent of disease when initial CT chest/abdomen/pelvis and MRI brain indicate limited stage disease (confirmed to one side of the chest); **or**

ii. To evaluate inconclusive findings on conventional imaging.

3. Restaging/Recurrence:

a. PET imaging is **not medically necessary** for evaluation of treatment response or recurrence of SCLC but can be considered on a case-by-case basis.

4. Surveillance:

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

<u>Lymphoma</u>

J. Hodgkin Lymphoma-Classical

1. PET/CT imaging may be used for **ANY** of the following indications:

a. As the initial imaging technique for staging/<u>diagnosis;</u>

b. Prior to initiation of therapy if one (1) month or more has passed since previous PET/CT was performed;

c. Treatment response as frequently as every two (2) cycles;

d. End of chemotherapy and again at the end of radiation therapy (at least 12 weeks after completion of radiation therapy);

e. If there is suspected recurrence greater or equal to three (3) months after completion of therapy

f. 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.

g. CAR-T cell therapy: Once before treatment and one 30-60 days after completion of treatment;

K. Predominant Hodgkin Lymphoma- Nodular Lymphocyte

1. PET/CT imaging may be used for **ANY** of the following indications:

a. As the initial imaging technique for staging/diagnosis;

b. At the end of chemotherapy and again at the end of radiation (at least 12 weeks after completion of radiation therapy);

c. Biopsy proven recurrence;

d. 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; **or**

iv. Significant recent rise in LDH above normal range.

e. 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.

f. CAR-T cell therapy: Once before treatment and once 30-60 days after completion of treatment.

2. PET/CT is **not medically necessary** for all other indications prior to histological confirmation of lymphoma.

Melanoma

L. Melanoma

1. Initial Work-up/Staging:

a. PET/CT imaging is **medically necessary** for initial staging for **any** of the following indications:

i. Stage III (sentinel node positive and palpable regional nodes);

ii. Stage IV (metastatic); **or**

iii. Primary site is unknown and CT chest and abdomen/pelvis are negative; **or**

2. Restaging/Recurrence:

a. PET/CT imaging is **medically necessary** for restaging/recurrence for **either** of the following indications:

i. Inconclusive findings on conventional imaging; **or**

ii. Isolated metastatic site found on conventional imaging.

3. Surveillance:

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

M. Non-Melanoma Skin Cancer

1. Initial Work-up/Staging:
    a. PET/CT is **medically necessary** for skin lesions that may be a dermal metastasis from distant primary when conventional imaging (CT or MRI) is unable to identify a primary site; **or**
    b. PET/CT is **medically necessary** for Merkel Cell Carcinoma if conventional imaging is inconclusive.
2. Restaging /Recurrence:
    a. PET/CT is **medically necessary** for **either** of the following:
        i. Suspected or biopsy-proven recurrence of Merkel cell carcinoma; **or**
        ii. Inconclusive findings on conventional imaging.
3. Surveillance/Follow-up:
    a. PET/CT imaging is **not medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of recurrent disease.

Metastatic Cancer, Carcinoma of Unknown Primary Site

N. Metastatic (Lung, Liver, Brain, Adrenal, Bone 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; **or**
    b. The cancer type is rare and does not have its own diagnosis-specific imaging guidelines;

    AND
2. PET/CT imaging is **medically necessary** for **any** of the following metastatic cancer indications:
    a. Adrenal with **any** of the following indications:
        i. Biopsy is not feasible or is non-diagnostic; **or**
        ii. Isolated metastasis on conventional imaging and patient is a candidate for aggressive surgical management.
    b. Bone:
        i. FDG PET/CT is **medically necessary** for individuals ≥40 years of age with **either** of the following indications:
            a) A bone lesion seen on x-ray; **or**
            b) No history of malignancy who has a symptomatic bone lesion seen on x-ray and malignancy is suspected; **or**

ii. ^{18}F-FDG-PET/CT is **medically necessary** when bone metastases are suspected and **both** bone scan and either CT or MRI are inconclusive.

c. Brain:

i. PET/CT is **medically necessary** for **any** of the following:

a) Inconclusive conventional imaging;

b) Brain metastases and no known primary tumor;

c) Solitary brain metastasis suspected in individual with prior diagnosis of cancer and not diagnosis-specific; **or**

d) To confirm either stable systemic disease or absence of other metastatic disease; **or**

ii. PET metabolic brain is appropriate for the following indication:

a) Brain metastases treated with radiation therapy, with recent MRI Brain and MR Perfusion studies both unable to distinguish radiation necrosis versus tumor progression.

d. Liver with **any** of the following indications:

i. To confirm solitary metastasis amenable to resection on conventional imaging; **or**

ii. Liver function tests (LFT's) and/or tumor markers continue to rise, and CT and MRI are negative.

iii. PET imaging of the liver is **not medically necessary** for **either** of the following indications:

a) Assessing the response to ablation therapy regardless of the modality of ablation; **or**

b) For routine surveillance of asymptomatic individuals after treatment completion.

e. Lung with **any** of the following indications:

i. Lung nodules greater than or equal to 8 mm; **or**

ii. To confirm solitary metastasis amenable to resection on conventional imaging.

f. Unknown (Occult) Primary Site with **any** of the following indications:

i. Primary cancer site cannot be determined by prior CT, MRI, bone scan or diagnostic mammogram and full pelvic exam; **or**

ii. CT imaging reveals isolated metastatic disease for which definitive curative therapy is planned.

Multiple Myeloma and Plasmacytomas

O. Multiple Myeloma and Plasmacytomas

1. Initial Work-up/Staging:

a. Whole-body FDG PET/CT is **medically necessary** for **any** of the following:

i. Suspected or known POEMS syndrome for sclerotic bone lesions on other imaging;

ii. Suspected or known systemic light chain amyloidosis; or

iii. Confirmed myeloma;

iv. Myeloma suspected based on **any** of the following:

a) Abnormal skeletal survey or other imaging;

b) Abnormal myeloma labs; **or**

c) Signs/symptoms of multiple myeloma; **or**

b. PET/CT imaging is **medically necessary** when there are inconclusive findings on whole-body low dose skeletal CT.

2. Restaging/Recurrence:

a. PET/CT imaging is **medically necessary** 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**

iv. Whole-body low-dose skeletal CT is unavailable or impractical, and recurrence or progression is suspected; **or**

b. Whole-body FDG PET/CT is **medically necessary** for **either** of the following indications:

i. Suspected progression or relapse/recurrence; **or**

ii. Suspected progression of MGUS or SMM to a more malignant form; **or**

c. Repeat Whole-body FDG PET/CT imaging is **medically necessary** when **either** of the following criteria are met:

i. PET/CT was used for initial diagnosis; **and**

ii. Treatment response assessment for **any o**f the following indications**:**

a) After completion of primary therapy;

b) For non-secretory multiple myeloma; **or**

c) To determine therapy response with inconclusive labs;

d) Extra-osseous plasmacytoma response to initial therapy; **or**

d. PET/CT imaging is **medically necessary** for stem cell transplant recipients, once before transplant and once within 30-100 days after transplant.

3. Surveillance:

a. Whole-body FDG PET/CT imaging is **medically necessary** (if it was the same imaging modality used at diagnosis) for **any** of the following indications:

i. Smoldering myeloma (annually);

ii. Multiple myeloma (annually); **or**

iii. Solitary plasmacytomas (annually for 5 years).

Neuroendocrine Cancers and Adrenal Tumors

P. Adrenal Tumors

1. Initial Work-up/Staging:

a. FDG PET/CT is **medically necessary** for initial work-up/staging for individuals with hypercortisolemia with **any** of the following:

i. Tumor greater than 4cm;

ii. Inhomogeneous;

iii. Irregular margins;

iv. Local invasion; **or**

v. Other malignant imaging characteristics; **or**

b. PET/CT or PET/MRI imaging is **medically necessary** for initial work-up/staging 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**

c. FDG PET/CT imaging is **medically necessary** initial staging if prior CT scans, MRI, Octreotide, iodine meta-iodobenzylguanidine (MIBG) scans, or SPECT are negative and/or inconclusive.

2. Restaging/Recurrence:

a. PET/CT or PET/MRI imaging is **medically necessary** for 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. PET/CT imaging is **medically necessary** 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**

c. FDG PET/CT is **medically necessary** for restaging/recurrence for **any** of the following:

i. If prior CT scans, MRI, Octreotide, MIBG scans, or SPECT are negative ~~and/~~or inconclusive;

ii. Hypercortisolemia with inconclusive findings on CT;

iii. Pheochromocytoma bone-dominant disease; **or**

iv. Paraganglioma bone-dominant disease.

3. Surveillance:

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

Q. Adrenocortical Carcinoma

1. Initial Staging:

a. FDG PET/CT imaging is **medically necessary** for initial staging; **or**

2. Suspected Recurrence:

a. FDG PET/CT imaging is **medically necessary** for suspected recurrence when there are inconclusive findings on conventional imaging.

R. Bronchopulmonary/Thymic Carcinoids

1. Initial Work-up/Staging:

a. PET/CT or PET/MRI imaging is **medically necessary** 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 or PET/MRI imaging is **medically necessary** for **either** of the following:

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; **or**

2. Restaging/Recurrence:

a. PET/CT or PET/MRI imaging is **medically necessary** 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.

3. Surveillance:

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

S. Gastrointestinal/Pancreatic Neuroendocrine Cancer

1. Initial Work-up/Staging:

a. PET/CT or PET/MRI imaging is **medically necessary** for initial work-up/staging for **any** of the following indications:

i. Jejunal;

ii. Ileal;

iii. Colon;

iv. Gastric type 3;

v. Neuroendocrine tumors of unknown primary;

vi. Grade 3 well-differentiated tumors;

vii. Inconclusive findings on CT or MRI imaging; **or**

With **one** of the following SSR radiotracers:

- ^{68}Gallium DOTATATE;
- ^{68}Ga-DOTATOC;

- ^{64}Cu-DOTATATE; **or**

b. FDG PET/CT imaging is **medically necessary** for initial work-up/staging for **either** of the following:

i. Markers fail to normalize after complete surgical resection **and** CT/MRI and somatostatin-receptor based study are negative;

ii. Biopsy proven neuroendocrine tumor of unknown primary site **and** CT/MRI and somatostatin-receptor based study are negative; **or**

2. Suspected/Diagnosis:

a. PET/CT or PET/MRI imaging is **medically necessary** for suspected/diagnosis 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**

3. Restaging/recurrence

a. PET/CT or PET/MRI imaging is **medically necessary** for restaging/recurrence with **either** of the following indications:

i. Suspected recurrence; **or**

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.

4. Surveillance

a. PET/CT imaging is **not medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Non-Hodgkin Lymphomas

T. Non-Hodgkin Lymphomas (General Criteria)

1. PET/CT imaging is **medically necessary** for **either** of the following indications:

a. To determine a more favorable site for biopsy when a relatively inaccessible site is contemplated; **or**

b. CAR-T cell therapy: Once before treatment and once 30-60 days after completion of treatment.

2. PET/CT is **not medically necessary** for all other indications prior to histological confirmation of lymphoma.

U. 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 **medically necessary** for restaging/recurrence for **any** of the following indications:

i. Treatment response for all stage I and II without extensive mesenteric disease after 3-4 cycles of chemotherapy (in lieu of CT or for inconclusive CT);

ii. Treatment response for stage II WITH extensive mesenteric disease and stages III-IV after 2-4 cycles for chemotherapy (in lieu of CT of for inconclusive CT);

iii. At the end of chemotherapy and/or again at the end of radiation therapy;

iv. Suspected recurrence (can be considered in rare circumstances (e.g., bone involvement);

v. Biopsy confirmed recurrence; **or**

vi. CAR-T cell therapy: Once before treatment and once 30-60 days after completion of treatment.

3. Surveillance:

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

V. 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 **medically necessary** 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. CT results lead to a plan for systematic therapy;

2. Restaging/Recurrence:

a. PET/CT imaging is **medically necessary** for end of therapy evaluation; **or**

b. PET/CT imaging is **medically necessary** 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; **or**

iv. Significant recent rise in LDH above normal range.

3. Surveillance:

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

W. 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 **medically necessary** for initial work-up/staging for **either** of the following indications:

i. If radiation therapy is being considered for stage, I or II disease; **or**

ii. If systemic therapy is planned; **or**

2. Restaging/Recurrence:

a. PET/CT imaging is **medically necessary** for **either** of the following indications:

i. End of therapy evaluation; **or**

ii. Suspected recurrence with **any** of the following:

a) Symptoms of end organ dysfunction;

b) Clinically significant or progressive cytopenias;

c) Bulky disease (single mass of ≥7cm or ≥3 or more nodal sites 3cm in diameter); **or**

d) Steady or rapid progression.

3. Surveillance:

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

X. Mantle Cell and Burkitt's Lymphoma

1. Initial Work-up/Staging:

a. PET/CT imaging is **medically necessary** for initial imaging work-up/staging/diagnosis for Mantle Cell and Burkitt's.

2. Treatment Response:
    a. PET/CT imaging is **not medically necessary** for monitoring treatment response but can be considered in rare circumstances when CT does not show disease (e.g., bone).
3. Restaging/Recurrence:
    a. PET/CT imaging is **medically necessary** 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); **or**
        ii. Suspected recurrence in rare circumstances (e.g., bone involvement).
4. Surveillance:
    a. PET/CT imaging is **not routinely medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Y. 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 **medically necessary** for initial work-up/staging/diagnosis for **any** of the following indications:
        i. T-Cell Lymphomas;
        ii. Post-transplant lymphoproliferative disorders;
        iii. Waldenstrom macroglobulinemia; **or**
        iv. Lymphoplasmacytic lymphoma; **or**
2. Restaging/Recurrence:
    a. PET/CT imaging is **medically necessary** 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; **or**
        iii. Suspected recurrence in rare circumstances (e.g., bone involvement).
3. Surveillance:
    a. PET/CT imaging is **not routinely medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

<u>Ovarian Cancer</u>

Z. Ovarian Cancer

1. Initial Work-up/Staging:
    a. PET/CT imaging is **medically necessary** 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**
        iii. Both CT and MRI are inconclusive; **or**
    b. PET/MRI imaging is **medically necessary** for initial work-up/staging when CT, MRI and PET/CT are inconclusive; **or**
2. Restaging/Recurrence:
    a. PET/CT imaging is **medically necessary** for restaging/recurrence with **any** 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**
        iii. Both CT and MRI are inconclusive; **or**
    b. PET/MRI imaging is **medically necessary** for initial work-up/staging when CT, MRI and PET/CT are inconclusive.
3. Surveillance:
    a. PET/CT imaging is **not routinely medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

Pancreatic Cancer

AA. Pancreatic Cancer

1. Initial Work-up/Staging:
    a. PET/CT imaging is **medically necessary** for initial work-up/staging when there is no evidence of metastatic disease on CT or MRI and **any** of the following:
        i. Equivocal or indeterminate conventional imaging findings;
        ii. Markedly elevated CA19-9;
        iii. Large primary tumor(s);
        iv. Enlarged regional lymph nodes; **or**
        v. Planned neoadjuvant therapy; **or**
2. Restaging/Recurrence:

a. PET/CT imaging is **medically necessary** when findings on conventional imaging are inconclusive.

3. Surveillance:

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

Primary Central Nervous System Tumors

BB. Brain Tumors (e.g., astrocytoma, oligodendroglioma)

1. Initial Work-up/Staging:

a. PET imaging is **not medically necessary** for initial work-up/staging of brain tumors.

2. PET Brain Metabolic imaging is **medically necessary** 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; **or**

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; **or**

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. CNS Lymphoma (i.e., microglioma)

i. PET/CT is **medically necessary** for extra-neural evaluation to confirm CNS primary when findings on CT imaging are inconclusive; **or**

4. Meningiomas (Intercranial and Intraspinal)

i. Dotatate PET/CT Brain is appropriate for the following indications:

a) MRI or CT are inconclusive, and further imaging is needed to confirm diagnosis; **or**

b) Suspected recurrence with inconclusive findings on MRI.

5. Fusion PET/CT and full body PET imaging are **not medically necessary** for the evaluation or management of primary CNS tumors.
6. PET Brain imaging is **not medically necessary** in gliomas occurring in the brain stem due to poor uptake and lack of impact on individual outcomes.

Prostate Cancer

CC. Prostate Cancer

1. Initial Work-up/Staging:
   a. PSMA PET/CT imaging is **medically necessary** for initial work-up/staging for localized prostate cancer with **any** of the following risk groups:
      i. Unfavorable Intermediate Risk;
      ii. High Risk; **or**
      iii. Very High Risk;

      With **one** of the following radiotracers:
      - ^{68}Ga PSMA-11;
      - ^{18}F Piflufolastat (Pylarify);
      - ^{68}Ga Gozetotide (Illuccix and Locametz); **or**
      - ^{18}F Flotufolastat (Posluma).

   b. PSMA PET/CT or PSMA PET/MRI imaging is **medically necessary** to confirm oligo- or low volume metastatic prostate cancer suspected on conventional imaging in individuals with biopsy-proven prostate cancer with **one** of the following radiotracers:
      - ^{68}Ga PSMA-11;
      - ^{18}F Piflufolastat (Pylarify);
      - ^{68}Ga Gozetotide (Illuccix and Locametz); **or**
      - ^{18}F Flotufolastat (Posluma).

   c. PET/CT or PET/MRI imaging is **medically necessary** for work-up/initial staging for localized prostate cancer when bone scan is inconclusive:

      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**
- ^{18}F sodium fluoride.

2. Restaging/Recurrence:
   a. PSMA PET/CT or PET/MRI imaging is **medically necessary** for non-metastatic prostate cancer previously treated with prostatectomy and **all** of the following are met:
      i. Persistent detectable PSA after prostatectomy; **or**
      ii. Undetectable PSA that subsequently becomes detectable with two (2) consecutive increases in PSA (to any amount); **or**
      iii. Any increase in PSA to 0.1 ng/ml or higher; **and**
      iv. 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); **or**
      - ^{18}F Flotufolastat (Posluma).

   b. PSMA PET/CT or PET/MRI imaging is **medically necessary** for non-metastatic prostate cancer previously treated with radiation therapy and **all** of the following are met:
      i. Two consecutive increases in PSA above nadir (lowest point); **and**
      ii. Individual is a candidate for salvage local therapy.

   c. PET/CT imaging is **medically necessary** 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;
      ii. PSA ≥1 ng/mL**;**
      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; **or**
      - ^{11}C Choline.

d. PMSA PET/CT imaging is **medically necessary** for previously treated metastatic cancer progressed on conventional imaging and being considered for ^{177}Lu-PSMA-617 (Pluvicto) treatment:

With **one** of the following radiotracers:

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

e. PET/CT or PET/MRI imaging is **medically necessary** when the bone scan is inconclusive;

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**
- ^{18}F sodium fluoride.

f. PET/CT imaging is appropriate for the following indication:

i. Conventional imaging studies (CT and bone scan) suggests oligo- or low volume metastatic disease that needs 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); **or**
- ^{18}F Flotufolastat (Posluma).

3. Surveillance:

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

4. PET/CT imaging using ^{18}F-FDG radiotracers are considered **investigational** for all

indications for prostate cancer.

Salivary Gland Cancers

DD. Salivary Gland Cancers

1. Initial Work-up/Staging:
    a. PET/CT imaging is **medically necessary** when findings are inconclusive on conventional imaging.
2. Restaging/Recurrence:
    a. PET/CT imaging is **medically necessary** when findings are inconclusive on conventional imaging.
3. Surveillance/Follow-up:
    a. PET/CT imaging is **not medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

<u>Sarcomas</u>

EE. Chordoma (Bone Sarcoma)

1. Initial Work-up/Staging:
    a. PET/CT is **not medically necessary** for surveillance of chordoma.
2. Restaging/Recurrence:
    a. PET/CT is **medically necessary** when findings on conventional imaging is inconclusive.
3. Surveillance:
    a. PET/CT is **not medically necessary** for surveillance of chordoma.

FF. 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 is **medically necessary** for 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 is **medically necessary** when treatment response following local control surgery and clinical or imaging findings are suggestive of local recurrence. **or**

4. Metastatic disease undergoing current chemotherapy:
    a. PET/CT whole body imaging is **medically necessary** 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 medically necessary** during active treatment for recurrent pediatric cancer;
    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 **medically necessary** 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; **or**
        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.

GG. Gastrointestinal Stromal Tumor (GIST)

1. Initial Work-up/Staging and Known or Suspected Recurrence:
    a. PET/CT imaging is **medically necessary** when the evaluation of findings on conventional imaging is inconclusive.
2. Surveillance:
    a. PET/CT imaging is **not routinely medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

HH. Soft Tissue Sarcoma

1. Initial Work-up/Staging:
    a. PET/CT imaging may be used for initial work-up/staging for **any** of the of the following indications:
        i. Grade of tumor in doubt following biopsy;
        ii. Conventional imaging suggests solitary metastasis amenable to surgical resection;
        iii. Inconclusive conventional imaging; **or**
        iv. Prior to planned neoadjuvant therapy; **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**
        iv. Baseline end of therapy evaluation; **or**
    b. If treated with radiation therapy, PET/CT no sooner than 12 weeks (3 months) post completion of radiation therapy.
3. Surveillance
    a. PET/CT is **not routinely medically necessary** for surveillance imaging in an asymptomatic individual.

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

II. Squamous Cell Carcinomas of the Head and Neck Cancers
1. Suspected/Diagnosis:
    a. PET/CT is **medically necessary** 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; **or**
        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 **medically necessary** for **any** of the following indications:
        i. Known stage III or IV disease;
        ii. To determine role for upfront surgery versus chemoradiation in T3-T4 size tumor;

iii. Prior to start of primary chemoradiotherapy and have not undergone definitive surgical resection;

iv. Nasopharyngeal (NPC) Cancer;

v. Inconclusive findings on conventional imaging (CT, MRI);

vi. In order to direct laryngoscopy/exam under anesthesia for biopsy;

vii. Pulmonary nodule(s) greater than or equal to 8 mm in size;

viii. Cervical lymph node biopsy positive for squamous cell carcinoma and no primary site identified on CT or MRI of neck and chest; **or**

ix. Inconclusive findings suggestive of disease outside the head and neck area; **or**

3. Restaging/Recurrence:

a. PET/CT imaging is considered **medically necessary** 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;

a) PET/CT no sooner than 12 weeks (3 months) post completion of radiation therapy.

ii. Post-treatment PET is equivocal for residual disease;

a) PET/CT should be completed at 3-6 months from prior post-treatment PET/CT.

iii. Concern for progression seen on imaging performed at completion of induction chemotherapy;

iv. Biopsy proven local recurrence; **or**

v. Inconclusive conventional imaging (CT or MRI).

b. PET imaging is **NOT** indicated for **any** of the following:

i. To assess response to induction chemotherapy;

ii. If post-treatment PET/CT scan is negative;

iii. If post-treatment PET is positive for residual disease.

4. Surveillance:

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

Testicular, and Extragonadal Germ Cell Tumors

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

1. Initial Work-up/Staging:

a. 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.

3. Surveillance:

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

Thoracic Tumors

KK. Malignant Pleural Mesothelioma

1. Initial Work-up/Staging:

a. PET/CT imaging is appropriate for initial work up/staging for **either** of the following:

i. If no evidence of distant metastatic disease on CT imaging; **or**

ii. Conventional 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 distant metastatic disease.

3. Surveillance:

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

LL. 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; **or**

ii. Inconclusive findings on CT imaging.

3. Surveillance:

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

Thyroid Cancers

MM. Follicular, Papillary and Hurthle Cell (Oncocytic) Carcinomas

1. Initial Staging:
    a. Routine preoperative advanced imaging is not **medically necessary** for initial work-up/staging; **or**
2. Restaging/Recurrence:
    a. FDG PET/CT imaging is **medically necessary** 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); **or**
        iii. Known radioiodine-refractory disease and CT scans are negative or inconclusive.
3. Surveillance:
    a. PET/CT imaging is **not routinely medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

NN. Medullary Thyroid Cancer

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

OO. Anaplastic/Poorly Differentiated Thyroid Cancer

1. Initial Work-up/Staging:
    a. FDG PET/CT imaging is **medically necessary** for all anaplastic thyroid carcinomas; **or**
2. Restaging/Recurrence:
    a. FDG PET/CT imaging is **medically necessary** for signs or symptoms of recurrence.
3. Surveillance:

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

Transitional Cell Cancers

PP. Tumors of the Bladder/Ureters/Urethra/Renal Pelvis

1. Initial Work-up/Staging:
   a. PET/CT imaging is **medically necessary** to evaluate inconclusive findings on conventional imaging; **or**
   b. FDG PET/CT imaging is **medically necessary** for the initial work-up/staging evaluation of suspected bone metastasis for **any** the following indications:
      i. Individuals with symptoms of bone metastasis;
      ii. Laboratory indicators of bone metastasis;
      iii. Individuals with muscle invasive disease; **or**
      iv. Suspected sites of extra-osseous metastatic disease; **or**
2. Restaging/Recurrence:
   a. PET/CT imaging is **medically necessary** to evaluate inconclusive findings on conventional imaging.
3. Surveillance:
   a. PET/CT imaging is **not routinely medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.
4. FDG PET/CT is **not** recommended to delineate the anatomy of the upper urinary tract as is does not provide detailed imaging of the bladder, reserving it as a tool when other imaging studies are inconclusive.

Upper GI Cancers

QQ. Hepatocellular (HCC)/Gallbladder/Biliary

1. Initial Work-up/Staging:
   a. Hepatocellular Carcinoma:
      i. PET/CT is considered **medically necessary** for evaluation of inconclusive conventional imaging.
   b. Gallbladder and Biliary Cancer:
      i. PET/CT imaging is **medically necessary** for evaluation of inconclusive findings on MRI of the abdomen; **or**
2. Restaging/Recurrence:
   a. Gallbladder and Biliary Cancer:

i. PET/CT imaging is **medically necessary** for evaluation of inconclusive findings on MRI of the abdomen.

b. Hepatocellular Carcinoma:

i. PET/CT imaging is **medically necessary** for evaluation of inconclusive findings.

3. Surveillance:

a. Gallbladder and Biliary Cancer:

i. PET/CT imaging is **not routinely medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

RR. 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 **medically necessary** when findings are inconclusive on conventional imaging; **or**

b. Restaging of individuals with unresectable disease who cannot undergo CT with contrast due to renal insufficiency or contrast allergy.

3. Surveillance:

a. PET/CT imaging **not routinely medically necessary** for surveillance imaging in an asymptomatic individual with no clinical or laboratory evidence of disease.

<u>Uterine Cancer</u>

SS. Uterine Cancer (for endometrial cancer see policy statement V.)

1. Initial Work-up/Staging:

a. PET/CT imaging is **medically necessary** to evaluate inconclusive findings on conventional imaging; **or**

2. Restaging/Recurrence:

a. PET/CT imaging is **medically necessary** to evaluate inconclusive findings on conventional imaging.

3. Surveillance:

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

III. 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;

K. ^{18}F Na Fluoride PET bone scan for breast cancer and prostate cancer.

IV. PET/CT imaging is considered **not medically appropriate** for the following indications, unless specified in the diagnosis-specific statement criteria:

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 of **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; or

4. Residual mass that has not changed in size since the last conventional imaging does not

justify PET imaging.

V. 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;

C. Acute lymphoblastic leukemia, acute myeloid leukemia, and chronic myeloid leukemia.

VI. PET/CT imaging using isotopes other than those specified in the above statement are considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

6.01.07 Positron Emission Tomography Non-Oncologic Applications

6.01.47 Positron Emission Tomography (PET) – Head Imaging

11.01.03 Experimental or Investigational Services

11.01.10 Clinical Trials

POLICY GUIDELINE(S)

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. For monitoring metastatic breast cancer, National Comprehensive Cancer Network (NCCN) Invasive Breast Cancer guidelines states:

A. “The most accurate assessments of disease activity typically occur when previously abnormal studies are repeated on a serial and regular basis. Generally, the same method of assessment should be used over time (e.g., an abnormality found on chest CT should generally be monitored with repeat chest CT)”

IV. For surveillance of follicular lymphoma NCCN guidelines for B-Cell Lymphomas it states:

A. “Follow-up includes diagnostic tests and imaging using the same modalities performed during workup as clinically indicated. Imaging should be performed whenever there are clinical indications.”

B. “Surveillance imaging is used for monitoring asymptomatic patients. When a site of disease can only be visualized on PET/CT scan (e.g., bone), it is appropriate to proceed with PET/CT scans for surveillance.”

V. 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.

VI. 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).

VII. 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.

VIII. 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.

IX. 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

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 theragnostic 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.

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.

The Deauville Criteria

Internationally accepted criteria that utilizes a five-point scoring system for the FDG avidity of a Hodgkin's lymphoma or non-Hodgkin's lymphoma tumor mass as seen on FDG PET:

Score 1: No uptake above the background.

Score 2: Uptake ≤mediastinum.

Score 3: Uptake > mediastinum but ≤liver.

Score 4: Uptake moderately increased compared to the liver at any site.

Score 5: Uptake markedly increased compared to the liver at any site.

Score X: New areas of uptake unlikely to be related to lymphoma.

Risk Group Chart (NCCN Prostate Cancer Guidelines)

Risk Group	**Clinical/Pathologic Features**	
Very Low	Has all of the following: • cT1c • Grade Group 1 • PSA <10 ng/mL • <3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/core. • PSA density <0.15 ng/mL/g	
Low	Has all of the following but does not qualify for very low risk: • Clinical T Stage- cT1–cT2a (palpable tumor limited to ≤1/2 of one side) • Gleason Grade Group 1 • PSA <10 ng/mL	
Intermediate	Has all of the following: • No high-risk group features. • No very-high-risk group features. Has one or more intermediate risk factors (IRFs): • cT2b–cT2c • Grade Group 2 or 3	Favorable intermediate Has ALL of the following: • 1 IRF • Grade Group 1 or 2 • <50% biopsy cores • positive (e.g., <6 of 12 cores)

	• PSA 10–20 ng/mL	Unfavorable intermediate Has one or more of the following: • 2 or 3 IRFs • Grade Group 3 • ≥ 50% biopsy cores positive (e.g., ≥ 6 of 12 cores).
High	Has one or more high-risk features but does not meet the criteria for very high risk. • cT3a-cT4 • Grade Group 4 or Grade Group 5 • PSA >20 ng/mL	
Very High	Has at least two of the following: • cT3–cT4 • PSA greater than 40 ng/ml • Grade Group 4 or 5	

SUPPORTIVE LITERATURE

Breast Cancer

Pérez-García et al (2021) conducted a multi-center, randomized, open label, non-comparative phase 2 trial in 45 hospitals across Europe. This study assessed early metabolic responses to neoadjuvant trastuzumab and pertuzumab using ^{18}F-FDG-PET and the possibility of chemotherapy de-escalation. Participants were women 18 or older with confirmed HER2-positive, stage I-IIIA, invasive, operable breast cancer with at least one lesion that is able to be evaluated by ^{18}F-FDG-PET. Participants were randomized into two groups, stratified by hormone receptor status: Group A consisted of 71 Group B consisted of 285 participants; Group A: docetaxel, carboplatin Group B: trastuzumab, and pertuzumab. Hormone positive patients in group B were given additional treatment based on menopause status. ^{18}F-FDG-PET was completed before randomization and two weeks after treatment cycles. Group A completed six cycles of treatment regardless of ^{18}F-FDG-PET results. Group B received two cycles of trastuzumab and pertuzumab, the ^{18}F-FDG-PET responders continued this treatment for six further cycles; the non-responders in this group were switched to six cycles of docetaxel, carboplatin, trastuzumab, and pertuzumab. Surgery was completed 2-6 weeks after the last dose. The coprimary endpoints were the proportion of ^{8}F-FDG-PET responders in group B with a pathological complete response in the breast and axilla, determined by pathology after surgery after eight cycles of treatment, and 3-year invasive disease-free survival of patients in group B. Of 285

patients in group B were ^{18}F-FDG-PET responders, of whom 86 of 227 had a pathological complete response. The researchers concluded that ^{18}F-FDG-PET identified patients with HER2-positive, early-stage breast cancer who were likely to benefit from chemotherapy-free dual HER2 blockade with trastuzumab and pertuzumab, and a reduced impact on global health status. Long term follow up will be needed to determine if this approach is valid for select patients not requiring chemotherapy.

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).

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.

Neuroendocrine tumors

Delssand et al (2020) conducted a phase III prospective clinical study evaluating the safety and diagnostic performance of the investigational radiopharmaceutical ^{64}Cu-DOTATATE for PET/CT imaging in patients with somatostatin receptor (SSTR)–positive neuroendocrine tumors (NETs). A dose-ranging study involving 12 patients divided into 3 dose groups (11Mbq, 148 MBq, and 185 MBq) to determine to e lowest does of ^{64}Cu-DOTATATE that produced diagnostic-quality PET/CT images. The dose ranging study identified 148 MBq (4.0 mCi) as the optimal dose for producing diagnostic-quality images. Using this dose, scans from 21 healthy volunteers and 42 NET-positive patients were assessed by three independent, blinded nuclear medicine physicians. The initial majority read showed a sensitivity of 90.9% and specificity of 96.6%, which improved to 100.0% sensitivity and 96.8% specificity after correcting for a misread in the standard of truth. The study also demonstrated excellent inter- and intrareader reliability and the ability to distinguish between localized and metastatic disease. No adverse or serious events were attributed to ^{64}Cu-DOTATATE, confirming its safety and effectiveness as a diagnostic imaging agent for SSTR-expressing NETs.

Prostate Cancer

Kuo et al (2024) conducted a post hoc analysis of 718 ^{18}F-flotufolastat PET/CT scans from the LIGHTHOUSE and SPOTLIGHT studies, 712/718 scans were deemed evaluable after excluding due to cystectomy, renal failure, or urinary catheter. The median bladder SUV_{max} and SUV_{mean} were 17.1 and 12.5, respectively. Among these, 682/712 (96%) patients showed either no urinary activity or activity distinguishable from disease. Urinary activity that interfered with assessment occurred in 24 (3.4%) patients. In cases where assessment was inhibited (score=2), the median bladder SUV_{mean} was notably higher at 20.5, compared to 3.8 for score 0 and 14.0 for score 1. Ureteric activity was absent in 401 patients (56.3%), and halo artifacts were observed in only two patients (0.3%). These findings suggest that urinary activity had minimal impact on scan interpretation, with bladder SUV values lower than those reported for other renally cleared PSMA-PET radiopharmaceuticals.

Jani et al (2023) reported the results from The SPOTLIGHT study (NCT04186845). The study assessed the diagnostic performance and safety of radiohybrid ^{18}F-rhPSMA-7.3, a novel PET

radiopharmaceutical for detecting recurrent prostate cancer. In the trial, 389 men underwent PET/CT scans after receiving the radiotracer, with 83% showing detectable cancer. Among 366 patients with confirmed disease status via histopathology or imaging, the verified detection rate ranged from 51% to 54%, surpassing the prespecified threshold. However, the combined region-level positive predictive value (PPV) ranged from 46% to 60%, not making the threshold. Notably, in the subgroup with histopathology-confirmed disease, both verified detection rate (81%) and PPV (72%) exceeded thresholds. No significant safety issues were reported. Overall, despite not meeting one coprimary endpoint, the data support the clinical utility of ^{18}F-rhPSMA-7.3 in identifying recurrent prostate cancer.

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).

PROFESSIONAL GUIDELINE(S)

Anal Cancer

National Comprehensive Cancer Network (NCCN) Guidelines for Anal Carcinoma Version 5.2025 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."

Biliary Tract Cancers

NCCN Guidelines for Biliary Tract Cancers Version 2.2025 recommend:

- "PET/CT has limited sensitivity but high specificity and may be considered when there is an equivocal finding or on a case-by-case basis. The routine use of PET/CT in the preoperative setting has not been established in prospective trials."

Breast Cancer

NCCN Guidelines for Breast Cancer Version 5.2025 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 useful for Stage IV (M1) or recurrent disease (consider FES-PET/CT for ER-positive disease and lobular histology."
- "If FDG-PET/CT is performed and clearly indicates bone metastasis on both the PET and CT

component, bone scan or sodium fluoride PET/CT may not be needed."

- "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."

Cervical Cancer

NCCN Guidelines for Cervical Cancer Version 2.2026 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 total hysterectomy (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 1.2026 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."
- "Prior to surgery, clinical staging should be performed to assess resectability with CT scan of the chest and abdomen, whole body FDG-PET (integrated FDG-PET/CT is preferred), and EUS."
- "CT scan is preferred but alternative imaging such as PET/CT or MRI can be considered as clinically indicated for patients who cannot undergo CT scan."

Hepatocellular Carcinoma

NCCN Guidelines for Hepatocellular Carcinoma Version 2.2025 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 2.2026 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 recommended, preferably within 4 weeks and no more than 8 weeks, before treatment. Ideally, FDG-PET/CT should be obtained in the treatment position."

NCCN Guidelines for Non-Small Cell Lung Cancer Version 2.2026 recommend:

- "PET/CT can be used to identify optimal biopsy targets in the setting of progression."
- "FDG PET/CT for solitary part-solid nodules if solid component greater than or equal to 6mm."
- "FDG-PET/CT for Incidental findings: solid nodule on chest CT greater than 8mm."
- "FDG-PET/CT is best performed before a diagnostic biopsy site is chosen in cases of high clinical suspicion for aggressive, advanced-stage tumors."
- "FDG-PET/CT should be completed if multiple lung cancers are suspected based on the presence of biopsy-proven synchronous lesions or history of lung cancer."
- "FDG-PET/CT should be performed to exclude disease progression or interval development of metastatic disease."
- "FDG-PET/CT should be obtained preferably within 4 weeks before treatment. It is ideal to obtain FDG-PET/CT in the treatment position."
- "PET scans can play a role in the evaluation and more accurate staging of NSCLC, for example, in identifying stage I (peripheral and central T1–2, N0), stage II, stage III, and stage IV diseases. However, FDG PET/CT is even more sensitive and is recommended by the panel."
- PET scans are not recommended for assessing whether brain metastases are present.
- "FDG PET/CT is not routinely recommended for routine surveillance and follow-up in patients with NSCLC, but it can be used to differentiate between benign conditions and true malignancies or as a tool in patients with recurrent disease after radiation therapy."

Melanoma

NCCN Guidelines for Melanoma Cutaneous Cancer Version 2.2025 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."
- "Routine cross-sectional imaging (CT, PET/CT, or MRI) is not recommended for workup of stage 0, I, II."
- "Stage III sentinel node positive- Cross-sectional imaging could be considered at baseline for staging (category 2B) or to assess specific signs or symptoms (category 2A)."
- "Regional nodal recurrence- Baseline imaging (CT and/or PET/CT or MRI) is recommended for staging and to evaluate specific signs or symptoms (category 2B)."
- "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)."

Neuroendocrine and Adrenal Tumors

NCCN Guidelines for Neuroendocrine Tumors and Adrenal Tumors Version 3.2025 recommend:

- "FDG-PET should be considered in select cases where G2 or higher NETs or NECs is documented."
- "SSTR-based imaging and fluorodeoxyglucose (FDG)-PET/CT scan are not recommended for routine surveillance after definitive resection but may be indicated to assess disease location and disease burden for comparison in cases of subsequent possible recurrence."

Occult Primary Cancer

NCCN Guidelines for Occult Primary Cancer Version 1.2026 recommend:

- "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 3.2025 recommend:

- "PET/CT, MRI, or PET/MRI may be indicated for indeterminate lesions if results will alter management."
- "PET/MRI or PET/CT is appropriate for newly diagnosed by previous surgery."
- "Pathologic staging for stage II-IV (post primary treatment)- Imaging as clinically indicated: PET/CT, or PET (skull base to mid-thigh)."
- "Stage I-IV (post primary treatment)- PET as clinically indicated for monitoring/follow-up for

patients not receiving treatment and recurrent disease."

- "For assessing advanced disease, FDG-PET/CT may also be useful if CT results are indeterminate."

Pancreatic Cancer

NCCN Guidelines for Pancreatic Adenocarcinoma Version 2.2025 recommend:

- "PET/CT or PET/MRI can be considered in patients with no metastatic disease with high-risk features."
- "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 or PET/MRI scan before and after initiation to assess response to systemic therapy and for restaging."

Prostate Cancer

NCCN Guidelines for Prostate Cancer Version 4.2026 recommend:

- Currently FDA-approved PSMA agents: ("PSMA-PET" refers to any of these FDA approved PSMA ligands)
  - Ga-68 PSMA-11,
  - F-18 piflufolastat PSMA (also known as F-18 DCFPyL),
  - F-18 flotufolastat PSMA (also known as rh-PSMA-7.3), and
  - C-11 choline,
  - F-18 fluciclovine,
  - F-18 sodium fluoride.
- "For M1 CRPC, PSMA-PET imaging only be used to determine if a patient is a candidate for Lu-177-PSMA-617."
- "PSMA-PET/CT or PET/MRI can be considered as an alternative to CT, MRI and bone scans for initial staging in unfavorable intermediate-, high-, and very high-risk disease, the detection of biochemically recurrent disease, and as workup for progression."
- "C-11 choline PET/CT or PET/MRI may be used to detect small volume recurrent disease in soft tissues and in bone."
- "PSMA-PET/CT or PSMA-PET/MRI can serve as a more effective frontline imaging tool for patients with micrometastatic disease."
- "PSMA imaging should be done before initiation of ADT."
- "Fluorodeoxyglucose (FDG)-PET/CT should not be used routinely for staging prostate cancer since data are limited in this setting."

- "F-18 FDG-PET has been shown to be prognostic in patients with progressive CRPC."
- "For active surveillance 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 1.2025 recommend:

- "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."

Testicular Cancer

NCCN Guidelines for Testicular Cancer Version1.2026 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."
- If PET/CT or CT scan is positive, resection or interventional radiology (IR)-guided biopsy of the residual mass should be considered or wait an additional 6 to 12 weeks and repeat imaging."

Non-Seminoma:

- Use of FDG-PET/CT scan is not clinically indicated for nonseminoma.

Thymoma and Thymic Carcinomas

NCCN Guidelines for Thymomas and Thymic Carcinomas Version 1.2026 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 1.2026 recommend:

- "Pre-treatment imaging with DOTATATE-PET can be used to guide radiotherapy volumes."
- "Consider FDG-PET/CT 3-6 months after initial therapy for stage IVC metastatic disease."

- "Consider FDG-PET/CT or MRI for anaplastic thyroid carcinoma on biopsy or dine needle biopsy (FNA)."
- "Consider FDG-PET/CT 2-3 months postoperative, when there is detectable basal calcitonin or elevated CEA."
- "Gross residual disease in neck- FDG-PET/CT or FDG-PET/MRI."
- "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."

REGULATORY STATUS

Medical Devices

The United States Food and Drug Administration (FDA) regulates imaging devices as medical devices. All imaging devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Dec 10]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2025 Dec 10]

Drugs

The United States Food and Drug Administration (FDA) is responsible for ensuring the safety, efficacy, and quality of drugs sold in the United States. This includes both prescription and over-the-counter medications. Refer to the FDA Drug website. Available from: https://www.fda.gov/drugs [accessed 2025 Dec 10]

The FDA maintains information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products. Available from: Drug Safety and Availability | FDA [accessed 2025 Dec 10]

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.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

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	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)

Code	Description
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
Multiple Codes	

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Positron Emission Tomography (FDG) for Oncologic Conditions (NCD 220.6.17) [accessed 2025 Dec 10]

Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer (NCD 220.6.19) [accessed 2025 Dec 10]

Positron Emission Tomography (FDG) for Solid Tumors (NCA CAG-00181R4) - Decision Memo [accessed 2025 Dec 10]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION

Committee Approval Dates

11/18/99, 04/19/00, 04/19/01, 01/17/02, 10/16/02, 01/16/03, 08/21/03, 05/19/04, 08/18/05, 03/16/06, 04/19/07, 09/20/07, 08/21/08, 11/19/09, 04/22/10, 04/21/11, 09/20/12, 08/15/13, 04/17/14, 04/16/15, 04/21/16, 01/19/17, 12/21/17, 10/18/18, 06/20/19, 05/21/20, 05/20/21, 09/16/21, 03/24/22, 09/15/22, 08/17/23, 01/18/24, 07/18/24, 11/21/24, 06/26/25, 10/16/25, 01/22/26

Date	Summary of Changes
01/22/26	• Off cycle review. Updates were made to policy criteria for Hodgkin and Follicular Lymphoma, and Prostate Cancer. All “medically appropriate” or indicated statements were changed to “medically necessary”.
10/16/25	• Off cycle review. Changes were made to criteria for cervical cancer, small

	bowel, lung, lymphoma (Hodgkin), melanoma, metastatic bone, multiple myeloma and plasmacytomas, ovarian, pancreatic, primary central nervous system, salivary gland, chondromas, soft tissue sarcoma, squamous cell carcinoma of head and neck, hepatocellular carcinoma, and gastric cancers.
06/26/25	• Off cycle review. Changes were made to criteria for cancers of the breast, esophageal and GE Junction, lung, melanoma, metastatic bone, multiple myeloma, adrenal, adrenocortical, bronchopulmonary, gastrointestinal/pancreatic neuroendocrine, pancreatic, brain, prostate, soft tissue, testicular, transitional cell and, diffuse large B cell, marginal zone and T-cell lymphomas. Added radiotracer ^{18}F Na Fluoride PET bone scan for breast cancer and prostate cancer.
01/01/25	• Summary of changes tracking implemented.
11/18/99	• Original effective date