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Clinical guidelines **PET SCANS** **includes** • **PET** • **PET with CT Attenuation** • **PET/CT**	**Original Date: September 1997**
78811 - Limited area e.g. Chest, head/neck **78812 - Skull base to mid thigh** **78813 - Whole Body 78814 - With CT attenuation (Limited area e.g. Chest, head/neck)** **78815 - With CT attenuation (Skull base to mid thigh) 78816 - With CT attenuation (Whole Body)**	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_070-1	**Implementation Date: January 2024**

GENERAL INFORMATION

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

GENERAL NOTES:

ADULT AND PEDIATRIC MALIGNANCIES[1]: ONCOLOGICAL PET IS INDICATED FOR BIOPSY-PROVEN CANCER **OR** STRONGLY SUSPECTED CANCER BASED ON OTHER DIAGNOSTIC TESTING. The appropriateness of an ordered PET/CT study is dependent on which radiopharmaceutical will be used for the PET/CT.

INDICATIONS FOR FDG PET:

See Legislative Requirements for specific mandates for the State of Washington

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The following list applies to biopsy-proven cancers **AND** lung nodules with no known history of malignancy**. This is NOT a comprehensive list. Additional indications for PET are found in the tables following this list.** The definitions regarding initial staging and restaging (**including time interval following treatment****) apply.

- Solid lung nodule > 8 mm and no prior PET – Indicated
- Mixed lung nodule* with solid component > 6 mm and no prior PET – Indicated
- Basal cell carcinoma of the skin – **Not indicated** for initial staging or restaging
- Castleman's Disease – Indicated for initial staging and restaging
- Cervical Cancer (stage IB1 or higher) – Indicated for initial staging and restaging**
- Chondrosarcoma – **Not indicated** for initial staging or restaging
- Ewing's Sarcoma* – Indicated for staging (all ages) and restaging age < 30
- Head and Neck Cancer – Indicated for initial staging and restaging**
- Non-Small Cell Lung Cancer – Indicated for initial staging and restaging
- Lymphoma (Hodgkin's and non-Hodgkins) – Indicated for initial staging and restaging
- Melanoma* – cutaneous – (stage III, IV) – indicated for initial staging and restaging
- Merkel Cell – Indicated for initial staging and restaging
- Osteosarcoma* – Indicated for initial staging (all ages) and restaging age < 30
- Peritoneal Mesothelioma – Indicated for initial staging and restaging
- Post Transplant Lymphoproliferative Disorder (PTLD) – indicated for initial staging and restaging
- Renal – **Not indicated** for initial staging or restaging
- Rhabdomyosarcoma (RMS) – Indicated for initial staging and restaging
- Small bowel carcinoma* – **Not indicated** for initial staging
- Soft Tissue Sarcoma* (other than RMS) – Indicated for initial staging (age < 30) and restaging (age < 30)
- Testicular Cancer – Seminoma* – **Not indicated** for initial staging
- Testicular Cancer – Non-Seminoma – **Not indicated** for initial staging or restaging
- Thymoma/Thymic Cancer – Indicated for initial staging and restaging

*See additional indications in table below

**If radiation or chemoradiation were given, 12 weeks must have elapsed since last radiation treatment. See table below for additional indications if < 12 weeks.

INDICATIONS FOR SPECIAL TRACER PET:

The following list applies to for biopsy-proven cancers for which a non-FDG tracer (special tracer) is indicated in the specific clinical scenarios described. **This is NOT a comprehensive list. Additional indications for non-FDG PET are found in the tables following this list.** The definitions regarding initial staging and restaging (including time interval following

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treatment**) apply. Diagnosis needs to be confirmed by biopsy and tracer planned clearly indicated.

- Prostate Cancer* – **PSMA** PET Indicated for initial staging **ONLY** of non-metastatic[2] Gleason 8, 9, 10 disease (or grade group 3, 4 or 5 disease)
- Carcinoid, Well-differentiated Neuroendocrine tumors, pheochromocytoma and paraganglioma* – **SSTR** PET (such as Ga68-Dotatate, Ga68-Dotattoc and Cu64-Dotatate) Indicated for initial staging ONLY

FDG-PET/CT (fluorodeoxyglucose-positron emission tomography)

LUNG NODULE[3] seen on LDCT or CT+ contrast (without known malignancy)

- Solid Component of Dominant Nodule (either solitary or clearly dominant) ≥ 8mm **OR**
- Part solid/mixed nodules with the solid component 6 mm or larger **OR**
- Mixed nodule (i.e., ground glass and solid nodule) with solid component of the nodule ≥ 4mm on LDCT when there has been
  - Interval growth of the solid component of at least 1.5mm on subsequent LDCT scans
    OR
  - Interval development of a new mixed nodule on subsequent LDCT with the solid nodule component ≥ 4mm

FDG PET

ONCOLOGICAL INDICATIONS FOR FDG PET

(SEE SPECIAL TRACERS SECTIONS FOR INDICATIONS OTHER TRACERS)

CANCER TYPE	INITIAL STAGING	RESTAGING
ADRENAL[4] (other than pheochromocytoma/ paraganglioma)	Indicated when conventional imaging (see Background) and biochemical evaluation are highly suggestive of adrenocortical carcinoma	with prior indeterminate imaging
AIDS-related KAPOSI SARCOMA[5]	If concerns for coexisting KSHV associated inflammatory cytokine syndrome (KICS), MCD, or KSHV+ lymphoma	**Not Indicated**
ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)[6]	lymphomatous extramedullary disease	lymphomatous extramedullary disease

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ONCOLOGICAL INDICATIONS FOR FDG PET
(SEE SPECIAL TRACERS SECTIONS FOR INDICATIONS OTHER TRACERS)

CANCER TYPE	INITIAL STAGING	RESTAGING
ACUTE MYELOGENOUS LEUKEMIA (AML)[7, 8]	If suspected extramedullary involvement	If suspected/known extramedullary involvement
ANAL[9]	with prior indeterminate imaging (see Background). (can consider PET/MR‡‡)	with prior indeterminate imaging
BASAL CELL[10] (BCC of the skin)	**Not Indicated**	**Not Indicated**
BILIARY TRACT CANCER[11] (Cholangiocarcinoma, Gall Bladder Cancer)	With prior indeterminate imaging	With prior indeterminate imaging
BLADDER[12]	With indeterminate imaging and muscle invasive disease only when the indeterminate finding is outside of the urinary tract	With indeterminate imaging and suspected metastatic disease or recurrence outside of the urinary tract
BONE CANCER[13]		
• **Chondrosarcoma**	**Not indicated**	**Not indicated**
• **Chordoma**	With prior indeterminate imaging	With prior indeterminate imaging
• **Ewing Sarcoma and Osteosarcoma**	Indicated (all ages)[13]; PET can be approved in conjunction with MR of primary site	Age < 30: Indicated Age > 30: Indicated for known or suspected metastatic disease based clinical or imaging findings or when PET was used for initial staging PET can be approved in conjunction with MR of primary site (all ages)

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ONCOLOGICAL INDICATIONS FOR FDG PET
(SEE SPECIAL TRACERS SECTIONS FOR INDICATIONS OTHER TRACERS)

CANCER TYPE	INITIAL STAGING	RESTAGING
BREAST[14] *See special tracer section below for FES PET*	with prior indeterminate imaging	with prior indeterminate imaging
CERVICAL[15]	Indicated for stage IB1 and above (can consider PET/MR‡‡)	Indicated
COLORECTAL[16, 17]	with prior indeterminate imaging **OR** potentially surgically curable metastatic disease **OR** when considered for image-guided liver-directed therapies	with prior indeterminate imaging (including discordance between tumor markers (CEA) and imaging) **OR** potentially surgically curable metastatic disease **OR** when considered for image-guided liver-directed therapies
ENDOMETRIAL[18]	with prior indeterminate imaging	with prior indeterminate imaging
ESOPHOGEAL and ESOPHAGOGASTRIC JUNCTION (EGJ)[19] (includes EGJ tumors with epicenter < 2 cm into stomach)	Indicated if no evidence of metastatic disease	Indicated following preoperative chemoradiation or definitive chemoradiation; **OR** with prior indeterminate imaging
FALLOPIAN TUBE CANCER	with prior indeterminate imaging	with prior indeterminate imaging
GASTRIC[20] (includes EGJ tumors with epicenter >2 cm into stomach)	with prior indeterminate imaging AND no evidence of metastatic disease	with prior indeterminate imaging

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ONCOLOGICAL INDICATIONS FOR FDG PET
(SEE SPECIAL TRACERS SECTIONS FOR INDICATIONS OTHER TRACERS)

CANCER TYPE	INITIAL STAGING	RESTAGING
GESTATIONAL TROPHOBLASTIC CANCER[21]	with prior indeterminate imaging	with prior indeterminate imaging or at completion of chemotherapy when hCG is not a reliable marker
GIST[22]	with prior indeterminate imaging	with prior indeterminate imaging
HEAD and NECK[23] (including mucosal melanoma of the head and neck)	Indicated Additionally, Face/Neck MRI (or CT) may be indicated concurrently with PET if needed for surgical planning	Indicated Additionally, Face/Neck MRI (or CT) may be indicated concurrently with PET 3-4 months after end of treatment in patients with locoregionally advanced disease or with altered anatomy If final PET/CT is equivocal or borderline for residual disease, a repeat PET/CT at $\geq$ 6 weeks may help identify those that can be safely observed without additional surgery
HEPATOCELLULAR[24]	with prior indeterminate imaging	with prior indeterminate imaging
LEUKEMIA (refer to specific types listed in table when possible)	If there is lymph node involvement (lymphomatous features), soft tissue and/or extramedullary involvement (myeloid sarcoma) and/or if	If there is lymph node involvement (lymphomatous features), soft tissue and/or extramedullary involvement (myeloid sarcoma) and/or if

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ONCOLOGICAL INDICATIONS FOR FDG PET
(SEE SPECIAL TRACERS SECTIONS FOR INDICATIONS OTHER TRACERS)

CANCER TYPE	INITIAL STAGING	RESTAGING
	forms “chloromas” (leukemia tumor balls)	forms “chloromas” (leukemia tumor balls)
LUNG		
• **Non-Small Cell**[25]	Indicated	Indicated
• **Limited stage small cell**[25]	Indicated	Indicated prior to radiation or with indeterminate imaging
• **Extensive stage small cell**	**Not indicated** unless conventional imaging is unable to conclusively classify the stage as extensive (see Background)	**Not indicated** unless consolidative thoracic radiation is planned (see Background)
LYMPHOCYTIC LEUKEMIA		
• **Chronic (CLL) and Small (SLL)**[26]	For suspected high-grade transformation or to guide biopsy with prior indeterminate imaging	with accelerated CLL or to guide biopsy with prior indeterminate imaging (includes negative CT with rising tumor markers or if conventional imaging documents mets, IF clearly considering resection)
LYMPHOMA (Non-Hodgkins and Hodgkins)[27-32]	Indicated (can consider PET/MR‡‡)	Indicated (can consider PET/MR‡‡)
MELANOMA		
• **Cutaneous**[33]	stage III, IV indicated; indicated for dermal melanomas that lack epidermal involvement	Indicated for stage III, IV disease **OR** for workup of local satellite/in-transit and/or nodal recurrences (see Background)
• **Uveal**[34]	**Not indicated**	With prior indeterminate imaging

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ONCOLOGICAL INDICATIONS FOR FDG PET
(SEE SPECIAL TRACERS SECTIONS FOR INDICATIONS OTHER TRACERS)

CANCER TYPE	INITIAL STAGING	RESTAGING
MERKEL CELL[35]	Indicated	Indicated
MESOTHELIOMA (malignant)		
• **Pleural**[36]	Indicated for stage I-IIIA when the patient is a potential surgical candidate (see Background)	Indicated only prior to surgery for stage I-IIIA
• **Peritoneal**[37]	Indicated	Indicated
MULTIPLE MYELOMA[38]		
• **Smoldering myeloma** (asymptomatic)	Indicated	Indicated annually or possibly more frequently as clinically indicated (labs and/or symptoms to suggest progression)
• **Active myeloma**	Indicated	Indicated
• **Plasmacytoma**	Indicated	Indicated
NEUROBLASTOMA	Indicated when MIBG is negative, indeterminate, or there are discordant findings between MIBG and pathology	Indicated when FDG PET was used for initial staging or if MIBG has become indeterminate or discordant
NEUROENDOCRINE TUMORS:[39]		
• **Poorly differentiated**	with prior indeterminate imaging (see Background)	with prior indeterminate imaging (see Background)
• **Well-differentiated grade 3 with high Ki-67 (≥ 55%)**	Indicated after prior negative or indeterminate SSTR (dotatate) PET (see Background)	Indicated after prior negative or indeterminate SSTR (dotatate) PET (see Background)

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ONCOLOGICAL INDICATIONS FOR FDG PET
(SEE SPECIAL TRACERS SECTIONS FOR INDICATIONS OTHER TRACERS)

CANCER TYPE	INITIAL STAGING	RESTAGING
OVARIAN[40]	with prior indeterminate imaging	with prior indeterminate imaging (including discordance between tumor markers (CA-125) and imaging)
OCCULT PRIMARY[41]	with prior indeterminate imaging (see Background)	with prior indeterminate imaging (see Background)
PANCREATIC	With prior indeterminate imaging OR with any of the following high-risk features: • borderline resectable disease • markedly elevated CA19-9 >180 U/ml • large primary tumor/lymph nodes • very symptomatic (jaundice, symptomatic gastric outlet obstruction, venous thromboembolism, extreme pain and excessive weight loss)	When PET was used for initial staging and need to assess response to treatment in order to determine if now a surgical candidate
PENILE[42]	with prior indeterminate imaging	with prior indeterminate imaging
PERITONEAL CANCER[40] **(PRIMARY)**	with prior indeterminate imaging	with prior indeterminate imaging
POST TRANSPLANT LYMPHOPROLIFERATIVE DISORDER (PTLD)	Indicated when the diagnosis is made OR if suspected based on abnormal PE, abnormal imaging	Indicated

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ONCOLOGICAL INDICATIONS FOR FDG PET
(SEE SPECIAL TRACERS SECTIONS FOR INDICATIONS OTHER TRACERS)

CANCER TYPE	INITIAL STAGING	RESTAGING
	or abnormal labs (i.e., significantly elevated or rising viral titers)	
PROSTATE (FDG PET only) (see Prostate Special Tracer section)	**Not Indicated**	**Not Indicated**
RENAL[43]	**Not indicated**	**Not indicated**
SKIN SQUAMOUS CELL[44]	Indicated for biopsy proven ≥N1 or ≥M1 disease (lymph node or metastatic site has been biopsied and shows disease spread)	Indicated for biopsy proven ≥N1 or ≥M1 disease (lymph node or metastatic site has been biopsied and shows disease spread)
SMALL BOWEL CARCINOMA[45]	**Not indicated**	with prior indeterminate imaging
SOFT TISSUE SARCOMA[46]		
• **Rhabdomyosarcoma**	Indicated	Indicated
• **All other soft tissue sarcomas**	For patients <30 years old: Indicated For patients >30 years old: with prior indeterminate imaging	For patients < 30 yrs old: Indicated For patients <30 yrs old: with prior indeterminate imaging
TESTICULAR[47]		
• **Seminoma**	**Not Indicated**	with prior indeterminate imaging OR residual mass >3cm with normal AFP and beta-hcG and 6 weeks post chemotherapy

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ONCOLOGICAL INDICATIONS FOR FDG PET
(SEE SPECIAL TRACERS SECTIONS FOR INDICATIONS OTHER TRACERS)

CANCER TYPE	INITIAL STAGING	RESTAGING (If this final PET/CT is equivocal or borderline for residual disease, an additional repeat PET/CT > 6 weeks later may help identify those that can be safely observed without additional surgery)
• **Non-Seminoma**	**Not Indicated**	**Not Indicated**
THYMOMA/THYMIC CANCER[48]	Indicated	Indicated
THYROID[49]		
• **Papillary, Follicular, Oncocytic (formerly Hurthle Cell)**	**Not Indicated**	with prior indeterminate imaging (including discordance between tumor markers (Tg, anti-Tg Ab) and imaging; see Background)
• **Anaplastic**	Indicated	Indicated
• **Medullary**	**Not Indicated** (see SSTR indications below)	With prior indeterminate imaging (including discordance between tumor markers (calcitonin, CEA) and imaging; see Background)
UTERINE (Endometrial Carcinoma and Uterine Sarcoma)[50]	with prior indeterminate imaging	with prior indeterminate imaging
VULVAR[51]	Indicated if ≥ T2 (extension beyond vulva/perineum) OR	Indicated

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ONCOLOGICAL INDICATIONS FOR FDG PET

(SEE SPECIAL TRACERS SECTIONS FOR INDICATIONS OTHER TRACERS)

CANCER TYPE	INITIAL STAGING	RESTAGING
	with prior indeterminate imaging	

MISCELLANEOUS INDICATIONS FOR FDG PET

(excluding brain and cardiac PET which have separate Guidelines)

TYPE	INITIAL STAGING	RESTAGING
CASTLEMAN'S DISEASE	Indicated	Indicated
HISTIOCYTIC NEOPLASMS[52]:		
• **Langerhan's**	Indicated	Indicated if on active treatment for multiple bone disease, high risk bone disease or multisystem involvement
• **Erdheim Chester**	Indicated	Indicated if on active treatment
• **Rosai-Dorfman**	Indicated	Indicated if on active treatment

ǂ SARCOIDOSIS

- **ONLY** if conventional testing (CXR, CT and inflammatory serology) remain indeterminate for known sarcoid to determine:
  - if treatment might be helpful
  - extent of disease, if it will potentially change management
  - response to treatment
- **OR** if strongly supected sarcoid to determine most suitable site to biopsy

ǂ VASCULITIS

- In limited circumstances, with known vasculitis, AFTER conventional imaging (MRA/CTA/MR/CT) has clearly been shown to be insufficient to determine treatment

ǂ NEUROFIBROMATOSIS TYPE 1[53-56]

- When there is a concern for transformation of a neurofibroma to a Malignant Peripheral Nerve Sheath Tumor (MPNST) based on a change in imaging (such as rapid growth or change in texture on exam or imaging) and/or symptoms (new or worsening pain in the location of a known neurofibroma), then a single FDG-PET is indicated (see Background).
- Restaging of a known MPNST with PET requires indeterminate imaging prior to PET approval.

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ǂ Adjudications should occur on a case-by-case basis

YTTRIUM-90 (Y90)

Y90 PET SCAN: Indicated when performed immediately after treatment of liver malignancy (primary or metastatic). The Y90 treatment is also the tracer for this and PET is performed within 24 hours of treatment (while Y90 is still detectible) to confirm the final distribution of the Y90. PET.

NON FDG PET TRACERS

Somatostatin Receptor (SSTR) PET FOR NET (Neuroendocrine Tumors) (GA68-DOTATATE, GA68-DOTATOC and CU64-DOTATATE)

CANCER TYPE	INITIAL STAGING	RESTAGING
CARCINOID,NEUROENDOCRINE TUMORS (NET)[57] OF THE GI TRACT, PANCREAS, LUNG, THYMUS AND UNKNOWN PRIMARY, PHEOCHROMOCYTOMA, PARAGANGLIOMA	Indicated (PET/MR‡‡ can be considered)	Indicated when there is progression or recurrence is known or suspected (based on labs and/or conventional imaging) and SSTR directed therapy is being considered (see Background) (PET/MR‡‡ can be considered)
MEDULLARY THYROID	with prior indeterminate imaging	with prior indeterminate imaging (including discordance between tumor markers (calcitonin, CEA) and imaging; see Background)

FES (fluoroestradiol F 18 (Cerianna®)) **PET**

CANCER TYPE	INITIAL STAGING	RESTAGING
BREAST CANCER	**Not Indicated**	Indicated for biopsy proven recurrent or metastatic **Estrogen Receptor Positive (ER-positive)** disease when receptor status of sites of disease will

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Somatostatin Receptor (SSTR) PET FOR NET (Neuroendocrine Tumors) (GA68-DOTATATE, GA68-DOTATOC and CU64-DOTATATE)

CANCER TYPE	INITIAL STAGING	RESTAGING
		result in a change treatment (see Background)

PSMA TRACERS (such as F18 piflufolastat (Pylarify®), GA 68 PSMA-11, GA 68 gozetotide (Locametz®), and GA 68 gozetotide (Illuccix®)) For PROSTATE CANCER[2, 58]

CANCER	INITIAL STAGING	RESTAGING
PROSTATE CANCER **TRACERS:** **Initial staging**: **PSMA** is the ONLY tracer potentially approvable for initial staging **Restaging**: PSMA is the preferred tracer, see Background for other tracers such as Axumin® and 11-Choline[58].	**PSMA** PET is indicated for initial staging of non-metastatic[2] very high risk, high risk and unfavorable intermediate risk prostate cancer (see Background) (can consider PET/MR‡‡) Pelvic MRI may be indicated concurrently if needed for surgical planning	**PSMA** PET is indicated in the following situations (see Background): **Post-radical prostatatectomy:** • For PSA persistence: detectable PSA (0.1 ng/mL or greater) at 3 months post-operatively (only one level required) • For rising PSA on two or more occasions OR a rise to > 0.1 ng/mL if was previously undetectable For **known metastatic disease** with progression **on treatment** and either: • Rising PSA (on two consecutive levels) • Disease progression on imaging (i.e. bone scan) A single restaging PSMA PET 12 weeks after treatment with radioligand therapy (Lu-177/Pluvicto) is indicated

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- Washington
    - Washington State Health Care Authority Health Technology Assessment 20181116B Positron Emission Tomography (PET) scans for lymphoma[59]
        - PET scans (i.e., PET with computed tomography or PET/CT) for lymphoma is a covered benefit with conditions.
        - An initial staging scan is covered followed by up to three (3) scans per active occurrence of lymphoma:
            - When used to assess a response to chemotherapy, scans should not be done any sooner than three (3) weeks after completion of any chemotherapy cycle, except for advanced stage Hodgkin's lymphoma, after four (4) cycles of ABVD chemotherapy.
            - When used to assess response to radiation therapy, scans should not be done any sooner than eight (8) weeks after completion of radiation or combined chemotherapy and radiation therapy.
        - Relapse: Covered when relapse is suspected in the presence of clinical symptoms or other imaging findings suggestive of recurrence
        - Surveillance: Not covered

Washington State Health Care Authority oversees the Apple Health (Medicaid) program and the Public Employees Benefits Board (PEBB) Program[60]

BACKGROUND

USEFUL DEFINITIONS: The **cancer specific details for adjudication still apply.**

- **INITIAL STAGING** refers to imaging that is performed AFTER the diagnosis of cancer is made, and generally before any treatment**.**
- **RESTAGING** includes scans that are either needed **during active treatment (subsequent treatment strategy)** to determine response to treatment/monitor treatment, a single **end of treatment** study done within 6 months of completion of treatment, or when there is clinical **concern for recurrence** (i.e., 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)
- **ACTIVE TREATMENT** includes chemotherapy, immunotherapy, radiation, as well as patients on "maintenance therapy" who have known, or existing, metastatic disease being held in check by this treatment. Allogenic bone marrow transplant and CART T-cell therapy should be considered 'active' treatment for at least 6 months after infusion/transplant and as such can be approved at 30 days, 100 days, and 6 months after the most recent infusion.
- **SUBSEQUENT TREATMENT STRATEGY:**

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- For restaging or monitoring response during active treatment (including immunotherapy), and/or a single evaluation after completion/cessation of therapy. The interval should **ideally**‡ be 6-12 weeks after surgery, and 12 weeks after radiation (to avoid false positive findings that can be caused by treatment changes or healing).
    - ‡NOTE: a valid clinical reason explaining why the interval needs to be shorter than ideal must be present
- PET/CT can be performed 1 - 3 weeks after neoadjuvant chemotherapy or neoadjuvant chemoradiation if done for presurgical planning to evaluate for distant metastatic disease or to evaluate known metastatic disease located in areas separate from the site(s) being radiated.
- When an end of treatment PET scan performed at an appropriate post-treatment interval (see above) shows indeterminate findings, one additional repeat PET in 3 months is indicated.

- **INDETERMINATE IMAGING:** When indeterminate imaging is required prior to PET, this typically means conventional imaging (CT, MRI, OR Nuclear Medicine Scan (i.e. bone scan)) shows a finding that is indeterminate **AND** clarification of that finding with PET will potentially change management. When PET is not indicated for a cancer type in the guideline (i.e. literature does not support the use of PET), PET is **not indicated** even if indeterminate imaging is provided. The information provided should clearly explain why conventional imaging is insufficient to determine treatment or management and includes situations such as the following:
    - **New or residual masses** described as **indeterminate** on conventional imaging
    - **Biopsy guidance:** To determine the best location to biopsy either within a tumor that has necrosis on imaging **OR** to determine the best location to biopsy when there are findings on standard imaging that would require a significantly invasive procedure (such as laparoscopic or open surgical procedures) **AND** malignancy is highly suspected based on imaging.
- When **previous conventional imaging has been shown to be negative**, yet a **concurrent PET scan was positive** (i.e. conventional imaging was falsely negative/ missed lesions seen on PET), we do not require repeat conventional imaging prior to every subsequent PET (because conventional imaging was already shown to be insufficient). Appropriate interval criteria should still be met.
- **SURVEILLANCE PET** is generally **not approvable**. Surveillance means no active treatment, no current suspicion of recurrence and occurs 6 months or more after completion of treatment. Generally, this would be accepted only when ordered by the treating oncologist or clearly at their recommendation (not as routine follow-up ordered by PCP). **Possible exceptions for the following indications only:**

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- Ewing's Sarcoma and Osteosarcoma in patients specified as high risk: every 3 months for 2 years, then every 4 months up to year 3 post completion of treatment.
- Small Cell Neuroendocrine Cervical every 3-6 months for the first 2 years post completion of treatment
- Diffuse Large B Cell Lymphoma when disease was only seen previously on PET: every 6 months for 2 years, then one at 12 months up to year 3 post completion of treatment.
- Gestational trophoblastic disease when hCG is not a reliable marker every 6-12 months for up to 3 years post completion of treatment
- Histiocytic neoplasms every 3-6 months for the first 2 years post completion of treatment
- Melanoma (stage 2b-4) specified as high risk every 3-12 months for 2 years, then every 6-12 months, up to 5 years after initial diagnosis[33, 61]
- Solitary plasmacytoma (up to 3 yrs after the diagnosis of plasmacytoma)[62, 63]

PET with CONTRAINDICATIONS to contrasted CT AND MRI:

When PET is requested for restaging due to the inability to image with contrasted conventional imaging, indeterminate non-contrasted studies must be provided prior to consideration of PET. The inability to image with contrasted conventional imaging includes contraindications to both CT (such as chronic renal failure with GFR < 30 **OR** significant iodinated contrast allergy) **AND** to MRI (such as gadolinium allergy, implanted device that is not MRI compatible, or GFR <40). When requested for surveillance due to the above reasons, PET can be considered during the time that the highest risk of recurrence for that cancer (typically the first two years after completion of treatment).

‡‡**PET/MR**: When PET/MR can be considered per the guideline, if the criteria are met for PET for that cancer and the plan is to do a PET/MR rather than a PET/CT, the PET scan can be approved. In the same way a separate approval for total body CT is not needed when a PET/CT is requested, a separate approval for the total body MR is not typically needed. However, until a PET/MR CPT code is implemented, unlisted MR in addition to PET can be considered on a case-to-case basis.

PET IN COMBINATION WITH DEDICATED SITE SPECIFIC MR (OR CT): Distinct from PET/MR, when PET is needed in addition to a dedicated site specific MRI (or CT), two authorizations may be issued: one for the PET scan and one for the site specific MRI (or CT). Clear indications for both must be provided.

STAGING: Staging for cancer is cancer-specific and is typically based on the TNM system of staging. T stage refers to the extent of the main (primary) tumor. N stage refers to the extent of

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spread to lymph nodes. M stage refers to whether or not the cancer has metastasized to other parts of the body. Clinical stage (such as cT2b) is determined by physical exam, imaging and possibly biopsy. Pathologic stage (such as pT2b) is determined after the tumor has been resected. Certain cancers have additional information that is needed to stage the patient (such as PSA level in prostate cancer).

CANCER SPECIFIC BACKGROUND:

Adrenal Tumors: Features of an adrenal mass on conventional imaging that are suspicious for adrenocortical carcinoma (ACC) include: size > 4 cm, inhomogenous mass with irregular margins and/or has local invasion. If there is no history of another primary malignancy and these features are present on imaging, then PET is reasonable. If there is a history of another primary tumor and a metastasis is suspected, biopsy should be done first to determine tissue type. A biochemical evaluation is also done to evaluate for other tumor types (such as pheochromocytoma) for which a different tracer (such as dotatate) may be more appropriate.

Anal Cancer: Normal pelvic lymph nodes are often not seen on imaging. When pelvic lymph nodes are visualized on imaging, even if normal in size, that finding raises concern for disease spread and can be considered indeterminate.

Brain Tumors: When an oncologic PET is requested for a primary brain malignancy, it typically should be reordered as a Brain PET (CPT 78608 and 78609). This includes requests for recurrent meningioma when dotatate PET is requested.

Breast Cancer: Fluoroestradiol F 18 (Cerianna® or FES) is a new tracer that is specific for estrogen receptor positive (ER-positive) breast cancer. It is used in recurrent or metastatic breast cancer that was known to be ER-positive at initial diagnosis to determine how much of the current disease has functional estrogen receptors. This can help determine whether endocrine therapy is appropriate. This tracer is **NOT** indicated for ER-negative disease. An FES PET is NOT done to monitor response to treatment but instead is done ONLY when the receptor status of the recurrent or metastatic sites is in question. FES PET is **NOT** used for assessing the primary site of disease.

Langerhans Cell Histiocytosis is the most common type of histiocytosis, with variable presentations and sites involvement. Some studies suggest PET/CT may be more effective in detecting bone lesions compared with MRI and bone scans in assessing disease response as healing/treatment changes of bone lesions on conventional imaging may be delayed. However, PET/CT is not the modality of choice in assessing disease response of lung or brain lesions.

Lung Cancer – Small Cell: Initial Staging is classified as Limited Stage (LS) and Extensive Stage (ES). In limited stage disease, the disease burden is localized to the chest (Any T, Any N, M0) AND able to be encompassed in a tolerable radiation plan. Patients with disease OUTSIDE of the chest (M1) or T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan are classified as extensive stage. When a patient cannot clearly be classified as ES but there are findings on

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imaging suggestive of disease (typically extra-thoracic findings such as a liver lesion), then PET may be used to help classify the extent of disease as ES or LS. If conventional imaging clearly shows ES disease, then PET is not indicated. **Restaging:** When radiation is planned (either for LS disease OR for ES disease that has responded to treatment), PET is indicated to determine radiation fields. Otherwise, disease reassessment/response to therapy is with conventional imaging[64].

Melanoma: Local satellite/in-transit recurrences are in the deep dermis or subcutaneous fat within or adjacent to the melanoma scar. They are recurrences that occur after an initial adequate wide excision, likely represent dermal lymphatic disease and do need imaging at diagnosis. Persistent disease, by contrast, is disease remaining in the melanoma scar after an initial resection (likely due to inadequate resection) and imaging would only be indicated if stage III or IV disease is present[33].

Mesothelioma[36, 65]: The evaluation of recurrent pleural effusion and/or pleural thickening includes CT chest, thoracentesis and pleural biopsy. The diagnostic sensitivity of this investigation is 70-75%. If the first biopsy is non-diagnostic, there is a higher chance that subsequent biopsies will be non-diagnostic, thus a PET to guide subsequent biopsy is reasonable in this situation.

Multiple Myeloma: Making the diagnosis of myeloma is complex and may include bone marrow biopsy, cytometry, imaging etc. However, once the diagnosis of myeloma (multiple myeloma or plasmacytoma) is confirmed, PET may be considered.

Neuroendocrine Tumors (NET)[57]: a Somatostatin Receptor (SSTR) analog PET (commonly dotatate) is indicated at initial diagnosis to evaluate for metastatic disease. If a moderately invasive procedure is needed to confirm the diagnosis (i.e. open surgery), PET prior to this open biopsy may be reasonable when the clinical picture, labs and imaging are consistent with a NET. Restaging can be done with conventional imaging (CT/MRI). However, if progression is seen and/or SSTR directed therapy is being considered, then SSTR-PET is indicated. Because liver lesions are often not well imaged on SSTR-PET, a dedicated liver MRI at the time of SSTR-PET may be indicated if there are known or suspected liver metastases.

FDG PET may be more useful when a NET is metabolically active, such as in poorly differentiated NET and well differentiated grade 3 NET with a high Ki67 (≥ 55%). For poorly differentiated NET, indeterminate conventional imaging is needed prior to FDG PET. For well-differentiated grade 3 NET with a high Ki-67 (≥55%), a negative dotatate PET is required before an FDG PET can be considered.

Neurofibromatosis type 1 (NF1): Surveillance of lesions is completed with MRI (often whole body MRI.) Approximately 5% of patients with neurofibromatosis are thought to develop soft tissue sarcomas, most commonly malignant peripheral nerve sheath tumors (MPNSTs), a type of sarcoma. Risk factors for MPNST transformation include: whole *NF1* gene deletion, family history of MPNST, prior radiation therapy, large plexiform neurofibroma burden or multiple distinct nodular lesions on magnetic resonance imagining (MRI), neurofibromatous neuropathy,

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and atypical neurofibroma(s). Once a PET has been done and was negative, rapid growth on conventional imaging and plan for biopsy need to be provided prior to consideration of another PET.

Occult Primary: The typical evaluation for a suspected metastatic malignancy includes a thorough physical exam, laboratory evaluation, CT of the Chest, Abdomen and Pelvis AND a biopsy of the site of disease. The biopsy results then indicate either a clear primary for which the relevant guideline is applied or an epithelial cancer (not site specific). Epithelial cancers are further classified as adenocarcinoma, carcinoma not specified, squamous cell carcinoma (SCC) or neuroendocrine carcinoma (see NET in guideline). If the primary is still not identified, further guidance is often complex and based on the site of disease identified.

Pheochromocytoma and Paraganglioma: Hypertension, tachycardia, sweating and syncope are typical symptoms. Biochemical workup includes catecholamines (such as metanephrines, normetanephrine, and/or dopamine). Elevations in catecholamines that are greater than two times above the upper limit of normal are usually present. Biopsy of a pheochromocytoma and paraganglioma that is biochemically active is contraindicated. Thus, when the clinical picture **AND** labs is consistent with pheochromocytoma/paraganglioma, the SSTR-PET can be approved without biopsy confirmation. However, if the catecholamines are not elevated (as above), in the setting of clinical concern and a mass, biopsy is required.

Prostate Cancer Initial Staging: PSMA is the only approvable tracer for initial staging. Risk groups are determined by the Gleason Score (on pathology report), PSA, clinical stage (by exam (digital rectal exam (DRE) and/or imaging such as pelvis MRI). This information may also be expressed as a grade group. The three risk groups for which PSMA PET is indicated are: very high risk, high risk and unfavorable intermediate risk. Any of the following criteria place the patient into one of these risk groups and PSMA PET may be approved for initial staging:

- Gleason score 8, 9 or 10
- Primary pattern 4 (Gleason 4+3=7)
- PSA > 20 AND Gleason score 3+3=6 or higher
- PSA > 10 AND Gleason score 3+4=7
- PSA > 10 AND Gleason score 3+3=6 AND clinical stage ≥ T2b
- Clinical stage ≥ T3a AND Gleason score 3+3=6 or higher
- Clinical stage ≥ T2b AND Gleason score 3+4=7 or higher
- ≥ 50% of cores positive for cancer in a random, non-targeted prostate biopsy
- Grade group 3, 4 or 5 disease

When **active surveillance** was selected as the initial plan of care, PSMA PET is indicated when the disease progresses to very high risk, high risk or unfavorable intermediate risk using the most recent Gleason score/biopsy result, clinical stage and PSA level.

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A biopsy typically needs to be done confirming the diagnosis of prostate cancer prior to PSMA PET. If the PSA is > 50, when there is no clinical concern for infection nor has there been recent instrumentation **AND** there is an intent to treat the patient for prostate cancer without biopsy confirmation, PSMA PET can be considered. Situations where this may be reasonable are when the biopsy poses significant risk (i.e., anticoagulation or significant comorbidity) **OR** if treatment is urgently needed (such as spinal cord compromise from metastases)[66].

Patients who are **metastatic at diagnosis** (no prior treatment) are staged with conventional imaging[2]. PSMA PET can be considered if there are indeterminate findings on conventional imaging and specific details regarding how clarification of these findings with PSMA PET would change treatment are provided.

Prostate Cancer Restaging: PSMA is the preferred tracer for restaging of prostate cancer due to the increased sensitivity and specificity for detection of disease. There may be situations where Axumin or Choline are approvable tracers such as for detection of inconclusive findings on bone scan, when prior PET scans have used that tracer and direct comparison is needed or if PSMA is not available. For both Axumin and Choline, inconclusive conventional imaging is required and the reason that tracer is being requested instead of PSMA needs to be provided. When a PSMA PET has failed to detect a site of recurrence (i.e. PSMA PET was negative previously yet PSA continues to rise), a repeat PSMA PET may be approved as early as 6 months if the PSA doubling time is < 12 months.

Thyroid Cancer: Thyroid cancer can be grouped into three main histologic subtypes: Differentiated (including papillary, follicular, and oncocytic), Anaplastic and Medullary.

Differentiated thyroid cancer: As iodine is taken up by differentiated thyroid cancers, an iodine scan (I-123 and/or I-131) is often the first line imaging modality (in addition to ultrasound). When there is a discordance between the tumor marker (thyroglobulin or thyroglobulin antibody) and imaging (I-123 or I-131 scan) **AND** the thyroid tissue has been removed (total or completion thyroidectomy) or ablated, this indicates that the tumor may have de-differentiated and FDG PET is indicated. After therapy with I-131 it can take several months for Tg to disappear from the circulation, so an early elevated level does not necessarily indicate a recurrence/persistence of the cancer. For **papillary**, **follicular and oncocytic** thyroid cancer, FDG PET can be approved for the following:

- A total (or completion) thyroidectomy **OR** radioiodine iodine has been completed; **AND**
- Serum thyroglobulin (Tg) is >2 ng/ml (unstimulated or stimulated) **OR** there is a high anti-thyroglobulin antibody (anti-Tg Ab) >1 year after treatment **AND**
- A Negative current I-123 (or I-131) scan **OR** a Negative prior stimulated whole body I-123 (or I-131) scan done at Tg level similar to the current Tg level (a current scan is needed if on radioiodine sensitizing medications)

Anaplastic thyroid cancers are aggressive and imaging with FDG PET is appropriate.

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Medullary thyroid cancers arise from the neuroendocrine parafollicular C cells of the thyroid and are not iodine-avid. Staging with SSTR PET is indicated for initial staging when indeterminate imaging is provided. For restaging, when calcitonin level is ≥ 150 pg/ml or CEA levels >5 ng/ml post-surgery **AND** indeterminate imaging (including negative CT/MRI with elevated calcitonin and/or CEA) is provided, PET is indicated. Typically the tracer for restaging is SSTR (dotatate), however, there may be situations where an FDG PET is reasonable.

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POLICY HISTORY

Date	Summary

May 2023	• Reorganized:
	  ○ Cancers where the guidance is straightforward into a list for ICRs and non-PET PCRs can approve/deny
	  ○ Definitions to background
	• Revised indeterminate imaging and contraindications to conventional imaging sections
	• Updated:
	  ○ Surveillance PET section with additional guidance
	  ○ Following Cancers to be consistent with updated version of NCCN
	  ▪ Adrenal: added indications in limited circumstances
	  ▪ Breast: changed to requiring inconclusive imaging and added a restaging indication for FES PET in special tracer section
	  ▪ Colorectal: added liver directed therapy and potentially curable M1 disease to restaging
	  ▪ Esophageal: initial staging clarified as indicated for non-metastatic, restaging changed from indicated to following chemoradiation or with indeterminate imaging
	  ▪ Small cell lung cancer: clarified staging in background section, limited stage: changed restaging to prior to radiation or with indeterminate imaging; for extensive stage: added indication for indeterminate imaging in initial staging, added indication when radiation is planned for restaging
	  ▪ Melanoma: added indication for satellite/in-transit and dermal melanomas that lack epidermal involvement
	  ▪ Neuroendocrine: separated types of NET, changed wording for poorly differentiated and well differentiated high grade in FDG section; added detail re what is needed for restaging in SSTR section
	  ▪ Renal: changed to not indicated
	  ▪ Skin squamous cell: added indication for biopsy proven lymph node positive and metastatic disease
	  ▪ Sarcoma: separated rhabdomyosarcoma as indicated (remainder require inconclusive imaging if > 30 yo)
	  ▪ Thyroid: moved most of detail into background section, made indications consistent with current NCCN guidance
	  ▪ MPNST: Added indication in section for NF1

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	▪ Prostate cancer: Moved detail for initial staging and non-PSMA tracers into background; updated restaging indications • Regrouped the following Cancers in the table to coincide with grouping in NCCN: o Biliary Tract o Bone Cancers o Uterine Cancers • Added TNM explanation and cancer-specific background sections when needed for additional • General information moved to the beginning of the guideline with added statement on clinical indications not addressed in this guideline
May 2022	• Updated changes based on NCCN including updates most notably for prostate cancer, Hurthle, NETs • Clarified when PET may be approved prior to biopsy for lung nodules and when PET is unnecessary (e.g., disease clearly present in both sides of chest and/or outside the chest) • Added indications for rare specific histiocytic syndromes and for sarcoid and vasculitis for non-oncological indications • Added restaging for RCC and pancreatic cancer in specific situations • Added indications for Y90 PET scan (liver malignancy) • Updated definitions of clinical guidelines (PET, PET/CT, and PET with CT Attenuation) • Minor wording clarifications, table adjustments

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Reviewed / Approved by NIA Clinical Guideline Committee

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