

# 2024 Positron Emission Tomography (PET) Whole Body

**Diagnostic Imaging** 

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# 2024 Positron Emission Tomography (PET) Oncology: Blood, Bone Marrow and Lymphatic System

#### **Diagnostic Imaging**

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Last Review Date: 10/28/2024
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# Positron Emission Tomography (PET) Oncology: Blood, Bone Marrow and Lymphatic System

Acute Lymphoblastic Leukemia (ALL) • Acute Myelogenous Leukemia (AML) • Leukemia • Lymphocytic Leukemia • Lymphoma • Multiple Myeloma • Smoldering Myeloma



#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/ computed tomography (CT) *depends on the radiopharmaceutical* to be used.



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx *if* applicable to individual's healthplan membership.

### **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

# **PET Oncology: Blood, Bone Marrow and Lymphatic System Guideline**

Positron emission tomography (PET) for blood, bone marrow or lymphatic system cancers is considered medically appropriate when the documentation demonstrates **ANY** of the following:



1. Acute lymphoblastic leukemia (ALL), with lymphomatous extramedullary disease, for initial staging and restaging.

**References:** [8] [17] [10]

- 2. Acute myelogenous leukemia (AML) for **ANY** of the following:
  - a. Initial staging when extramedullary involvement is <u>suspected</u>.
  - b. Restaging when extramedullary involvement is <u>suspected</u> or <u>known</u>.

**References:** [8] [17] [9] [12]

3. Leukemia, if there is lymph node involvement (lymphomatous features), soft tissue/ extramedullary involvement (myeloid sarcoma) and/or it forms "chloromas" (leukemia tumor), for initial staging and/or restaging.

**References:** [8] [17] [15] [11]

- 4. Lymphocytic leukemia (chronic [CLL] and small [SLL]) for **ANY** of the following:
  - a. Initial staging when high-grade transformation is suspected.
  - b. Biopsy guidance for initial staging and restaging **AND** prior imaging is non-diagnostic or indeterminate.
  - c. Restaging with accelerated CLL

**References:** [8] [17] [14]

5. Lymphoma (Non-Hodgkin's and Hodgkin's) for initial staging or restaging. (\***NOTE:** *PET/MR may be appropriate.*)

**References:** [8] [3] [16] [5] [4] [7] [2]

- 6. Multiple myeloma (active and plasmacytoma) for initial staging or restaging. **References:** [8] [6] [1] [13]
- 7. Smoldering multiple myeloma for initial staging or restaging. (\*NOTE: Restaging is indicated annually or more frequently if disease progression is suspected.)

  References: [8] [6] [1] [13]



#### LCD 35391

See also, LCD 35391: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.





#### LCD 39521

See also, **LCD 39521**: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

# PET Oncology: Blood, Bone Marrow and Lymphatic System Guideline Procedure Codes

Table 1. PET Oncology: Blood, Bone Marrow, Lymphatic System Cancers

Code	Description
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

# **PET Oncology: Blood, Bone Marrow and Lymphatic System Summary of Changes**

PET Oncology: Blood, Bone Marrow and Lymphatic System guideline had the following version changes from 2023 to 2024:

- Citations updated per the evidence.
- Evidence reviewed and indications remained the same.
- Mid-cycle update: added Pediatric Preamble

# **PET Oncology: Blood, Bone Marrow and Lymphatic System Guideline Definitions**

**Acute lymphoblastic leukemia (ALL)** is a type of lymphocytic leukemia marked by an abnormal increase in the number of lymphoblasts and characterized by rapid onset and progression of symptoms which include fever, anemia, pallor, fatigue, appetite loss, bleeding, thrombocytopenia, granulocytopenia, bone and joint pain, and enlargement of the lymph nodes, liver and spleen that occurs chiefly during childhood.

**Acute myeloid leukemia (AML)** is a type of myelogenous leukemia with rapid onset and progression that is marked by an abnormal increase in the number of myeloblasts, especially in



bone marrow and blood, that is characterized by symptoms similar to those of acute lymphoblastic leukemia and that occurs chiefly during adulthood.

**Chloroma (myeloid sarcoma)** is a pathologic diagnosis for an extramedullary proliferation of blasts of one or more of the myeloid lineages that disrupt the normal architecture of the tissue in which it is found.

**Chronic lymphocytic leukemia (CLL)** is a type of lymphocytic leukemia that is marked by an abnormal increase in the number of mature lymphocytes especially B cells, that is characterized by slow onset and progression of symptoms which include anemia, pallor, fatigue, appetite loss, granulocytopenia, thrombocytopenia, hypogammaglobulinemia and enlargement of the lymph nodes, liver, and spleen, and that occurs especially in older adults.

**Hodgkin lymphoma** is a malignant lymphoma marked by the presence of Reed-Sternberg cells and characterized by progressive enlargement of lymph nodes, spleen and liver and progressive anemia.

**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Leukemia** is a type of cancer that affects the blood and bone marrow. It's caused by the rapid production of abnormal white blood cells. These abnormal white blood cells can't fight infection and make it harder for the bone marrow to produce red blood cells and platelets.

**Lymphadenopathy** refers to the swelling of lymph nodes which can be secondary to bacterial, viral, or fungal infections, autoimmune disease, and malignancy.

**Lymphoma** is a type of blood cancer that affects the immune system. Lymphoma occurs when abnormal white blood cells, called lymphocytes, grow in the lymphatic system.

**Magnetic resonance imaging (MRI)** is a non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

**Metastases** is the spread of a disease-producing agency (such as cancer cells) from the initial or primary site of disease to another part of the body.

**Multiple myeloma** is a blood cancer that develops in plasma cells in the bone marrow. Plasma cells are white blood cells that produce antibodies to protect the body from infection. In multiple myeloma, the plasma cells grow too much, crowding out normal bone marrow cells.

**Myeloid sarcoma (chloroma)** is a pathologic diagnosis for an extramedullary proliferation of blasts of one or more of the myeloid lineages that disrupt the normal architecture of the tissue in which it is found.

Non-diagnostic is a result that does not lead to a confirmed diagnosis.

**Non-Hodgkin lymphoma** is any of various malignant lymphomas that are not classified as Hodgkin's lymphoma, have malignant cells derived from B cells, T cells or natural killer cells characterized especially by enlarged lymph nodes, fever, night sweats, fatigue and weight loss.



**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15-17 years),
  - 3. Late (ages 18–21 years)
  - 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Plasmacytoma** is a rare blood cancer that occurs when healthy plasma cells become abnormal. It's a tumor of plasma cells that can occur in soft tissue or bone. Plasmacytomas can occur anywhere in the body, but they're most common in the spine.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Sarcoma** is a malignant tumor arising in tissue (such as connective tissue, bone, cartilage or striated muscle) of mesodermal origin.

**Small lymphocytic lymphoma** is a slow growing non-Hodgkin lymphoma that affects B cells (also known as B lymphocytes), which are specialized white blood cells that produce immunoglobulins (also called antibodies) that help protect against infection and disease.



**Smoldering multiple myeloma** is a precancerous condition that alters certain proteins in blood and/or increases plasma cells in bone marrow, but it does not cause symptoms of disease. About half of those diagnosed with the condition, however, will develop multiple myeloma within 5 years. **Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

# **PET Oncology: Blood, Bone Marrow and Lymphatic System Guideline References**

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- [9] Pollyea, D.A., Altman, J.K., . . . Uy, G. (2024). Acute Myeloid Leukemia (Age ≥ 18) Version 2.2024. *National Comprehensive Cancer Network*. Retrieved: May 2024. https://www.nccn.org/professionals/physician\_gls/pdf/aml.pdf
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### 2024 Positron Emission Tomography (PET) Breast

#### **Diagnostic Imaging**

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### Positron Emission Tomography (PET) Oncology: Breast Cancer



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.





#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/computed tomography (CT) *depends on the radiopharmaceutical* to be used.

### **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

### **PET Oncology: Breast Cancer Guideline**



#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/computed tomography (CT) *depends on the radiopharmaceutical* to be used.

Positron emission tomography (PET) of the breast is considered medically appropriate when the documentation demonstrates breast cancer is <u>known</u>, for initial staging or restaging, **AND** <u>prior</u> imaging is non-diagnostic or indeterminate

**References**:[3] [2] [1]



#### LCD 35391

See also, **LCD 35391**: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



#### LCD 39521

See also, **LCD 39521**: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



### **PET Oncology: Breast Cancer Procedure Codes**

#### **Table 1. PET Breast Cancer Associated Procedure Codes**

CODE	DESCRIPTION
G0252	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)
78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

### **PET Oncology: Breast Cancer Summary of Changes**

PET Oncology: Breast Cancer guideline had the following version changes from 2023 to 2024:

- Removed the following as research does not support the indication:
  - "Breast cancer screening" indication
  - "Breast cancer surveillance" indication
- Mid-cycle update: added Pediatric Preamble

### **PET Oncology: Breast Cancer Definitions**

**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

Non-diagnostic is a result that does not lead to a confirmed diagnosis.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15–17 years),



- 3. Late (ages 18–21 years)
- 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

**TNM staging system** is a system to describe the amount and spread of cancer in a person's body. T describes the size of the tumor and any spread of cancer into nearby tissue; N describes the spread of cancer to nearby lymph nodes; and M describes metastasis (spread of cancer to other parts of the body).

**Table 1. TNM Staging System** 

T describes the original Primary Tumor	N category describes whether or not the cancer has reached nearby lymph nodes	M category tells whether there are distant metastases (spread of cancer to other parts of the body).
<b>TX</b> Primary tumor cannot be evaluated	<b>NX</b> Regional lymph nodes cannot be evaluated	
TO No evidence of primary tumor	<b>NO</b> No regional lymph node involvement (no cancer found in the lymph nodes)	<b>M0</b> No distant metastasis (cancer has not spread to other parts of the body)



T describes the original Primary Tumor	N category describes whether or not the cancer has reached nearby lymph nodes	M category tells whether there are distant metastases (spread of cancer to other parts of the body).
<b>Tis</b> Carcinoma in situ (early cancer that has not spread to neighboring tissue)		

**N1 to N3** Involvement of regional lymph

nodes (number and/or extent of spread)

**M1** Distant metastasis (cancer has

spread to distant parts of the body)

### **PET Oncology: Breast Cancer References**

- [1] Groheux, D. (2022). FDG-PET/CT for primary staging and detection of recurrence of breast cancer. *Seminars in Nuclear Medicine*, *52*(5), 352-370.
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# 2024 Positron Emission Tomography (PET) Central Nervous System

### **Diagnostic Imaging**

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T1 to T4 Size and/or extent of the

primary tumor



# Positron Emission Tomography (PET) Central Nervous System (CNS)

Brain • Chordoma • Neuroblastoma • Neuroendocrine Cancers • Neurofibromatosis Type 1 • Paraganglioma



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx *if* applicable to individual's healthplan membership.



#### NCD 220.6.13

See also, **NCD 220.6.13**: FDG PET for Dementia and Neurodegenerative Diseases at https://www.cms.gov/medicare-coverage-database/search.aspx *if applicable to individual's healthplan membership*.



#### NCD 220.6.9

See also, **NCD 220.6.9**: FDG PET for Refractory Seizures at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/ computed tomography (CT) *depends on the radiopharmaceutical* to be used.

### **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.



### **PET CNS Guidelines**



#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/ computed tomography (CT) *depends on the radiopharmaceutical* to be used.

Positron emission tomography (PET) for the central nervous system (CNS) is considered medically appropriate when the documentation demonstrates **ANY** of the following:

- 1. Brain evaluation for **ANY** of the following:
  - a. Cancer or brain tumor is known, <u>brain MRI is non-diagnostic or indeterminate</u> and **ANY** of the following:
    - i. High-grade glioma differentiation
    - ii. Lymphoma of the brain, primary, evaluation
    - iii. Meningioma evaluation
    - iv. Procedural guidance (eg, biopsy, intervention)
    - v. Radiation necrosis differentiation from residual/recurrent tumor **AFTER** treatment
  - b. Cognitive impairment or dementia is known and **ALL** the following:
    - i. Condition includes **ANY** of the following:
      - A. Alzheimer's disease, dementia with Lewy body disease (DLB) and frontotemporal lobar degeneration (FTD), for condition differentiation
      - B. Beta amyloid plaque presence (in Alzheimer's disease) is <u>suspected</u> and imaging is needed to be considered for treatment with Aduhelm or Legumbi (\***NOTE**: *MRI is NOT indicated for Legembi*)
      - C. Early Alzheimer's disease detection
    - ii. Brain MRI is non-diagnostic or indeterminate and **ALL** of the following:
      - A. Mini Mental Status Evaluation (MMSE) or Montreal Cognitive Assessment (MoCA) with results less than 26 **OR** neuropsychological test (eg, memory testing, mood and personality, motor speed and dexterity) showing **AT LEAST** mild cognitive impairment.



- B. Potential treatable causes (eg, anemia, medication side effects, inflammatory disease, vascular disease) are assessed and treated.
- c. Post-treatment/procedural evaluation of progress after brain intervention, procedure, surgery or treatment.
- d. Prior <u>PET CNS imaging is non-diagnostic or indeterminate</u>. (\***NOTE**: One follow-up is appropriate to evaluate for changes since preceding imaging finding[s]. Further surveillance is appropriate when lesion is specified as "highly suspicious" or there is a change since last exam.)
- e. Seizure is refractory, to determine candidacy for intervention.

**References:** [13] [9] [22] [25] [11] [6] [20] [19] [5] [1] [17] [16] [15]

2. Chordoma evaluation, for initial staging or restaging **AND** <u>prior imaging is non-diagnostic</u> or indeterminate.

**References:** [21] [24]

- 3. Neuroblastoma **AND EITHER** of the following:
  - a. Initial staging, when meta-iodobenzylguanidine (MIBG) scan is negative **OR** there are discordant findings between MIBG and pathology.
  - b. Restaging, when FDG PET was used for initial staging **OR** MIBG scan is non-diagnostic or indeterminate.

**References:** [18] [12]

- 4. Neuroendocrine tumors (NET) evaluation with **ANY** of the following:
  - a. FDG PET **AND EITHER** of the following:
    - i. Poorly differentiated tumor, for initial staging or restaging, when **AND** prior imaging is non-diagnostic or indeterminate.
    - ii. Well differentiated tumor grade 3 with high Ki-67 (at least 55%), for staging or restaging, **AND** prior PET somatostatin receptor (SSTR [dotatate]) is non-diagnostic or indeterminate.
  - b. Non-FDG PET tracers (eg, CU64-Dotatate, GA68-Dotatoc, GA68-Dotatate, somatostatin receptor [SSTR]), for NET of the gastrointestinal tract, lung, pancreas, thymus AND unknown primary, AND EITHER of the following:
    - i. Initial staging (\***NOTE**: *PET/MR may be considered*.)
    - ii. Restaging, when progression or recurrence is suspected, based on labs and/or prior imaging **AND** SSTR directed therapy is being considered.

**References:** [2] [3] [10]



- 5. Neurofibromatosis Type 1 evaluation **AND EITHER** of the following:
  - a. Neurofibroma is <u>known</u> **AND** transformation to malignant peripheral nerve sheath tumor (MPNST) is <u>suspected</u> based on change in imaging (eg, change in texture, rapid growth) **OR** symptoms (eg, new or worsening pain in the location of the neurofibroma)
  - b. MPNST is known, for restaging, **AND** prior <u>PET is non-diagnostic or indeterminate</u>.

**References:** [7] [23]

- 6. Paraganglioma, with non-FDG PET tracers (eg, CU64-Dotatate, GA68-Dotatoc, GA68-Dotatate, SSTR) evaluation for **EITHER** of the following:
  - a. Initial staging (\***NOTE**: *PET/MR may be considered*.)
  - b. Restaging, when progression or recurrence is suspected or known, based on labs and/or prior imaging, **AND** SSTR directed therapy is being considered.

**References:** [4] [14]



#### LCD 35391

See also, LCD 35391: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



#### LCD 39521

See also, **LCD 39521**: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

### **PET CNS Procedure Codes**

### Table 1. Central Nervous System Cancers Positron Emission Tomography (PET) Associated Procedure Codes

Code	Description
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	Brain imaging, positron emission tomography (PET); perfusion evaluation
78813	Positron emission tomography (PET) imaging; whole body
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh



Code	Description
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

### **PET CNS Summary of Changes**

PET Central Nervous System guideline had the following version changes from 2023 to 2024:

- Added the following to keep in line with current research:
  - "Early Alzheimer's disease" under "Cognitive impairment or dementia is known"
  - "Meningioma evaluation" under "Cancer or brain tumor is known"
  - "Neurofibromatosis Type 1" indication
  - "Paraganglioma" indication
  - "Prior PET CNS imaging" indication
- Mid-cycle update: added Pediatric Preamble

### **PET CNS Definitions**

**Alzheimer's disease** is a degenerative brain disease of unknown cause that is the most common form of dementia, it usually starts in late middle age or in old age and results in progressive memory loss, impaired thinking, disorientation and changes in personality and mood.

**Beta-amyloid plaque** is a build-up or "clumping" of the beta-amyloid protein that occurs between neurons and disrupt cell function.

**Chordoma** is a rare, slow-growing bone cancer that can occur in the spine or skull base.

**Dementia** is a usually progressive condition marked by the development of multiple cognitive deficits, such as memory impairment, aphasia and the inability to plan and initiate complex behavior.

**Glioma** is a type of tumor that occurs in the brain and spinal cord.

**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Ki-67**, also known as Marker of Proliferation Ki-67 (MKI67), is a protein found in dividing cells that is used as a proliferation marker for human tumor cells.

**Lewy body dementia (LBD)** is a disease associated with abnormal deposits of a protein called alpha-synuclein in the brain. These deposits, called Lewy bodies, affect chemicals in the brain whose changes, in turn, can lead to problems with thinking, movement, behavior, and mood.



**Lymphoma** is a type of blood cancer that affects the immune system. Lymphoma occurs when abnormal white blood cells, called lymphocytes, grow in the lymphatic system.

**Magnetic resonance imaging (MRI)** is a non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

**Meningioma** is a slow-growing, encapsulated, typically benign tumor arising from the meninges and often causes damage by pressing upon the brain and adjacent parts.

**Meta-iodobenzylguanidine (MIBG) scan** is a nuclear scan test that uses injected radioactive material (radioisotope) and a special scanner to locate or confirm the presence of pheochromocytoma and neuroblastoma, which are tumors of specific types of nervous tissue. An alternative name is adrenal medullary imaging.

**Mini-Mental State Examination** is a set of 11 questions that doctors and other healthcare professionals commonly use to check for cognitive impairment (problems with thinking, communication, understanding and memory).

**Montreal Cognitive Assessment (MoCA)** is a brief test of cognitive function, taking 10 minutes to administer. It assesses short-term memory, visuospatial function, executive function, attention, concentration and working memory, language, and orientation.

Necrosis is localized death of living tissue.

**Neuroblastoma** is a cancer that develops from immature nerve cells found in several areas of the body. Neuroblastoma most commonly arises in and around the adrenal glands, which have similar origins to nerve cells and sit atop the kidneys.

**Neurofibromatosis** is a rare genetic disorder that causes benign tumors to grow on nerves and other parts of the body. There are three types of neurofibromatosis: neurofibromatosis 1 (NF1), neurofibromatosis 2 (NF2) and schwannomatosis.

**Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Paraganglioma** is a type of neuroendocrine tumor that forms near certain blood vessels and nerves outside of the adrenal glands.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15-17 years),
  - 3. Late (ages 18–21 years)
  - 4. Older ages may be appropriate for children with special healthcare needs.



**Pheochromocytoma** is a small vascular tumor of the adrenal medulla, causing irregular secretions of epinephrine and norepinephrine, leading to attacks of raised blood pressure, palpitations and headaches.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Refractory** is resistance to treatment or cure.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Seizure** is a sudden, uncontrolled electrical disturbance in the brain. It can cause changes in behavior, movements or feelings, and in levels of consciousness.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

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# 2024 Positron Emission Tomography (PET) Gastrointestinal

#### **Diagnostic Imaging**

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# Positron Emission Tomography (PET) Oncology: Gastrointestinal Cancers

Anal • Colorectal • Esophageal • Gastric/Stomach • Gastrointestinal Stromal Tumors (GIST) • Small Bowel Cancers



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx *if applicable to individual's healthplan membership*.



#### WARNING

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/ computed tomography (CT) *depends on the radiopharmaceutical* to be used.

### PET Oncology: Gastrointestinal Cancers Contraindications/ Exclusions

Positron emission tomography (PET) contraindications and exclusions for small bowel cancer may include when PET evaluation is **NOT** indicated for initial imaging.

### **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

### **PET Gastrointestinal Cancers Guidelines**

Positron emission tomography (PET) for gastrointestinal cancers is considered medically appropriate when the documentation demonstrates **ANY** of the following:

- Anal cancer evaluation for initial staging or restaging AND prior imaging (eg, computed tomography [CT] or magnetic resonance imaging [MRI]) is non-diagnostic or indeterminate. (\*NOTE: PET/MR can be done if available)
   References: [3] [11]
- 2. Colorectal cancer evaluation for initial staging or restaging and ANY of the following:



- a. Liver-directed imaging guided therapies are being considered.
- b. Metastatic disease is potentially curable by surgery.
- c. Prior <u>imaging (eg, CT or MRI) is non-diagnostic or indeterminate</u>. (\***NOTE**: For restaging, include discordance between tumor markers (eg, carcinoembryonic antigen [CEA])

**References:** [4] [5] [8] [9]

- 3. Esophageal and esophagogastric junction (EGJ) cancer evaluation for **EITHER** of the following:
  - a. Initial staging when there is **NO** evidence of metastases.
  - b. Restaging **AFTER** pre-operative or definitive chemoradiation **OR** when <u>prior</u> imaging is non-diagnostic or indeterminate.

**References:** [1] [13] [10]

- 4. Gastric/stomach cancer evaluation for **EITHER** of the following:
  - a. Initial staging, when <u>prior imaging is non-diagnostic or indeterminate</u> **AND** there is **NO** prior confirmation of metastases.
  - b. Restaging when prior imaging is non-diagnostic or indeterminate

**References:** [2] [12]

5. Gastrointestinal stromal tumors (GIST) for initial staging and restaging **AND** <u>prior imaging</u> is non-diagnostic or indeterminate.

**References:** [14] [7]

6. Small bowel carcinoma evaluation for restaging **AND** <u>prior imaging (CT or MRI) is non-diagnostic or indeterminate.</u>

Reference: [6]



#### LCD 35391

See also, **LCD 35391**: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.





#### LCD 39521

See also, **LCD 39521**: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

### **PET Oncology: Gastrointestinal Cancers Procedure Codes**

### Table 1. Gastrointestinal Cancers Positron Emission Tomography (PET) Associated Procedure Codes

Codes	Description
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

### **PET Oncology: Gastrointestinal Cancers Summary of Changes**

PET Oncology; Gastrointestinal guideline had the following version changes from 2023 to 2024:

- Added the following to keep in line with current evidence:
  - Gastrointestinal stromal tumor indication
  - Indications under "Esophageal"
- Removed the following as current evidence no longer supports the indication:
  - Indications under "Initial staging" under "Gastric/stomach cancer"
  - Indications under "Restaging" under "Gastric/stomach cancer"
- Mid-cycle update: added Pediatric Preamble

### **PET Oncology: Gastrointestinal Cancers Definitions**

**Carcinoembryonic antigen (CEA)** is a glycoprotein present in fetal digestive-tract tissues and in peripheral blood of people with some forms of cancer.

**Computed tomography (CT)** refers to a computerized X-ray imaging procedure in which a three-dimensional image of a body structure is revealed through a series of cross-sectional images or "slices."

**Indeterminate** findings are inconclusive or insufficient for treatment planning.



**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Magnetic resonance imaging (MRI)** is a non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

**Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15-17 years),
  - 3. Late (ages 18–21 years)
  - 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

**TNM staging system** is a system to describe the amount and spread of cancer in a person's body. T describes the size of the tumor and any spread of cancer into nearby tissue; N describes



the spread of cancer to nearby lymph nodes; and M describes metastasis (spread of cancer to other parts of the body).

**Table 1. TNM Staging System** 

T describes the original Primary Tumor	N category describes whether or not the cancer has reached nearby lymph nodes	M category tells whether there are distant metastases (spread of cancer to other parts of the body).
<b>TX</b> Primary tumor cannot be evaluated	<b>NX</b> Regional lymph nodes cannot be evaluated	
<b>TO</b> No evidence of primary tumor	<b>NO</b> No regional lymph node involvement (no cancer found in the lymph nodes)	<b>M0</b> No distant metastasis (cancer has not spread to other parts of the body)
<b>Tis</b> Carcinoma in situ (early cancer that has not spread to neighboring tissue)		
<b>T1 to T4</b> Size and/or extent of the primary tumor	<b>N1 to N3</b> Involvement of regional lymph nodes (number and/or extent of spread)	<b>M1</b> Distant metastasis (cancer has spread to distant parts of the body)

### **PET Oncology: Gastrointestinal Cancers References**

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# 2024 Positron Emission Tomography (PET) Genitourinary

#### **Diagnostic Imaging**

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Last Review Date: 10/28/2024
Previous Review Date: 07/19/2024
Guideline Initiated: 06/30/2019



# Positron Emission Tomography (PET) Oncology: Genitourinary Cancers

Adrenal • Bladder • Mesothelioma: Peritoneal • Penile • Peritoneal • Renal • Testicular Cancers



#### WARNING

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/computed tomography (CT) *depends on the radiopharmaceutical* to be used.

# **PET Oncology: Genitourinary Cancers Contraindications/ Exclusions**

Positron emission tomography (PET) contraindications and exclusions for genitorurinary cancers may include **ANY** of the following:

- Renal cancer is **NOT** indicated for initial staging or restaging.
- Testicular cancer, non-seminoma, PET evaluation is NOT indicated for initial staging or restaging.
- Testicular cancer, seminoma, PET evaluation is NOT indicated for initial staging.
   References: [13] [8]



### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

### **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

### **PET Genitourinary Cancers Guidelines**

Positron emission tomography (PET) for genitourinary cancers is considered medically appropriate when the documentation demonstrates **ANY** of the following:



- 1. Adrenal cancer evaluation (**NOT** pheochromocytoma or paraganglioma) and **EITHER** of the following:
  - a. Initial staging when <u>prior imaging (computed tomography [CT] or magnetic resonance imaging [MRI]) is suspicious</u> for adrenocortical carcinoma (eg, inhomogenous mass with irregular margins, local invasion and/or size is more than 4 cm).
  - b. Restaging when prior imaging (CT or MRI) is non-diagnostic or indeterminate.

References:[3] [12]

- 2. Bladder cancer evaluation for initial staging and restaging, when muscle invasive disease is known, and **BOTH** of the following:
  - a. Indeterminate finding is outside of the urinary tract.
  - b. Prior imaging is non-diagnostic or indeterminate.

**References**: [16] [1] [6]

3. Mesothelioma (peritoneal) evaluation for initial staging or restaging.

**References**: [10] [11] [5]

4. Penile cancer evaluation for initial staging and restaging when <u>prior imaging is non-diagnostic</u> or indeterminate.

References: [4] [7]

5. Peritoneal cancer evaluation for initial staging and restaging when <u>prior imaging is non-diagnostic or indeterminate</u>.

**References**: [2] [14]

- 6. Testicular cancer, seminoma, evaluation for restaging and **EITHER** of the following:
  - a. Prior imaging is non-diagnostic or indeterminate.
  - b. Residual mass (greater than 3 cm) is known and lab results (Alpha fetoprotein [AFP] and beta human chorionic gonadotropin [beta-HCG]) are normal **AND** chemotherapy was at least 6 weeks ago (\***NOTE**: *if final PET/CT is non-diagnostic or indeterminate, a repeat PET/CT at least 6 weeks later may be warranted.*).

**References**: [8] [15]



#### LCD 35391

See also, **LCD 35391**: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.





#### LCD 39521

See also, **LCD 39521**: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

### **PET Oncology: Genitourinary Cancers Procedure Codes**

### Table 1. Genitourinary Cancers Positron Emission Tomography (PET) Associated Procedure Codes

Code	Description
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

### **PET Oncology: Genitourinary Cancers Summary of Changes**

PET Oncology: Genitourinary Cancers guideline had the following version changes from 2023 to 2024:

- Added the following to keep in line with current research:
  - "Adrenal cancer" indication
  - Indications under "Bladder cancer"
  - "Peritoneal cancer' Indication
  - "Peritoneal (mesothelioma)" indication
- Moved "Renal cell carcinoma" to the contraindications/Exclusions section
- Mid-cycle update: added Pediatric Preamble

### **PET Oncology: Genitourinary Cancers Definitions**

**Alpha-fetoprotein (AFP)** is a fetal blood protein present abnormally in adults with some cancers (as of the liver) and normally in the amniotic fluid of pregnant women with high or low levels tending to be associated with certain birth defects (such as spina bifida or Down syndrome). **Computed tomography (CT)** refers to a computerized X-ray imaging procedure in which a three-dimensional image of a body structure is revealed through a series of cross-sectional images or "slices."



**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Magnetic resonance imaging (MRI)** is a non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

**Mesothelioma** is an agressive cancer that affects the thin membrane protecting several of the body's most important organs, including the lungs, abdomen and heart.

**Metastases** is the spread of a disease-producing agency (such as cancer cells) from the initial or primary site of disease to another part of the body.

Non-diagnostic is a result that does not lead to a confirmed diagnosis.

**Paraganglioma** is a type of neuroendocrine tumor that forms near certain blood vessels and nerves outside of the adrenal glands.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15-17 years),
  - 3. Late (ages 18–21 years)
  - 4. Older ages may be appropriate for children with special healthcare needs.

**Peritoneum** is the serous membrane that lines the abdominal cavity and covers most of the organs in the abdomen.

**Pheochromocytoma** is a small vascular tumor of the adrenal medulla, causing irregular secretions of epinephrine and norepinephrine, leading to attacks of raised blood pressure, palpitations and headaches.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.



**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Recurrence** is a new occurrence of something that happened or appeared before.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Seminoma** is a malignant germ cell tumor that most commonly involves the testicle and less frequently the mediastinum, retroperitoneum or other extra-gonadal sites.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

### **PET Oncology: Genitourinary Cancers References**

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# 2024 Positron Emission Tomography (PET) Oncology: Gynecological Cancers

#### **Diagnostic Imaging**

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Last Review Date: 10/28/2024
Previous Review Date: 07/20/2024
Guideline Initiated: 06/30/2019



# Positron Emission Tomography (PET) Oncology: Gynecological Cancers

Cervical • Fallopian Tube • Gestational Trophoblastic • Ovarian • Uterine/ Endometrial • Vaginal • Vulvar Cancers



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/computed tomography (CT) *depends on the radiopharmaceutical* to be used.

## **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

## **PET Oncology: Gynecological Cancers Guideline**

Positron emission tomography (PET) for gynecological cancers (cervical, fallopian tube, gestational trophoblastic, ovarian, uterine/endometrial, vaginal and vulvar) is considered medically appropriate when the documentation demonstrates **ANY** of the following:

- 1. Cervical cancer evaluation and **EITHER** of the following:
  - a. Initial staging for stage IB1 and above (\***NOTE**: *May consider PET/magnetic resonance [MR]*.)
  - b. Restaging, when it is at least 12 weeks since last chemoradiation or radiation treatment.

**References:** [10] [6] [1] [16]

2. Fallopian tube cancer evaluation for initial staging and restaging when <u>prior imaging is non-diagnostic or indeterminate</u>.

**Reference:** [10] [2]



- 3. Gestational trophoblastic cancer evaluation for **EITHER** of the following:
  - a. Initial staging and prior imaging is non-diagnostic or indeterminate.
  - b. Restaging and <u>prior imaging is non-diagnostic or indeterminate</u> **OR** when chemotherapy is completed **AND** human chorionic gonadotropin (hCG) is **NOT** a reliable marker.

**Reference:** [10] [9] [2]

- 4. Ovarian cancer evaluation for **EITHER** of the following:
  - a. Initial staging and prior imaging is non-diagnostic or indeterminate.
  - b. Restaging and <u>prior imaging is non-diagnostic or indeterminate</u>, including discordance between tumor markers (Cancer antigen [CA] -125) and imaging.

**References:** [10] [12] [2] [8]

5. Uterine/endometrial cancer evaluation for initial staging and restaging when <u>prior imaging</u> <u>is non-diagnostic or indeterminate</u>.

**References:** [10] [17] [3]

6. Vaginal cancer evaluation for initial staging or restaging.

**References:** [10] [11] [15] [4]

- 7. Vulvar cancer evaluation for **ANY** of the following:
  - a. Initial staging and **ANY** of the following:
    - i. Prior <u>imaging is non-diagnostic or indeterminate</u>.
    - ii. T2 disease or higher (extension beyond vulva/perineum)
  - b. Restaging

**References:** [10] [14] [18] [5] [13]



#### LCD 35391

See also, **LCD 35391**: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



#### LCD 39521

See also, **LCD 39521**: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



## **PET Oncology: Gynecological Cancers Procedure Codes**

## Table 1. Gynecological Cancers Positron Emission Tomography (PET) Associated Procedure Codes

Code	Description
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

## **PET Oncology: Gynecological Cancers Summary of Changes**

PET Oncology: Gynecological Cancers guideline had the following version changes from 2023 to 2024:

- Added the following to keep in line with current research:
  - Indications under "Cervical cancer"
  - Indications under "Gestational trophoblastic cancer"
  - Indications under "Ovarian cancer"
- Removed the following to keep in line with current research (moved to PET Genitourinary):
  - "Mesothelioma (periotoneal)" indication
  - "Peritoneal cancer" indication
- Mid-cycle update: added Pediatric Preamble

## **PET Oncology: Gynecological Cancers Definitions**

**Endometrial (Endometroid)** is the mucous membrane lining the uterus.

**Gestational trophoblastic cancer** is the name given to a group of tumors that form during abnormal pregnancies.

**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Magnetic resonance imaging (MRI)** is a non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

**Mesothelioma** is an agressive cancer that affects the thin membrane protecting several of the body's most important organs, including the lungs, abdomen and heart.



**Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15-17 years),
  - 3. Late (ages 18–21 years)
  - 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

**TNM staging system** is a system to describe the amount and spread of cancer in a person's body. T describes the size of the tumor and any spread of cancer into nearby tissue; N describes the spread of cancer to nearby lymph nodes; and M describes metastasis (spread of cancer to other parts of the body).



### **Table 1. TNM Staging System**

T describes the original Primary Tumor	N category describes whether or not the cancer has reached nearby lymph nodes	M category tells whether there are distant metastases (spread of cancer to other parts of the body).
<b>TX</b> Primary tumor cannot be evaluated	<b>NX</b> Regional lymph nodes cannot be evaluated	
<b>T0</b> No evidence of primary tumor	<b>NO</b> No regional lymph node involvement (no cancer found in the lymph nodes)	<b>M0</b> No distant metastasis (cancer has not spread to other parts of the body)
<b>Tis</b> Carcinoma in situ (early cancer that has not spread to neighboring tissue)		
<b>T1 to T4</b> Size and/or extent of the primary tumor	<b>N1 to N3</b> Involvement of regional lymph nodes (number and/or extent of spread)	<b>M1</b> Distant metastasis (cancer has spread to distant parts of the body)

## **PET Oncology: Gynecological Cancers References**

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# 2024 Positron Emission Tomography (PET) Head and Neck

#### **Diagnostic Imaging**

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# Positron Emission Tomography (PET) Oncology: Head and Neck Cancers

Head and Neck • Thymoma • Thyroid • Uveal Melanoma



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx *if* applicable to individual's healthplan membership.



#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/ computed tomography (CT) *depends on the radiopharmaceutical* to be used.

## **PET Oncology: Head and Neck Cancers Contraindications**

Positron emission tomography (PET) contraindications for head/neck may include **ANY** of the following:

- Thyroid, follicular, oncocytic or papillary, PET is NOT indicated for initial staging.
   References: [8]
- Thyroid, medullary, PET is **NOT** indicated for initial staging.

References: [8]

Uveal melanoma PET is NOT indicated for initial staging.

References: [16]



## **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

## **PET Oncology: Head and Neck Cancers Guideline**

Positron emission tomography (PET) for head/neck, thymoma, thyroid and uveal melanoma cancers is considered medically appropriate when the documentation demonstrates **ANY** of the following:

- 1. Head and neck cancer evaluation, including mucosal melanoma of the head and neck, for **EITHER** of the following:
  - a. Initial staging (\*NOTE: Face/neck magnetic resonance imaging [MRI] or computed tomography [CT] may also be indicated, if needed for treatment planning.)
  - b. Restaging when it is at least 12 weeks since last chemoradiation or radiation treatment. (\*NOTE: Face/neck MRI or CT may also be indicated 3 to 4 months after treatment, with advanced locoregional disease or altered anatomy.) (\*NOTE: If final PET/CT is non-diagnostic or indeterminate for residual disease, repeat PET/CT at 6 weeks or more, to help identify surveillance WITHOUT surgery.)

**References:** [11] [17] [7]

2. Thymoma cancer evaluation for initial staging or restaging.

**References:** [15] [4] [10]

- 3. Thyroid cancer evaluation for **ANY** of the following:
  - a. Anaplastic cancer initial staging and restaging
  - b. Follicular, oncocytic or papillary cancer restaging **AND** prior imaging is non-diagnostic or indeterminate (including discordance between tumor markers (eg, thyroglobulin [TG], anti-TG antibody [Ab]) and imaging).
  - c. Medullary cancer evaluation and **ANY** of the following:
    - i. FDG PET for restaging AND prior imaging is non-diagnostic or indeterminate (including discordance between tumor marker (eg, calcitonin, carcinoembryonic antigen [CEA]) and imaging).
    - ii. Non-FDG PET tracers (eg, somatostatin receptor [SSTR]) and **EITHER** of the following:
      - A. Initial staging **AND** prior imaging is non-diagnostic or indeterminate.



B. Restaging **AND** prior imaging is non-diagnostic or indeterminate (including discordance between tumor marker (eg, calcitonin, carcinoembryonic antigen [CEA]) and imaging).

**References:** [18] [3] [8] [6] [12] [2] [9] [13] [5]

4. Uveal melanoma evaluation for restaging **AND** <u>prior imaging is non-diagnostic or</u> indeterminate.

**References:** [1] [16] [14]



#### LCD 35391

See also, LCD 35391: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



#### LCD 39521

See also, LCD 39521: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

## **PET Oncology: Head and Neck Cancers Procedure Codes**

## Table 1. Head and Neck Cancers Positron Emission Tomography (PET) Associated Procedure Codes

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

## **PET Oncology: Head and Neck Cancers Summary of Changes**

PET Oncology: Head and Neck Cancers guideline had the following version changes from 2023 to 2024:



- Added indications under "Head and neck cancer" to keep in line with current evidence
- Removed the following as current evidence no longer supports the indication:
  - Indications under "Follicular, oncocytic or papillary"
  - Indications under "Medullary thyroid" and "FDG PET"
- Mid-cycle update: added Pediatric Preamble

## **PET Oncology: Head and Neck Cancers Definitions**

**Anaplastic** is reversion of cells to a more primitive or undifferentiated form.

**Calcitonin** is a polypeptide hormone especially from the thyroid gland that lowers the level of calcium in the blood plasma.

**Carcinoembryonic antigen (CEA)** is a glycoprotein present in fetal digestive-tract tissues and in peripheral blood of people with some forms of cancer.

**Computed tomography (CT)** refers to a computerized X-ray imaging procedure in which a three-dimensional image of a body structure is revealed through a series of cross-sectional images or "slices."

**Follicular thyroid cancer** is a type of cancer that is derived from the follicular cells in the thyroid gland, which secrete the iodine-containing thyroid hormones.

**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Magnetic resonance imaging (MRI)** is a non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

**Medullary** is the inside of the thyroid containing the cells that produce and release hormones. **Melanoma** is a highly malignant tumor that starts in melanocytes of normal skin or moles and metastasizes rapidly and widely.

**Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Oncocytic thyroid carcinoma** is a rare cancer that affects the thyroid gland.

**Papillary carcinoma** is the most common form of well-differentiated thyroid cancer, and the most common form of thyroid cancer to result from exposure to radiation. Papillary carcinoma appears as an irregular solid or cystic mass or nodule in a normal thyroid parenchyma.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:



- 1. Early (ages 11–14 years)
- 2. Middle (ages 15-17 years),
- 3. Late (ages 18–21 years)
- 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

**Thymoma** is a tumor of the thymous, an organ that is of the lymphatic system and is located in the chest, behind the chest bone.

**Thyroglobulin** is an iodine-containing protein of the thyroid gland that is the precursor of thyroxine and triiodothyronine (thyroid hormones).

**TNM staging system** is a system to describe the amount and spread of cancer in a person's body. T describes the size of the tumor and any spread of cancer into nearby tissue; N describes the spread of cancer to nearby lymph nodes; and M describes metastasis (spread of cancer to other parts of the body).



## Table 1. TNM Staging System

T describes the original Primary Tumor	N category describes whether or not the cancer has reached nearby lymph nodes	M category tells whether there are distant meta- stases (spread of cancer to other parts of the body).
<b>TX</b> Primary tumor cannot be evaluated	<b>NX</b> Regional lymph nodes cannot be evaluated	
<b>T0</b> No evidence of primary tumor	<b>NO</b> No regional lymph node involvement (no cancer found in the lymph nodes)	<b>M0</b> No distant metastasis (cancer has not spread to other parts of the body)
<b>Tis</b> Carcinoma in situ (early cancer that has not spread to neighboring tissue)		
<b>T1 to T4</b> Size and/or extent of the primary tumor	<b>N1 to N3</b> Involvement of regional lymph nodes (number and/or extent of spread)	<b>M1</b> Distant metastasis (cancer has spread to distant parts of the body)

**Thyroglobulin** is an iodine-containing protein of the thyroid gland that is the precursor of thyroxine and triiodothyronine (thyroid hormones).

**Thyroidectomy** is the surgical removal of thyroid gland tissue.

## **PET Oncology: Head and Neck Cancers References**

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# 2024 Positron Emission Tomography (PET) Hepatobiliary

#### **Diagnostic Imaging**

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Last Review Date: 10/28/2024
Previous Review Date: 07/08/2024
Guideline Initiate: 06/30/2019



# Positron Emission Tomography (PET) Oncology: Hepatobiliary Cancers

Biliary Tract • Hepatocellular • Pancreatic



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx *if applicable to individual's healthplan membership*.



#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/ computed tomography (CT) *depends on the radiopharmaceutical* to be used.

## **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

## **PET Oncology: Hepatobiliary Cancers Guideline**

Positron emission tomography (PET) for biliary tract, hepatocellular and pancreatic cancers is considered medically appropriate when the documentation demonstrates **ANY** of the following:

1. Biliary tract cancer evaluation (eg, cholangiocarcinoma, gall bladder cancer) for initial staging and restaging **AND** prior imaging is non-diagnostic or indeterminate.

**References:** [1] [4] [5] [9]

2. Hepatocellular cancer evaluation for initial staging and restaging **AND** <u>prior imaging is non-diagnostic or indeterminate</u>.

References: [2] [3]

- 3. Pancreatic cancer evaluation for **ANY** of the following:
  - a. Initial staging and **ANY** of the following:
    - i. Borderline resectable disease
    - ii. Cancer antigen (CA) 19-9 is markedly elevated, more than 180 U/m/



- iii. Prior imaging is non-diagnostic or indeterminate.
- iv. Primary tumor or lymph nodes are large.
- v. Symptomatic (eg, excessive weight loss, extreme pain, jaundice, symptomatic gastric outlet obstruction, venous thromboembolism)
- b. Restaging, when PET was used for initial staging **AND** assessment of treatment response is needed for determining surgical candidacy.

**References:** [6] [7] [8]



#### LCD 35391

See also, **LCD 35391**: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



#### LCD 39521

See also, LCD 39521: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

## **PET Oncology: Hepatobiliary Cancers Definitions**

**Cancer Antigen (CA) 19-9** is a tumor marker that can indicate advanced pancreatic cancer. It's also associated with cancers in the colon, stomach, and bile duct.

**Cholangiocarcinoma** is a usually slow-growing malignant tumor of the bile duct that arises from biliary epithelium and is typically an adenocarcinoma.

**Embolism** is an obstruction of an artery, typically by a clot of blood or an air bubble.

**Hepatocellular carcinoma** is cancer involving the epithelial parenchymatous cells of the liver.

**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Jaundice** is the yellowish pigmentation of the skin, tissues and body fluids caused by the deposition of bile pigments and indicates increased production or impaired excretion.

**Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:



- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15-17 years),
  - 3. Late (ages 18–21 years)
  - 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

**Thrombosis** is the formation of a blood clot (partial or complete blockage) within blood vessels, whether venous or arterial, limiting the natural flow of blood and resulting in clinical sequela.

## **PET Oncology: Hepatobiliary Cancers References**

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## 2024 Positron Emission Tomography (PET) Lung

#### **Diagnostic Imaging**

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Last Review Date: 10/28/2024
Previous Review Date: 08/05/2024
Guideline Initiated: 06/30/2019

## **Positron Emission Tomography (PET) Lung**

Lung Nodules • Mesothelioma (Pleural) • Non-Small Cell Lung Cancer • Small Cell Lung Cancer



#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/ computed tomography (CT) *depends on the radiopharmaceutical* to be used.





#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

## **PET Lung Contraindications**

Positron emission tomography (PET) for extensive small cell cancers lung cancers is **NOT** indicated for initial staging **OR** restaging.

## **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

## **PET Lung Guideline**

Positron emission tomography (PET) for lung cancer and lung nodules is considered medically appropriate when the documentation demonstrates **ANY** of the following:

- 1. Lung nodule, incidentally found on low dose computed tomography (LDCT) or CT (+ contrast), when cancer is **NOT** known and **ANY** of the following:
  - a. Mixed nodule (eg, ground glass and solid nodule), with solid component 8 mm or more in size, visualized on LDCT and **EITHER** of the following:
    - New mixed nodule, with solid component 8 mm or more in size, on subsequent interval LDCT
    - ii. Solid component shows at least 1.5 mm in growth on subsequent interval LDCT.
  - b. Part solid/mixed nodules, with solid component 6 mm or larger in size.
  - c. Solid component of dominant nodule (largest of multiple nodules, solitary nodule) is 8 mm or larger in size.

**References:** [7] [13] [6] [8] [1]

Mesothelioma (pleural) evaluation, stage I to IIIA ONLY, for initial staging or restaging, for pre-operative evaluation

**References:** [7] [12] [4] [11]

3. Non-small cell lung cancer evaluation for initial staging or restaging

**References:** [7] [11] [10]



- 4. Small cell lung cancer evaluation and **EITHER** of the following:
  - a. Extensive stage small cell lung cancer and **EITHER** of the following:
    - i. Initial staging when prior imaging (computed tomography [CT], magnetic resonance imaging [MRI]) is non-diagnostic or indeterminate to classify stage as extensive.
    - ii. Restaging, when consolidative thoracic radiation is planned.
  - b. Limited stage small cell lung cancer and **EITHER** of the following:
    - i. Initial staging
    - ii. Restaging prior to radiation treatment **OR** when <u>prior imaging is non-diagnostic or indeterminate</u>.

**References:** [7] [5] [3]



#### LCD 35391

See also, **LCD 35391**: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



#### LCD 39521

See also, LCD 39521: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

## **PET Lung Procedure Codes**

## Table 1. Lung Cancers Positron Emission Tomography (PET) Associated Procedure Codes

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



Code	Description
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

## **PET Lung Summary of Changes**

PET Lung guideline had the following version changes from 2023 to 2024:

- Added the following to keep in line with current research:
  - "Limited stage small cell lung cancer" indication
  - "Lung nodule" indication
- Mid-cycle update: added Pediatric Preamble

## **PET Lung Definitions**

Adenocarcinoma is a malignant tumor originating in glandular epithelium.

**Computed tomography (CT)** refers to a computerized X-ray imaging procedure in which a three-dimensional image of a body structure is revealed through a series of cross-sectional images or "slices."

**Extensive stage small cell lung cancer** is a type of lung cancer that has spread beyond the lungs or to other parts of the body. It can spread to the other lung, lymph nodes, bones, brain, bone marrow, or fluid around the heart or lungs.

Fleischner Society Guidelines for Management of Incidental Pulmonary Nodules Detected on CT Images: is a characterization tool to support lung cancer diagnosis and treatment planning. The recommendations refer to incidentally encountered lung nodules detected at CT in adult patients that are age 35 years or older. These are not intended for routine screening, when there is metastasis risk with known primary cancer, or when there is risk of infection due to immunocompromise.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup>MacMahon H, Naidich DP, Goo JM, Lee KS, Leung ANC, Mayo JR, Mehta AC, Ohno Y, Powell CA, Prokop M, Rubin GD, Schaefer-Prokop CM, Travis WD, Van Schil PE, Bankier AA. Guidelines for Management of Incidental Pulmonary Nodules Detected on CT Images: From the Fleischner Society 2017. Radiology. 2017 Jul;284(1):228-243.



## Table 1. Solid Nodules, Fleischner Society Guidelines for Incidentally Detected Pulmonary Nodules

NODULE SIZE/ TYPE	SIZE smal ler than 6 mm (100 mm <sup>3</sup>	SIZE 6 mm (100 mm <sup>3</sup> ) to 8 mm (250 mm <sup>3</sup> )	SIZE larger than 8 mm (250 mm <sup>3</sup> )	COMMENTS
Single				
• Low risk	NO routine follow- up	CT at 6 to 12 months, then consider CT at 18 to 24 months	Consider CT at 3 months, PET/CT or tissue sampling	Nodules smaller than 6 mm do <b>NOT</b> require routine follow-up in low-risk situations (recommendation 1A)
• High risk	Option- al CT at 12 months	CT at 6 to 12 months, then consider CT at 18 to 24 months	Consider CT at 3 months, PET/CT, or tissue sampling	Certain high risk individuals with suspicious nodule morphology, upper lobe location (or both), may be appropriate for 12 month follow-up (Recommendation 1A)
Multiple				
• Low risk	NO routine follow- up	CT at 3 to 6 months, then consider CT at 18 to 24 months	CT at 3 to 6 months then consider CT at 18 to 24 months	Most suspicious nodule should be used to guide management. Follow-up intervals vary by this nodule's risk and size. (recommendation 2A)
• High risk	Option- al CT at 12 months	CT at 3 to 6 months, then consider CT at 18 to 24 months	CT at 3 to 6 months then consider CT at 18 to 24 months	Most suspicious nodule should be used to guide management. Follow-up intervals vary by this nodule's risk and size. (recommendation 2A)

## Table 2. Subsolid Nodules, Fleischner Society Guidelines for Incidentally Detected Pulmonary Nodules

NODULE SIZE/TYPE	SIZE small- er than 6 mm (100 mm <sup>3</sup> )	SIZE larger than 6 mm (100 mm <sup>3</sup> )	COMMENTS
Single			
<ul><li>Ground glass</li></ul>	<b>NO</b> routine follow-up	CT at 6 to 12 months to confirm persistence then CT every 2 years until year 5	Certain suspicious nodules smaller than 6 mm consider follow-up at 2 years and 4 years.  If solid component develops or growth occurs consider resection (Recommendation 3A and 4A)



NODULE SIZE/TYPE	SIZE small- er than 6 mm (100 mm <sup>3</sup> )	SIZE larger than 6 mm (100 mm <sup>3</sup> )	COMMENTS
Partly solid	<b>NO</b> routine follow-up	CT at 3 to 6 months to confirm persistence, if unchanged lesion with part solid area staying less than 6 mm an annual CT for 5 years	Partly solid nodules are <b>NOT</b> defined until they are 6 mm or larger. Nodules less than 6 mm usually do <b>NOT</b> require follow-up. Persistent partly solid nodules with solid part 6 mm or larger should be considered as 'highly suspicious." (Recommendation 4A to 4 C)
Multiple	CT at 3-6 months; if lesion is stable, consider CT at 2 years and 4 years	CT at 3 to 6 months, most suspicious nodule guides subsequent management	Multiple ground glass nodules less than 6 mm are usually benign, but consider follow-up at 2 years and 4 years in select individuals at high risk (Recommendation 5A)

**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Limited stage small cell lung cancer (LS-SCLC)** is when the cancer is contained to a single area on one side of the chest. This includes cancer that is only in one lung, and may have spread to the lymph nodes on the same side of the chest.

**Low dose computed tomography (LDCT)** refers to a computerized X-ray imaging procedure in which a three-dimensional image of a body structure is revealed through a series of cross-sectional images or "slices" that uses 1/5 the radiation of a conventional CT. The scan uses a lower dose of radiation because it is designed to evaluate nodules in low-density lung tissue but is less effective in evaluating bones, organs or other tissues.

**Mesothelioma** is an agressive cancer that affects the thin membrane protecting several of the body's most important organs, including the lungs, abdomen and heart.

**Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Non-small cell lung cancer** is a group of lung cancers named for the kinds of cells found in the cancer and how the cells look under a microscope. The three main types of non-small cell lung cancer are adenocarcinoma (most common), squamous cell carcinoma, and large cell carcinoma. Non-small cell lung cancer is the most common of the two main types of lung cancer (non-small cell lung cancer and small cell lung cancer).

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)



- 2. Middle (ages 15-17 years),
- 3. Late (ages 18–21 years)
- 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Small cell lung cancer** is a highly malignant form of cancer that affects the lungs, tends to metastasize to other parts of the body, is characterized by small round or oval cells which resemble oat grains and have little cytoplasm.

**Squamous cell carcinoma (SCC)** is carcinoma that is made up of or arises from squamous cells (stratified epithelium that consists at least in its outer layers of small scale like cells) and usually occurs in areas of the body exposed to strong sunlight over many years.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

**TNM staging system** is a system to describe the amount and spread of cancer in a person's body. T describes the size of the tumor and any spread of cancer into nearby tissue; N describes the spread of cancer to nearby lymph nodes; and M describes metastasis (spread of cancer to other parts of the body).



### **Table 3. TNM Staging System**

T describes the original Primary Tumor	N category describes whether or not the cancer has reached nearby lymph nodes	M category tells whether there are distant metastases (spread of cancer to other parts of the body).
<b>TX</b> Primary tumor cannot be evaluated	<b>NX</b> Regional lymph nodes cannot be evaluated	
<b>T0</b> No evidence of primary tumor	<b>NO</b> No regional lymph node involvement (no cancer found in the lymph nodes)	<b>M0</b> No distant metastasis (cancer has not spread to other parts of the body)
<b>Tis</b> Carcinoma in situ (early cancer that has not spread to neighboring tissue)		
<b>T1 to T4</b> Size and/or extent of the primary tumor	<b>N1 to N3</b> Involvement of regional lymph nodes (number and/or extent of spread)	<b>M1</b> Distant metastasis (cancer has spread to distant parts of the body)

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## 2024 Positron Emission Tomography (PET) Non-Oncological

#### **Diagnostic Imaging**

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Last Review Date: 10/28/2024 Previous Review Date: 08/05/2024 Guideline Intiated: 09/06/2023

## Positron Emission Tomography (PET) Non-Oncological

Castleman's Disease • Histiocytic Neoplasms • Sarcoidosis • Vasculitis



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



## A

#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/ computed tomography (CT) *depends on the radiopharmaceutical* to be used.

## **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

## **PET Non-Oncological Guideline**

Positron emission tomography (PET) for non-cancerous indications is considered medically appropriate when the documentation demonstrates **ANY** of the following:

- Castleman's disease evaluation for initial staging or restaging
   References: [2021 Emerging role of 18F-FDG PET/CT in Castleman disease: a review]
   [2021 18F-FDG PET/CT imaging features of patients with multicentric Castleman disease]
   [6]
- 2. Histiocytic neoplasms evaluation and **ANY** of the following:
  - a. Erdheim-Chester disease evaluation for **EITHER** of the following:
    - i. Initial staging
    - ii. Restaging, if on active treatment
  - b. Langerhan's cell histiocytosis evaluation for **EITHER** of the following:
    - i. Initial staging
    - ii. Restaging when on active treatment and **ANY** of the following:
      - A. High risk bone disease
      - B. Multiple bone disease
      - C. Multisystem involvement
  - c. Rosai-Dorfman disease evaluation for **EITHER** of the following:
    - i. Initial staging
    - ii. Restaging, if on active treatment

**References:** [3] [2020 Erdheim-Chester disease: consensus recommendations for evaluation, diagnosis, and treatment in the molecular era] [2022 Role of 18F-FDG PET/CT



in the diagnosis and management of patients with Langerhans cell histiocytosis] [2022 Application of 18F-FDG PET/CT in Langerhans Cell Histiocytosis] [2023 The value of 18F-FDG PET/CT in the systemic evaluation of patients with Rosai-Dorfman disease: a retrospective study and literature review]

- 3. Sarcoidosis evaluation and **ANY** of the following:
  - a. <u>Prior testing (eg, chest X-ray, computed tomography [CT], inflammatory serology [c-reactive protein, erythrocyte sedimentation rate]) is non-diagnostic or indeterminate for **ANY** of the following:</u>
    - i. Determination of extent of disease, when results may change treatment management
    - ii. Treatment evaluation
  - b. Sarcoidosis is suspected, to determine most suitable biopsy site.

**References:** [4] [5]

4. Vasculitis is known and <u>prior imaging (eg, CT, CTA [computed tomography angiography], magnetic resonance [MR], MRA) is non-diagnostic or indeterminate.</u>

\*\*References: [2021 Diagnostic value of [18F]FDG-PET/CT for treatment monitoring in large vessel vasculitis: a systematic review and meta-analysis] [2] [1]



#### LCD 39521

See also, **LCD 39521**: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



#### LCD 35391

See also, **LCD 35391**: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

## **PET Non-Oncological APC section**

### **Table 1. PET Non-Oncological Associated Procedure Codes**

Codes	Description
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh



Codes	Description
78813	Positron emission tomography (PET) imaging; whole body
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
G0235	PET imaging, any site, not otherwise specified

## **PET Non-Oncological Summary of Changes**

PET Non-Oncological guideline had the following version changes from 2023 to 2024:

- Citation updated per the evidence.
- Evidence reviewed and indications remained the same.
- Mid-cycle update: added Pediatric Preamble

## **PET Non-Oncological Definitions**

**Castleman's disease** is a rare disease of the lymphatic system marked by non-malignant overgrowth of lymphoid tissue and lymph node enlargement that occurs either in a localized or a systemic form.

**Computed tomography (CT)** refers to a computerized X-ray imaging procedure in which a three-dimensional image of a body structure is revealed through a series of cross-sectional images or "slices."

**Computed tomography angiography (CTA)** is a medical test that combines a computed tomography (CT) scan with an injection of a special dye to produce pictures of blood vessels and tissues in a part of the body.

**C-reactive protein (CRP)** is a pentameric protein synthesized by the liver, whose level rises in response to inflammation.

**Erdheim-Chester Disease (ECD)** is a rare blood disorder that causes the body to produce too many white blood cells. These cells, called histiocytes, are large phagocytic cells that normally respond to injury and infection. ECD is characterized by the accumulation of histiocytes in multiple tissues and organs.

**Erythrocyte sedimentation rate (ESR)** is a commonly performed hematology test that may indicate and monitor an increase in inflammatory activity within the body caused by one or more conditions such as autoimmune disease, infections or tumors.

**Histiocytic neoplasms** are rare hematologic disorders accounting for less than 1% of cancers of the soft tissue and lymph nodes. Clinical presentation and prognosis of these disorders can be highly variable, leading to challenges for diagnosis and optimal management of these patients.

**Indeterminate** findings are inconclusive or insufficient for treatment planning.



**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Langerhans cell histiocytosis (LCH)** is a rare, cancer-like condition that occurs when the body produces too many immature Langerhans cells.

**Magnetic resonance angiogram (MRA)** is a test that uses a magnetic field and pulses of radio wave energy to provide images of blood vessels inside the body, allowing for evaluation of blood flow and blood vessel wall condition. MRA is used to look for aneurysms, clots, tears in the aorta, arteriovenous malformations and stenosis caused by plaque in the carotid arteries (neck) or blood vessels leading to the lungs, kidneys or legs.

**Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15-17 years),
  - 3. Late (ages 18–21 years)
  - 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.



**Rosai-Dorfman disease** is an uncommon histiocytic disorder most frequently presenting as bilateral cervical lymphadenopathy in children and young adults.

**Sarcoidosis** is a chronic disease of unknown cause, that is characterized by the formation of nodules, especially in the lymph nodes, lungs, bones and skin.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

**Vasculitis** involves inflammation of the blood vessels. The inflammation can cause the walls of the blood vessels to thicken, which reduces the width of the passageway through the vessel. If blood flow is restricted, it can result in organ and tissue damage.

## **PET Non-Oncological References**

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# 2024 Positron Emission Tomography (PET) Occult Primary

### **Diagnostic Imaging**

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Last Review Date: 10/28/2024
Previous Review Date: 07/08/2024
Guideline Initiated: 06/30/2019



# Positron Emission Tomography (PET) Oncology: Occult Primary Cancer



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx *if applicable to individual's healthplan membership*.



#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/ computed tomography (CT) *depends on the radiopharmaceutical* to be used.

## **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

## **PET Oncology: Occult Primary Cancer Guideline**

Positron emissions tomography (PET) for occult primary cancer is considered medically appropriate when the documentation demonstrates that occult primary cancer evaluation is for initial staging or restaging **AND** prior imaging is non-diagnostic or indeterminate.

**References:** [2] [1] [3]



#### LCD 35391

See also, **LCD 35391**: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.





#### LCD 39521

See also, **LCD 39521**: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

## **PET Oncology: Occult Primary Cancers Procedure Codes**

## Table 1. Occult Primary Cancers Positron Emission Tomography (PET) Associated Procedure Codes

Code	Description
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
G0235	PET imaging, any site, not otherwise specified

## **PET Oncology: Occult Primary Cancers Summary of Changes**

PET Oncology: Occult Primary Cancers guideline had the following version changes from 2023 to 2024:

- Citation update
- Evidence reviewed and indications remained the same.
- Mid-cycle update: added Pediatric Preamble

## **PET Oncology: Occult Primary Cancers Definitions**

**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Occult** means the problem was hidden, not immediately apparent, or cannot be detected with clinical methods alone.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

Infancy, between birth and 2 years of age



- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15-17 years),
  - 3. Late (ages 18–21 years)
  - 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

## **PET Oncology: Occult Primary Cancers References**

- [1] Nissan, E., Amit, U., . . . Davidson, T. (2021). The usefulness of [18F]FDG-PET/CT in detecting and managing cancers with unknown primary site depends on histological subtype. *Scientific Reports*, 11(1), Article: 17732.
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## 2024 Positron Emission Tomography (PET) Post-Transplant Proliferative Disorder

#### **Diagnostic Imaging**

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Last Review Date: 10/28/2024
Previous Review Date: 07/08/2024
Guideline Initiated: 06/30/2019

# Positron Emission Tomography (PET): Post Transplant Proliferative Disorder



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/ computed tomography (CT) *depends on the radiopharmaceutical* to be used.

## **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

## **PET Post Transplant Proliferative Disorder Guideline**

Positron emission tomography (PET) for post transplant lymphoproliferative disorder (PTLD) is considered medically appropriate when the documentation demonstrates the evaluation is indicated for **ANY** of the following:



- 1. Initial staging for **ANY** of the following:
  - a. PTLD is suspected, based on abnormal physical exam, abnormal labs (eg, elevated or rising viral titers) **OR** <u>prior imaging is abnormal, non-diagnostic or indeterminate.</u>
  - b. Staging, at the time diagnosis is determined.

References: [2] [1]

2. Restaging

References: [2] [1]



#### LCD 35391

See also, LCD 35391: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



#### LCD 39521

See also, **LCD 39521**: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

## **PET Post Transplant Proliferative Disorder Procedure Codes**

## Table 1. Post transplant proliferative disorder Positron Emission Tomography (PET) Associated Procedure Codes

Code	Description
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body



# **PET Post-Transplant Proliferative Disorder Summary of Changes**

PET Post-Transplant Proliferative Disorder guideline had the following version changes from 2023 to 2024:

- Citation update
- Evidence reviewed and indications remained the same.
- Mid-cycle update: added Pediatric Preamble

# **PET Post Transplant Proliferative Disorder Definitions**

**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15–17 years),
  - 3. Late (ages 18–21 years)
  - 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.



**Post-transplant lymphoproliferative disorders (PTLD)** is a group of conditions that may happen after a transplant. It involves the immune system and causes white blood cells (called lymphocytes) to multiply out of control. The seriousness varies from an overgrowth of the lymphocytes that is not harmful, to full-blown lymph node cancer (called lymphoma).

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

# **PET Post Transplant Proliferative Disorder References**

- [1] Lee, C., Colletti, P.M., . . . Kanne, J.P. (2019). ACR Appropriateness Criteria Acute Respiratory Illness in Immunocompromised Patients. *Journal of the American College of Radiology*, *16*(11), S331-S339.
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# 2024 Positron Emission Tomography (PET) Prostate

## **Diagnostic Imaging**

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Last Review Date: 10/28/2024
Previous Review Date: 08/06/2024
Guideline Initiated: 06/30/2019

# Positron Emission Tomography (PET) Oncology: Prostate Cancer



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.





#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/computed tomography (CT) *depends on the radiopharmaceutical* to be used.

# **PET Oncology: Prostate Cancer Contraindications/Exclusions**

FDG positron emission tomography (PET) for prostate cancer is **NOT** indicated for initial staging **OR** restaging.

# **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

# **PET Oncology: Prostate Cancer**

Prostate-specific membrane antigen (PSMA) PET (eg, flotufolastat F18 [Posluma], Ga 68 gozetotide [Illucix® gallium Ga 68 PSMA 11, Ga 68 gozetotide [Locametz®], F18 piflufolastat [Pylarify®]) for prostate cancer is considered medically appropriate when the documentation demonstrates **ANY** of the following:

- 1. Initial staging, when Prostate Cancer Risk Classification is <u>High</u>, <u>Very High</u> or <u>Unfavorable</u> <u>Intermediate-Risk</u>. (\*NOTE: Can consider PET/magnetic resonance [MR]) (\*NOTE: Pelvic MRI may be indicated concurrently if needed for surgical planning.)
- 2. Restaging and **ANY** of the following:
  - a. Castration-resistant prostate cancer is known and **NO** metastatic disease is demonstrated on conventional imaging (computed tomography [CT] or magnetic resonance imaging [MRI]).
  - b. Metastatic disease is known, with progression while on treatment, and **EITHER** of the following:
    - i. Disease progression is seen on prior imaging (eg, bone scan).
    - ii. Prostate specific antigen (PSA) is rising on **AT LEAST 2** consecutive levels.
  - c. Radiotherapy is definitive **AND** PSA rise above nadir.
  - d. Recurrence is suspected after radical prostatectomy and **ANY** of the following:
    - i. PSA is detectable (0.1 ng/ml or more) at 3 months post-operative. (\*NOTE: Only 1 level is required.)



- ii. PSA is rising on **AT LEAST 2** consecutive levels.
- iii. PSA has risen to more than 0.1 ng/ml, when PSA was previously undetectable.
- e. Treatment with radioligand therapy (Lu-177 or Pluvicto) was at least 12 weeks ago.

**References:** [4] [1] [2] [3] [7] [4] [5] [6]



#### LCD 35391

See also, LCD 35391: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



## LCD 39521

See also, **LCD 39521**: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

# **PET Oncology: Prostate Cancer APC section**

## **Table 1. PET Prostate Associated Procedure Codes**

Codes	Description
78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
A9587	Gallium Ga-68, dotatate, diagnostic, 0.1 mCi
A9593	Gallium Ga-68 PSMA-11, diagnostic, (UCSF), 1 mCi
A9594	Gallium Ga-68 PSMA-11, diagnostic, (UCLA), 1 mCi
A9595	Piflufolastat f-18, diagnostic, 1 mCi
A9596	Gallium Ga-68 Gozetotide, diagnostic, (Illuccix), 1mCi
A9597	Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified



Codes	Description
A9608	Flotufolastat f 18, diagnostic, 1 millicurie

# **PET Oncology: Prostate Cancer Summary of Changes**

PET Prostate guideline had the following version changes from 2023 to 2024:

- Added the following to keep in line with current evidence:
  - "Initial staging" indication
  - Pediatric Preamble
  - "Restaging" indication
- Citations updated per the evidence.
- Removed indications under "Initial staging" as current evidence no longer supports them.
- Mid-cycle update: added Pediatric Preamble

# **PET Oncology: Prostate Cancer Definitions**

**Castration-resistant prostate cancer (CRPC)** is cancer that continues to grow even when the testosterone levels are at or below the castrate level.

**Computed tomography (CT)** refers to a computerized X-ray imaging procedure in which a three-dimensional image of a body structure is revealed through a series of cross-sectional images or "slices."

**Gleason score** is a score that is the sum of the two Gleason grades assigned to a prostate tumor that is based on a scale of 2 to 10 with the lowest numbers indicating a slow-growing tumor unlikely to spread and the highest numbers indicating an aggressive tumor.

**Table 1. Prostate Cancer Grade Groups** 

<b>Grade Group</b>	Gleason Score	Cancer Grade
Grade Group 1	Gleason score of 6 or less	Low grade cancer
Grade Group 2	Gleason score 3+4=7	Medium grade cancer
Grade Group 3	Gleason score 4+3=7	Medium grade cancer with more abnormal cells
Grade Group 4	Gleason score of 8	High grade cancer
Grade Group 5	Gleason score of 9 to 10	High grade cancer

**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Magnetic resonance imaging (MRI)** is a non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

**Metastases** is the spread of a disease-producing agency (such as cancer cells) from the initial or primary site of disease to another part of the body.



**Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15-17 years),
  - 3. Late (ages 18–21 years)
  - 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Prostate specific antigen (PSA)** is a protease (an enzyme that hydrolyzes proteins) secreted by epithelial cells of the prostate gland. PSA's concentration in blood serum tends to be proportional to the clinical stage of the disease, making it useful in detecting prostate cancer.

**Prostate-specific membrane antigen (PSMA)** is a type II membrane protein originally characterized by the murine monoclonal antibody (mAb) 7E11-C5.3 and is expressed in all forms of prostate tissue, including carcinoma.

**Recurrence** is a new occurrence of something that happened or appeared before.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).



**Taxanes** are chemotherapy drugs that stop cancer cells from replicating.

**TNM staging system** is a system to describe the amount and spread of cancer in a person's body. T describes the size of the tumor and any spread of cancer into nearby tissue; N describes the spread of cancer to nearby lymph nodes; and M describes metastasis (spread of cancer to other parts of the body).

**Table 2. TNM Staging System** 

T describes the original Primary Tumor	N category describes whether or not the cancer has reached nearby lymph nodes	M category tells whether there are distant metastases (spread of cancer to other parts of the body).
<b>TX</b> Primary tumor cannot be evaluated	<b>NX</b> Regional lymph nodes cannot be evaluated	
<b>TO</b> No evidence of primary tumor	<b>NO</b> No regional lymph node involvement (no cancer found in the lymph nodes)	<b>M0</b> No distant metastasis (cancer has not spread to other parts of the body)
<b>Tis</b> Carcinoma in situ (early cancer that has not spread to neighboring tissue)		
<b>T1 to T4</b> Size and/or extent of the primary tumor	<b>N1 to N3</b> Involvement of regional lymph nodes (number and/or extent of spread)	<b>M1</b> Distant metastasis (cancer has spread to distant parts of the body)

# **PET Oncology: Prostate Cancer References**

- [1] Akin, O,. Woo, S., . . . Nikoladis,. P. (2023). ACR Appropriateness Criteria Pretreatment Detection, Surveillance, and Staging of Prostate Cancer: 2022 Update. *Journal of the American College of Radiology*, 20(5), S187-S210.
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- [3] Fanti, S., Goffin, K., . . . Bjartell, A. (2021). Consensus statements on PSMA PET/CT response assessment criteria in prostate cancer. *European Journal of Nuclear Medicine and Molecular Imaging*, 48(2), 469-476.
- [4] Jadvar, H., Calais, J., . . . Hope, T.A. (2021). Appropriate Use Criteria for Prostate-Specific Membrane Antigen (PSMA) PET Imaging. *Society of Nuclear Medicine & Membrane & Membrane*
- [5] Lowrance, W.T., Breau, R.H., . . . Cookson, M.S. (2021). 2023 Advanced Prostate Cancer: AUA/SUO Guideline. *The Journal of Urology*, 209(6), 1082-1090.
- [6] (2022). Pluvicto. US Food & Drug Administration. Retrieved: September 2024. https:// us.pluvicto.com/



[7] Schaeffer, E.M., Srinivas, S., . . . Wong, J.K. (2024). Prostate Cancer Version 4.2024. *National Comprehensive Cancer Network*. Retrieved: June 2024. https://www.nccn.org/professionals/physician\_gls/pdf/prostate.pdf

# 2024 Positron Emission Tomography (PET) Sarcomas

## **Diagnostic Imaging**

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Last Review Date: 10/28/2024
Previous Review Date: 07/23/2024
Guideline Initiated: 06/30/2019

# Positron Emission Tomography (PET) Oncology: Sarcomas

Chondrosarcoma • Ewing Sarcoma • Kaposi Sarcoma • Osteosarcoma • Soft Tissue Sarcoma



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx *if* applicable to individual's healthplan membership.



#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/computed tomography (CT) *depends on the radiopharmaceutical* to be used.

## **PET Sarcomas Contraindications**

Positron emission tomography (PET) contraindications for sarcomas may include **ANY** of the following:

- Chondrosarcoma PET imaging is **NOT** indicated for staging or restaging.
- Kaposi sarcoma, AIDS-related, PET imaging is NOT indicated for restaging.

References: [3] [8]



# **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

## **PET Sarcomas Guideline**

Positron emission tomography (PET) for sarcoma is considered medically appropriate when the documentation demonstrates **ANY** of the following:

- 1. Ewing Sarcoma and osteosarcoma (osseous) evaluation for **ANY** of the following: (\***NOTE**: PET can be approved with MR of primary site.)
  - a. Initial staging (all ages)
  - b. Restaging and **ANY** of the following:
    - i. Age is 30 years old or younger.
    - Age is older than 30 years old and metastatic disease is suspected or known, based on physical exam or prior imaging **OR** PET was used for initial imaging.

**References:** [5] [3] [1] [4]

- 2. Kaposi sarcoma herpesvirus (KSHV) associated inflammatory cytokine syndrome (KICS), KSHV+lymphoma **OR** multicentric Castleman's disease is suspected, that is related to Kaposi sarcoma, adult immunodeficiency syndrome (AIDS), for initial staging. **References:** [5][7] [2] [8]
- 3. Soft tissue sarcoma (eg, soft tissue/extraosseous Ewing sarcoma, soft tissue/extraosseous osteosarcoma, rhabdomyosarcoma) evaluation for **ANY** of the following:
  - All sarcomas, **EXCLUDING Rhabdomyosarcoma** (eg, soft tissue/extraosseous Ewing sarcoma or osteosarcoma) for initial staging or restaging and **EITHER** of the following:
    - i. Age is 30 years old or younger.
    - ii. Age is over 30 years and prior imaging is non-diagnostic or indeterminate.
  - b. **Rhabdomyosarcoma** evaluation for initial staging and restaging

**References:** [5] [10] [9] [6]





### LCD 35391

See also, **LCD 35391**: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



### LCD 39521

See also, **LCD 39521**: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

## **PET Sarcomas Procedure Codes**

## Table 1. Sarcomas Positron Emission Tomography (PET) Associated Procedure Codes

Code	Derscription
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

# **PET Sarcomas Summary of Changes**

PET Oncology: Sarcomas guideline had the following version changes from 2023 to 2024:

- Added Pediatric Preamble to keep in line with current evidence.
- Citation update
- Combined Ewing sarcoma and osteosarcoma into one indication.
- Mid-cycle update: added Pediatric Preamble

## **PET Sarcomas Definitions**

**Acquired immunodeficiency syndrome (AIDS)** is the final stage of infection with human immunodeficiency virus (HIV) and it happens when the body's immune system is badly damaged because of the virus.



**Castleman's disease** is a rare group of disorders characterized by enlarged lymph nodes and a broad range of inflammatory symptoms, with two main forms: unicentric (affecting a single lymph node region) and multicentric (affecting multiple regions).

**Chondrosarcoma** is a type of bone cancer that develops in cartilage cells.

**Chordoma** is a rare, slow-growing bone cancer that can occur in the spine or skull base.

**Computed tomography (CT)** refers to a computerized X-ray imaging procedure in which a three-dimensional image of a body structure is revealed through a series of cross-sectional images or "slices."

**Ewing sarcoma** is a rare type of cancer that occurs in bones or in the soft tissue around the bones. Ewing sarcoma most often begins in the leg bones and in the pelvis.

**Gastrointestinal stromal tumor (GIST)** is a rare type of cancer that starts in the digestive system. GISTs are thought to grow from specialized nerve cells in the walls of the digestive organs. They most often occur in the stomach and small intestine.

**Giant cell tumor of bone (GCTB)** is a benign, but locally aggressive, bone tumor that typically occurs in young adults, often near the ends of long bones and near joints, characterized by the presence of large, multinucleated cells.

**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Kaposi sarcoma** is a disease in which cancer cells are found in the skin or mucous membranes that line the gastrointestinal (GI) tract, from mouth to anus, including the stomach and intestines. These tumors appear as purple patches or nodules on the skin and/or mucous membranes and can spread to lymph nodes and lungs.

**Magnetic resonance imaging (MRI)** is a non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

**Metastases** is the spread of a disease-producing agency (such as cancer cells) from the initial or primary site of disease to another part of the body.

**Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Osteosarcoma** is a malignant tumor derived from bone or containing bone tissue.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15–17 years),



- 3. Late (ages 18–21 years)
- 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Rhabdomyosarcoma** is a rare type of cancer that forms in soft tissue — specifically skeletal muscle tissue or sometimes hollow organs such as the bladder or uterus.

**Sarcoma** is a malignant tumor arising in tissue (such as connective tissue, bone, cartilage or striated muscle) of mesodermal origin.

**Soft tissue sarcoma** is a malignant tumor arising in the tissue (such as tendon, muscle, skin, fat and fascia) that typically connects, supports or surrounds bone and internal organs.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

## **PET Sarcomas References**

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- [9] Sharon, C.E., Straker, R.J. & Karakaousis, G.C. (2022). The Role of Imaging in Soft Tissue Sarcoma Diagnosis and Management. *The Surgical Clinics of North America, 102*(4), 539-550.
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# 2024 Positron Emission Tomography (PET) Oncology: Skin Cancers

## **Diagnostic Imaging**

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Last Review Date: 10/28/2024
Previous Review Date: 07/08/2024
Guideline Initiated: 06/30/2019

# Positron Emission Tomography (PET) Oncology: Skin Cancers

Basal Cell • Melanoma • Merkel Cell • Skin Squamous Cell Cancers



#### NCD 220.6.17

See also, **NCD 220.6.17**: Positron Emission Tomography (FDG) for Oncologic Conditions at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.





#### **WARNING**

**Oncological PET** is indicated for biopsy-proven known cancer or if cancer is highly suspected based on other diagnostic testing. The appropriateness of an ordered PET/computed tomography (CT) *depends on the radiopharmaceutical* to be used.

# PET Oncology: Skin Cancers Contraindications/Exclusions

Positron emission tomography (PET) contraindications or exclusions for skin cancers may include basal cell PET evaluation is **NOT** indicated for staging or restaging. [1]

# **Preamble: Pediatric Diagnostic Imaging**

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

# **PET Oncology: Skin Cancers Guideline**

Positron emission tomography (PET) for skin cancers is considered medically appropriate when the documentation demonstrates **ANY** of the following:

- 1. Melanoma evaluation for **EITHER**:
  - a. Initial staging AND EITHER:
    - i. Dermal melanomas that lacks epidermal involvement
    - ii. Stage III or IV
  - b. Restaging and **AND EITHER**:
    - i. Recurrences (eg, in-transit, local satellite or nodal) are known, for work-up.
    - ii. Stage III or IV

**References:** [8] [7] [2]

2. Merkel Cell cancer evaluation for initial staging or restaging.

**References:** [3] [4] [9]

3. Skin, squamous cell, evaluation for initial staging or restaging **AND** biopsy proven disease is N1 or more **OR** M1 or more (lymph node or metastatic site has been biopsied and shows disease spread).

**References:** [5] [6]





### LCD 35391

See also, **LCD 35391**: Multiple Imaging in Oncology at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



## LCD 39521

See also, LCD 39521: PET Scan for Inflammation and Infection at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

# **PET Oncology: Skin Cancers Procedure Codes**

## Table 1. Skin Cancers Positron Emission Tomography (PET) Associated Procedure Codes

Codes	Description
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
G0219	PET imaging whole body; melanoma for noncovered indications

# **PET Oncology: Skin Cancers Summary of Changes**

PET Oncology: Skin Cancers guideline had the following version changes from 2023 to 2024:

- Added the following to keep in line with current research:
  - Indications under "Melanoma evaluation"
  - Pediatric Preamble
  - Restaging to "Skin, Squamous cell"
- Citation update
- Mid-cycle update: added Pediatric Preamble

# **PET Oncology: Skin Cancers Definitions**

**Basal cell carcinoma (BCC)** is a skin cancer derived from and preserving the form of the basal cells of the skin.



**Indeterminate** findings are inconclusive or insufficient for treatment planning.

**Initial staging** refers to imaging that is performed **AFTER** the diagnosis of cancer is made, and generally before any treatment.

**Melanoma** is a highly malignant tumor that starts in melanocytes of normal skin or moles and metastasizes rapidly and widely.

**Merkel cell carcinoma** is a very rare disease in which merkel cells of the skin grow rapidly. **Non-diagnostic** is a result that does not lead to a confirmed diagnosis.

**Pediatric approximate ages** are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
  - 1. Early (ages 11–14 years)
  - 2. Middle (ages 15-17 years),
  - 3. Late (ages 18–21 years)
  - 4. Older ages may be appropriate for children with special healthcare needs.

**Positron emission tomography (PET) scan** is a procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. It is a medical imaging test that shows the metabolic or biochemical function of organs and tissues.

**Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI)** is a hybrid imaging modality that combines the anatomical and quantitative strengths of MRI with the physiological information obtained from PET, providing high accuracy and specificity in detecting, classifying, staging, and evaluating treatment responses of malignant lesions.

**Positron emission tomography/computed tomography (PET/CT)** imaging is a hybrid imaging technique that combines the functional imaging capabilities of PET with the anatomical detail provided by CT, primarily used for diagnosing, staging, and monitoring various diseases, especially cancers.

**Restaging** includes scans that are either needed during active treatment (subsequent treatment strategy) to determine response to treatment, within 6 months after the end of treatment, or when there is clinical concern for recurrence (eg, new imaging, new signs, rising labs/tumor markers or symptoms relative to type of cancer and entire clinical picture). Recurrence is not required to be biopsy proven.

**Staging** in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).



**Squamous cell carcinoma (SCC)** is carcinoma that is made up of or arises from squamous cells (stratified epithelium that consists at least in its outer layers of small scale like cells) and usually occurs in areas of the body exposed to strong sunlight over many years.

**TNM staging system** is a system to describe the amount and spread of cancer in a person's body. T describes the size of the tumor and any spread of cancer into nearby tissue; N describes the spread of cancer to nearby lymph nodes; and M describes metastasis (spread of cancer to other parts of the body).

**Table 1. TNM Staging System** 

T describes the original Primary Tumor	N category describes whether or not the cancer has reached nearby lymph nodes	M category tells whether there are distant meta- stases (spread of cancer to other parts of the body).
<b>TX</b> Primary tumor cannot be evaluated	<b>NX</b> Regional lymph nodes cannot be evaluated	
<b>T0</b> No evidence of primary tumor	<b>NO</b> No regional lymph node involvement (no cancer found in the lymph nodes)	<b>M0</b> No distant metastasis (cancer has not spread to other parts of the body)
<b>Tis</b> Carcinoma in situ (early cancer that has not spread to neighboring tissue)		
<b>T1 to T4</b> Size and/or extent of the primary tumor	<b>N1 to N3</b> Involvement of regional lymph nodes (number and/or extent of spread)	<b>M1</b> Distant metastasis (cancer has spread to distant parts of the body)

# **PET Oncology: Skin Cancers References**

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## **Disclaimer section**

# **Purpose**

The purpose of the HealthHelp's clinical guidelines is to assist healthcare professionals in selecting the medical service that may be appropriate and supported by evidence to safely improve outcomes. Medical information is constantly evolving, and HealthHelp reserves the right to review and update these clinical guidelines periodically. HealthHelp reserves the right to include in these guidelines the clinical indications as appropriate for the organization's program objectives. Therefore the guidelines are not a list of all the clinical indications for a stated procedure, and associated Procedure Code Tables may not represent all codes available for that state procedure or that are managed by a specific client-organization.

## **Clinician Review**

These clinical guidelines neither preempt clinical judgment of trained professionals nor advise anyone on how to practice medicine. Healthcare professionals using these clinical guidelines are responsible for all clinical decisions based on their assessment. All Clinical Reviewers are instructed to apply clinical indications based on individual patient assessment and documentation, within the scope of their clinical license.

# **Payment**

The use of these clinical guidelines does not provide authorization, certification, explanation of benefits, or guarantee of payment; nor do the guidelines substitute for, or constitute, medical advice. Federal and State law, as well as member benefit contract language (including definitions and specific contract provisions/exclusions) take precedence over clinical guidelines and must be considered first when determining eligibility for coverage. All final determinations on coverage and



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# **National and Local Coverage Determination (NCD and LCD)**



## **NOTICE**

To ensure appropriate review occurs to the most current NCD and/or LCD, always defer to <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>.

# **Background**

National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) are payment policy documents outlined by the Centers for Medicare and Medicaid Services (CMS) and the government's delegated Medicare Audit Contractors (MACs) that operate regionally in jurisdictions.

CMS introduced variation between different jurisdictions/Medicare Audit Contractors (MACs) and their associated covered code lists with the transition to ICD 10. The variation resulted in jurisdictions independently defining how codes are applied for exclusions, limitations, groupings, ranges, etc. for the medical necessity indications outlined in the NCD and LCD. Due to this variation, there is an inconsistent use/application of codes and coverage determinations across the United States between the different MACs.

In addition, **WITHOUT** notice, CMS can change the codes that indicate medical necessity and the format of the coverage determinations/associated documents (eg, Articles). This is an additional challenge for organizations to keep up with ongoing, unplanned changes in covered codes and medical necessity indications.

# **Medical Necessity Codes**

Due to the variation in code application between jurisdictions/MACs and that updates can happen without notification, HealthHelp is not able to guarantee full accuracy of the codes listed for any Coverage Determination, and advises that prior to use, the associated Coverage Determination



Articles are reviewed to ensure applicability to HealthHelp's programs and any associated NCDs and LCDs.

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