National Imaging Associates, Inc.	
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 2022~~February May 2023**
Guideline Number: NIA_CG_070-1	**Implementation Date: January 2024~~23~~**

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.

~~* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.~~

INDICATIONS FOR FDG PET:

See Legislative Requirements for specific mandates for the State of Washington

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)

~~– **Not indicated** for initial staging~~

- 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 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 stagin
- g 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 ~~and < 3cm or~~ **OR**
- Part solid/mixed nodules with the solid component 6~~8~~ 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

~~NOTE: > 3cm is considered a MASS; therefore, a tissue type is usually needed prior to PET (to determine if SCLC or NSCLC). However, if the chest CT imaging findings meet criteria for limited stage SCLC and no prior imaging shows metastatic disease elsewhere, PET can be approved prior to biopsy in order to guide biopsy of any FDG-avid adenopathy at the same time the primary is biopsied. If disease clearly is in both sides of the chest and/or outside the chest, then PET is not needed/approvable prior to tissue diagnosis.~~

~~USEFUL DEFINITIONS~~ ~~t~~(~~to aid in using the following table(s)~~. 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, within 6 months after the **end 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 traditional 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**
    - 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).
    - 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.

      ‡NOTE: a valid clinical reason explaining why the interval needs to be shorter than ideal must be present

- **INCONCLUSIVE INDETERMINATE IMAGING see Background** section at end of guidelines
- **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. **Possible exceptions† where PET "may be considered" for surveillance need to include a clinical reason why PET is needed (i.e., being considered), rather than conventional imaging (CT, MRI, bone scan):**
    - Ewing's every 2-3 months for 2 years, surveillance intervals should be increased years 2- 5, then annually after 5 yrs (for as long as as clinically indicted)
    - Osteosarcoma every 3 months for 2 years, then every 4 months for year 3, then every 6 months for years 4 and 5, and annually thereafter (for as long as clinically indicated.
    - Breast (Stage 4)
    - Cervical (stage 2-4)

- ~~Diffuse Large B Cell Lymphoma when disease was only seen previously on PET~~
- ~~Histiocytic neoplasms every 3-6 months for the first 2 years post completion of treatment~~
- ~~Melanoma (stage 2b-4)~~
- ~~Myeloma/plasmacytoma (ideally use same type imaging as was used in initial dx, up to 5 yrs after the diagnosis of plasmacytoma)~~
- ~~Seminoma (Stage 2b, 2c and 3)~~

~~‡NOTE: These cases would need to include a clinical reason why PET is needed (i.e., being considered), rather than conventional imaging (CT, MRI, bone scan). 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).~~

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~~**Not Indicated**~~	with prior indeterminate imaging~~**Not Indicated**~~
AIDS-related KAPOSI SARCOMA[5]	If concerns for coexisting KSHV associated inflammatory cytokine syndrome (KICS), MCD, or KSHV+ lymphoma~~with prior inconclusive imaging~~	**Not Indicated**
ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)[6]	lymphomatous extramedullary disease	lymphomatous extramedullary disease
ACUTE MYELOGENOUS LEUKEMIA (AML)[7, 8]	If suspected extramedullary involvement	If suspected/known extramedullary involvement

ANAL[9] ~~(Note that normal size pelvic adenopathy can be considered as inconclusive)~~	with prior ~~inconclusive~~indeterminate imaging (~~can be done with PET (PET/CT or PET/MR‡‡ if available)~~see Background). (can consider PET/MR‡‡)	with prior ~~inconclusive~~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~~Muscle invasive only, with prior inconclusive imaging~~ only when the indeterminate finding is outside of the urinary tract	With ~~inconclusive~~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)

BREAST[14] *See special tracer section below for FES PET*	~~Indicated for stage IIb and above (if only T and N are provided, this equates to T3 (tumor > 50mm); or T4 (tumor of any size with direct extension to chest wall and/or skin); or N2 (>3 axillary LN, ipsilateral internal mammary node); or the combination of T2 (tumor >20mm but <50mm) plus N1 (any positive lymph node involvement)~~with prior indeterminate imaging	with prior ~~inconclusive~~indeterminate imaging~~, if initial staging was performed with PET OR if recurs with IIb or higher disease (based on pathology/imaging/exam) since no previous initial staging would have typically been performed for lower grade breast cancer~~
~~**CERVICAL**~~ **CERVICAL**[15]	~~Indicated (can consider PET/MR‡‡ if available)for stage IB1 and above~~ Indicated for stage IB1 and above (can consider PET/MR‡‡)	~~Indicated~~Indicated
~~**CHORDOMA**~~	~~with prior inconclusive imaging~~	~~**with prior inconclusive imaging**~~
~~**CHOLANGIOCARCINOMA**~~	~~with prior inconclusive imaging~~	~~with prior inconclusive imaging~~
~~**CHONDROSARCOMA (bone)**~~	~~**Not Indicated**~~	~~**Not Indicated**~~
COLORECTAL[16, 17]	with prior indeterminate imaging~~with prior inconclusive imaging OR~~ **OR** ~~-~~potentially surgically curable ~~M1~~ metastatic disease **OR**	with prior ~~inconclusive~~indeterminate imaging (including discordance between tumor markers (CEA) and imaging) **OR**

	when considered for image-guided liver-directed therapies ~~NOT indicated for nonmetastatic colon cancer that is appropriate for resection~~	potentially surgically curable metastatic disease **OR** when considered for image-guided liver-directed therapies
ENDOMETRIAL[18]	with prior ~~inconclusive~~indeterminate imaging	with prior ~~inconclusive~~indeterminate imaging
ESOPHOGEAL and ESOPHAGOGASTRIC JUNCTION~~EGJ~~ (EGJ)[19] (includes ~~esophagogastric junction~~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
~~**EWING SARCOMA Osseous**~~	~~Indicated (all ages)~~	~~Patients <30 yrs old: Indicated Patients >30 yrs old: Indicated for known or suspected metastatic disease (based on PE/imaging)~~
FALLOPIAN TUBE CANCER	with prior ~~inconclusive~~indeterminate imaging	with prior ~~inconclusive~~indeterminate imaging
~~**GALLBLADDER**~~	~~with prior inconclusive imaging~~	~~with prior inconclusive imaging~~
GASTRIC[20] (includes EGJ tumors with epicenter >2 cm into stomach)	with prior ~~inconclusive~~ indeterminate imaging AND no evidence of metastatic disease ~~or if radiation is being considered **(Not indicated for T1N0M0 or M1)**~~	with prior ~~inconclusive~~ indeterminate imaging~~, PET/CT is indicated or for post radiation imaging~~

GESTATIONAL TROPHOBLASTIC CANCER[21]	with prior ~~inconclusive~~indeterminate imaging	with prior ~~inconclusive~~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 ~~May be done in conjunction with a dedicated face/neck MRI (or CT) when surgery or radiation is planned~~	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 > 6 weeks may help identify those that can be safely observed without additional surgery ~~Can concurrently approve a Neck MRIMRI (or CT) and PET 3-4 months after definitive treatment in patients with locoregionally advanced disease or with altered anatomy.~~ ~~PET should not be done earlier than 12 weeks after definitive treatment unless signs or symptoms of recurrence~~ ~~If final PET/CT is equivocal or borderline for residual disease, a repeat PET/CT at ≥ 6 weeks may help identify those that can~~

		~~be safely observed without additional surgery~~
HEPATOCELLULAR[24]	with prior ~~inconclusive~~indeterminate imaging	with prior ~~inconclusive~~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 forms "chloromas" (leukemia tumor balls)	If there is lymph node involvement (lymphomatous features), soft tissue and/or extramedullary involvement (myeloid sarcoma) and/or if forms "chloromas" (leukemia tumor balls)
LUNG • **Non-Small Cell**[25]	Indicated	Indicated
• **Limited stage small cell**[25] ~~Stage I-III~~ • ~~And T3/T4 if disease is encompassed in tolerable radiation plan (potentially curable)~~	Indicated	~~Indicated~~Indicated prior to radiation or with indeterminate imaging
•	**Not indicated** unless conventional imaging is unable to conclusively classify the stage as extensive (see Background)~~**Not indicated**~~	**Not indicated** unless consolidative thoracic radiation is planned (see Background)
• **Extensive stage small cell** ○ ~~Stage IV and T3 or T4 disease not able to be treated with curative intent~~		

LYMPHOCYTIC LEUKEMIA • **Chronic (CLL) and Small (SLL)**[26]	For suspected high-grade transformation or to guide biopsy with prior ~~inconclusive~~indeterminate imaging	with accelerated CLL or to guide biopsy with prior ~~inconclusive~~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] ~~(See Uveal melanoma below for indications)~~ • **Uveal**[34]	~~only~~ stage III, IV indicated; indicated for dermal melanomas that lack epidermal involvement **Not indicated**	Indicated for ~~only~~ stage III, IV disease OR for workup of local satellite/in-transit and/or nodal recurrences (see Background) ~~indicated~~ With prior indeterminate imaging
MERKEL CELL[35]	Indicated	Indicated
MESOTHELIOMA (malignant) • **Pleural**[36]	Indicated ~~only prior to surgery~~ 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, ~~inconclusive~~indeterminate, or there are discordant findings between MIBG and pathology	Indicated when FDG PET was used for initial staging or if MIBG has become ~~inconclusive~~indeterminate or discordant
NEUROENDOCRINE TUMORS:[39] ~~• **Poorly differentiated (NET) WHEN**~~ • ~~UNDIFFERENTIATED/DE-DIFFERENTIATED (including pheochromocytoma, paraganglioma, extrapulmonary large/small cell)~~	~~Indicated if used after prior negative or inconclusive Ga68 Dotatate scan~~with prior indeterminate imaging (see Background) Indicated after prior negative or indeterminate SSTR (dotatate) PET (see Background)	with prior indeterminate imaging~~Indicated when FDG was used for initial staging, or when used after prior negative/inconclusive Ga68 Dotatate scan (or MIBG scan) OR after inconclusive conventional imaging~~ (see Background) Indicated after prior negative or indeterminate SSTR (dotatate) PET (see Background)
• **Well-differentiated grade 3 with high Ki-67 (≥ 55%)**		
OVARIAN[40]	with prior ~~inconclusive~~indeterminate ~~-~~imaging	with prior ~~inconclusive~~indeterminate imaging (including discordance between tumor markers (CA-125) and imaging)
OCCULT PRIMARY[41]	with prior ~~inconclusive~~indeterminate imaging ~~appropriate to pathology of the biopsy that identified the occult malignancy~~(see Background)	with prior ~~inconclusive~~indeterminate imaging (see Background)

PANCREATIC	With prior ~~inconclusive~~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 ~~inconclusive~~indeterminate imaging	with prior ~~inconclusive~~indeterminate imaging
PERITONEAL CANCER[40] (PRIMARY)	with prior ~~inconclusive~~indeterminate imaging	with prior ~~inconclusive~~indeterminate imaging
POST TRANSPLANT LYMPHOPROLIFERATIVE DISORDER (PTLD)	Indicated when the diagnosis is made OR if suspected based on abnormal PE, abnormal imaging or abnormal labs (i.e., significantly elevated or rising viral titers)	Indicated
PROSTATE (FDG PET only) (see Prostate Special Tracer section)~~other PET tracer section below for prostate cancer*~~	**Not Indicated**	**Not Indicated**

RENAL[43]	~~**ONLY when conventional imaging is equivocal for metastatic disease and if present would alter initial treatment plan**~~ **Not indicated**	~~ONLY when conventional imaging is clearly insufficient in these circumstances:~~ • ~~For suspected recurrence/metastatic disease outside of the urinary tract~~ ~~**To monitor treatment with a Tyrosine Kinase Inhibitor (such as sunitinib, sorafenib) for advanced RCC when disease was only seen previously on PET**~~**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)~~with prior inconclusive imaging~~	Indicated for biopsy proven ≥N1 or ≥M1 disease (lymph node or metastatic site has been biopsied and shows disease spread)~~**Not Indicated**~~
SMALL BOWEL CARCINOMA[45]	**Not indicated**	with prior ~~inconclusive~~indeterminate imaging
SOFT TISSUE SARCOMA[46]		
• **Rhabdomyosarcoma**	Indicated	Indicated
• ~~-~~**All other soft tissue sarcomas**	For patients ~~<~~>30 years old: ~~with prior inconclusive imaging~~Indicated	For patients ~~<~~ ~~>~~30 yrs old ~~with prior inconclusive imaging~~: Indicated
~~**(including soft tissue/extraosseous Ewing sarcoma and soft tissue/extraosseous osteosarcoma)/ GIST/**~~ ~~**Rhabdomyosarcoma**~~	For patients ~~>~~<30 years old: ~~Indicated (does not require inconclusive conventional imaging)~~with prior indeterminate imaging	For patients <30 yrs old: with prior indeterminate imaging ~~Indicated (does not require inconclusive conventional imaging)~~

TESTICULAR[47]		
• **Seminoma**	**Not Indicated**	with prior ~~inconclusive~~indeterminate imaging OR residual mass >3cm with normal AFP and beta-hcG and 6 weeks post chemotherapy (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)
	Not Indicated	**Not Indicated**
• **Non-Seminoma**		
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)~~Indicated with the following 3 criteria: A thyroidectomy and radioiodine ablation were done initially; 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-131/I-123 scan OR a Negative prior~~

~~Hurthle~~	~~If Tg is high and/or pathology is high risk~~	~~stimulated whole body I-131/ I-123 scan done at Tg level similar to the current Tg level (a current scan is needed if on radioiodine sensitizing medications)~~
• **Anaplastic** • **Medullary**	~~With prior inconclusive imaging~~ Indicated **Not Indicated** (see ~~NET/Dotatate~~ SSTR indications below)	~~IF Tg is high and/or pathology is high risk~~ Indicated~~With prior inconclusive imaging~~ With prior ~~inconclusive~~indeterminate imaging (including discordance between tumor markers (calcitonin, CEA) and imaging; see Background)~~when calcitonin levels ≥ 150 pg/ml or CEA levels >5 ng/ml post-surgery with prior insufficient Dotatate scan~~
UTERINE (Endometrial Carcinoma and Uterine Sarcoma)[50]	with prior ~~inconclusive~~indeterminate imaging	~~with prior inconclusive imaging~~ with prior ~~inconclusive~~indeterminate imaging
~~**UVEAL MELANOMA**~~	~~**Not Indicated**~~	~~with prior inconclusive imaging~~
~~**VAGINAL**~~ **VAGINAL when not classified as cervical or vulvar**	~~Indicated~~ Indicated	~~Indicated~~ Indicated
VULVAR[51]	Indicated if ≥ T2 (extension beyond vulva/perineum) OR with~~≥T2 or after~~ prior ~~inconclusive~~indeterminate imaging	Indicated

MISCELLANEOUS ~~(NON-ONCOLOGIC)~~ 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 ~~inconclusive~~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.

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) ~~FOR NET (Neuroendocrine Tumors)~~

CANCER TYPE	INITIAL STAGING	RESTAGING
~~CARCINOID~~CARCINOID, ~~EXTRAPULMONARY LARGE AND SMALL CELL~~ ~~MEN-1/MEN-2 SYNDOMES~~ 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~~Prior CT/ MRI insufficient to Determine extent of treatment plan Determine if candidate for invasive diagnostic/ therapeutic procedure Determine optimal anatomic location for invasive procedure~~	~~When calcitonin levels ≥ 150 pg/ml or CEA levels >5 ng/ml post-surgery~~ 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

FES (fluoroestradiol F 18 (Cerianna®)) PET		
CANCER TYPE	**INITIAL STAGING**	**RESTAGING**
		status of sites of disease will 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®))~~; F18 FLUCICLOVINE (AXUMIN®) and C11 CHOLINE~~

For PROSTATE CANCER[2, 58]

CANCER	INITIAL STAGING	RESTAGING

PROSTATE
~~(PET/CT or PET/MRI‡‡)~~ **CANCER**

~~TAfter a negative Axumin® PET, a subsequent PSMA PET is not covered until a repeat PSA (done at least 3 months later) shows a progressive rise~~

~~11-Choline should be approved only if PSMA and/or Axumin® are not available.~~ RACERS:

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 ~~Order of preference typically would be PSMA, then~~ Axumin® and~~, then~~ 11-Choline[58].

~~**Only** **PSMA**~~ PET~~(not Axumin® or Choline)~~ is indicated for ~~in~~ initial staging of non-metastatic[2] ~~for~~ very high risk, high risk and unfavorable intermediate risk prostate cancer (see Background)
(can consider PET/MR‡‡)~~;~~
~~defined as 1 or more of the following:~~
~~Gleason 8, 9 or 10 (specimen contains pattern 4 or 5)~~
~~Gleason 7 IF primary pattern** is 4 (4+3=7)~~
~~Gleason 7 primary pattern 3 (3+4=7) must ALSO have a PSA >10 and/or cT2b-cT3c disease~~
- ~~Gleason 6 disease (3+3=6) must ALSO have a PSA > 20 and/or cT3a-cT4 disease~~

~~>50% cores positive for cancer in random biopsy~~

~~**The Primary Pattern refers to the 1st number in the Gleason Pattern~~

Pelvic MRI may be indicated concurrently if needed for surgical planning
~~can be approved 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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~~**Y90 PET SCAN:** Indicated when performed immediately after treatment of liver malignancy (primary or metastatic). with Y90 (usually within 24 hours while Y90 is still detectible). 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 (see Y90 background section~~PET**LEGISLATIVE REQUIREMENTS**

- 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

~~**Inconclusive Imaging INDETERMINATE IMAGING includes the following:**~~

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.

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- **SUBSEQUENT TREATMENT STRATEGY:**
  - 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.

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- **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:**
    - 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]

~~When our GLs require **Indeterminate imaging** prior to PET (used when NCCN says PET "may be considered" or some other vague term), "in order to conider" means:~~
~~Conventional imaging (CT, MRI, OR NUCLEAR MEDICINE) is indeterminate, or insufficient in determining treatment AND PET results will potentially change management.~~

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).

~~Information should clearly explain why conventional imaging is (or reasonably would be expected to be) insufficient to determine treatment/management and includes the following:~~
~~Equivocal or ambiguous other prior standard imaging if results will change management~~

To guide bBiopsy guidance such as for the (e.g., best location to biopsy within a tumors with necrosis, best location to biopsy most readily accessible avid lesion with known cancer)or in situations where there is questionable disease in an area that requires significantly invasive procedures to obtain tissue (such as open surgical procedures), and malignancy is high on the radiographic differential diagnosis (it is reasonable and medically appropriate to attempt to gain as much information about diagnosis from imaging prior to subjecting the patient to tissue diagnosis that has real risk of morbidity/mortality).

High suspicion of metastases due to clinical or histopathological or laboratory considerations but with no evidence of metastases on standard initial staging When there is **negative routine** cross-sectional imaging (of the appropriate body parts) and **NO tumor markers** exist (or not rising), **PET is not appropriate** (however we can recommend MRI if CT originally performed if provider has valid concerns).

With **negative standard imaging**, yet certain **reliable tumor markers are high/rising**.
Reliable tumor markers which have been shown in literature to be most reliable for disease recurrence/progression (this is not an all-inclusive list)
Clinical or laboratory disease progression with negative standard imaging • Breast CA 15-3
• Colorectal CEA
• Pancreatic CA 19
• Ovarian CA 125
• Neuroblastoma HVA, VMA
• Prostate PSA

Contraindications to IV contrast, including allergy and chronic renal failure precluding MRI in a patient with a known or highly suspected malignancy
PET/CT may be indicated if CT cannot be performed due to significant iodinated contrast allergy or chronic renal failure **AND** MRI cannot be performed due to significant gadolinium contrast allergy or if renal failure with GFR < 30.[4]
Evaluation for other distant metastases prior to surgical resection of limited metastases/local disease and otherwise negative prior standard imaging
Response to neoadjuvant therapy when CT/MR insufficient •
Residual masses after completion of therapy
Target definition for radiation planning

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 evry subsequent PET (because conventional imaging was already shown to be insufficient). Appropriate interval criteria should still be met.If previous conventional imaging has been inconclusive, and it seems reasonable to expect that to still be the case, new conventional imaging is NOT required

- In situations where there is questionable disease in an area that requires significantly invasive procedures to obtain tissue (such as open surgical

procedures), and malignancy is high on the radiographic differential diagnosis, it is reasonable and medically appropriate to attempt to gain as much information about diagnosis from imaging prior to subjecting the patient to tissue diagnosis that has real risk of morbidity/mortality.

Definition of Disease Progression:

For any signs of progression, as noted below, that could not be confirmed by other imaging, PET/CT is needed. Findings concerning for progression of disease include:

- Worsening of symptoms such as pain or dyspnea
- Evidence of worsening or new disease on physical examination
- Declining performance status
- Unexplained weight loss
- Increasing alkaline phosphatase, alanine aminotransferase (ALT), aspartate transaminase (AST), or bilirubin
- Hypercalcemia
- New radiographic abnormality or increase in the size of pre-existing radiographic abnormality
- New areas of abnormality on functional imaging (e.g., bone scan, PET/CT)
- Increasing tumor markers (e.g., carcinoembryonic antigen [CEA], CA 15-3, CA27.29)
- To help differentiate possible recurrent/active tumor from necrotic or inactive scar tissue, malignant from benign tissue, and nondescript benign changes.

PET and separate CT/MR: Positron emission tomography-Computed Tomography (PET/CT) is a rapidly developing and changing technology that is able to detect biochemical reactions, e.g., metabolism, or abnormal distribution of cell receptors within body tissues. A radioactive tracer is used during the procedure. Unlike other nuclear medicine examinations, PET/CT can measure metabolic activity of the cells of body tissues, providing information about the functionality and structure of the particular organ or tissue examined. PET/CT may also detect biochemical changes that help to evaluate malignant tumors and other lesions.

TYPICALLY, separate CT/MR scans being requested concurrently with a PET are not needed. There should be very few instances where separate studies are needed, and when this does happen, it is usually SITE-SPECIFIC. Most PET scanners now in use can "simultaneously" perform PET and CT (whether for CT Attenuation or a Diagnostic CT). Contrast can be given for the CT portion of the PET/CT. A separate request for diagnostic CTs in addition to PET is, therefore, not needed. The ordering MDO can specify to the imaging provider details about what type of CT scan is desired to be done with the PET portion. "Exceptions" generally occur when CT is needed in a plane other than standard axial imaging (for example: coronal CT for facial bone imaging that might be needed for surgical reconstruction). Separate MRIs are likewise rarely needed, but are perhaps somewhat more frequently needed than additional, separate CTs, since MRI does allow multiple imaging planes and may provide additional information. When

~~evaluating for these "exceptions", the reason additional separate imaging is needed should be clearly delineated before approval.~~

~~‡‡~~**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, ~~When a PET/MR can be considered according to the guideline~~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.
~~tables and a valid reason is given where MR is needed rather than CT, the~~PET can be approved. ~~A separate approval for the MR portion is not needed. This is distinct from a situation when PET is needed in addition to a dedicated site specific MRI (such as for Osteosarcoma). When a dedicated site specific MRI is indicated in addition to the PET and supported by the guideline, two authorizations may be issued: one for the PET scan and one for the site specific MRI. Patients with certain malignancies may benefit from PET/MRI since it detects brain and liver metastases better when compared with PET/CT. NCCN does suggest consideration of PET/MR in some malignancies, but not specifically for replacing PET/CT. PET/MRI should only be considered for those specific malignancies (see table for specific cancers) and in certain situations. Typically, PET/CT should suffice; however, under some circumstances, with clear explanation of why PET/MR is preferred rather than PET/CT, PET/MR may be an appropriate study.~~
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 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 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.

~~**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.~~**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, 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.

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.

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.

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 contraindication. Thus, when the clinical picture **AND** labs is consistent with pheochromocytoma/paraganglioma, the SSTR-PET can be approved without biopsy confirmation.Y90 PET Scans:

Hepatic radioembolization, involving intraarterial injection of yttrium-90 (Y90)-labeled glass or resin microspheres, is used for liver-dominant malignancy or metastases that are unresectable. A Tc99m MAA nuclear scan (typically requiring SPECT) is performed before the actual treatment with Y90. MAA, which is similar in size to the Y90 microspheres, mimics the distribution of the Y90 particles and should embolize within the tumor's hepatic arterioles, thus outlining the expected localization of the radiation. The scan is compared to a CTA/MRA to evaluate for any possible shunting of the treatment agent to the lungs or the GI tract. Coils can be placed as needed to minimize any shunting of Y90 to areas other than the desired target.

Post-procedure imaging (within 24 hours) with either SPECT or **PET** (at the discretion of the treating physicians) is then performed to confirm the final distribution of the Y90 and to calculate the actual radiation dose delivered to the tumor. Utilizing the Bremsstrahlung radiation of the Y90 embolization agent, SPECT (or SPECT/CT) can be completed with routine nuclear medicine collimators. However, due to their higher energy level (as compared to routine nuclear medicine agents), the Y90 photons scatter and/or pass through the collimator septa and degrade the image quality. Alternatively, **PET scanning can be done, again using the Y90 treatment agent itself**, but for PET via a minor decay pattern that emits a positron (32 in every one million decays) that is detectable with PET scanners. confirming the diagnosis of for prostate cancer ,rom[662]

FDG PET may be needed later (ideally performed >12 weeks after treatment) to access tumor response to this radiation, in accordance with the tumor-specific gudielines for FDG PET restaging (in the table above) and may still require inconclusive conventional imaging, if necessary for the type of cancer being treated.

POLICY HISTORY

Date	Summary
2023	—
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~~
~~June 2021~~	~~Added:~~ • ~~Definitions~~ • ~~CART T info~~ • ~~PTLD information added~~ • ~~PET/MRI information~~ • ~~Updated/added details for Prostate cancer and PSMA, Axumin and Choline~~ • ~~Minor adjustments to the PET FDG table, such as added details from NCCN, clarifications, separation of non-malignant uses~~

~~May 2020~~	• ~~Modified to table format~~
	• ~~Added section of follow up of a new or interval growth of a mixed pulmonary lung nodule on subsequent LDCT (NCCN 2020)~~
	• ~~Initial staging indicated~~
	  ○ ~~Changed AML to extramedullary disease (previously lymphomatous involvement)~~
	  ○ ~~Changed Breast cancer stage IIb and above (previously III and IV)~~
	  ○ ~~Added Castleman's disease~~
	  ○ ~~Added for Chronic Lymphocytic Leukemia to guide biopsy~~
	  ○ ~~Changed Mesothelioma to only prior to surgery for stage I-IIIA~~
	  ○ ~~Added "soft tissue" sarcoma in pediatric patient~~
	  ○ ~~Added Thymoma and thymic cancer~~
	  ○ ~~Added Langerhans Cell Histiocytosis-predominantly osseous disease (previously not included)~~

	• ~~Initial staging which is only indicated after prior inconclusive imaging (NCCN 2019/2020)~~
	  ○ ~~Added AIDS-related Kaposi sarcoma~~
	  ○ ~~Changed Anal carcinoma (previously indicated)~~
	  ○ ~~Added Ewing sarcoma-osseous~~
	  ○ ~~Added Gestational trophoblastic disease~~
	  ○ ~~Added Hepatocellular/Intrahepatic Cholangiocarcinoma (previously not included)~~
	  ○ ~~Added Fallopian tube and primary peritoneal cancer~~
	  ○ ~~Added Osteosarcoma-osseous~~
	  ○ ~~Changed Penile cancer (previously indicated with palpable nodes)~~
	• ~~Initial staging NOT indicated (NCCN 2019/2020)~~
	  ○ ~~Changed testicular (previously indicated)~~
	  ○ ~~Added Uveal Melanoma~~
	  ○ ~~Added Langerhans Cell Histiocytosis-predominantly non-osseous disease (previously not included)~~
	• ~~Restaging indicated (NCCN 2019/2020)~~
	  ○ ~~Added Castleman's disease~~
	  ○ ~~Added for accelerated Chronic Lymphocytic Leukemia and to guide biopsy~~
	  ○ ~~Added Gastric Cancer post radiation treatment~~
	  ○ ~~Changed Mesothelioma to only prior to surgery for stage I-IIIA~~
	  ○ ~~Added "soft tissue" to sarcoma in pediatric patient~~
	  ○ ~~Added Thymoma and thymic cancer~~
	  ○ ~~Added Langerhans Cell Histiocytosis-predominantly osseous disease (previously not included)~~
	• ~~Restaging which are only indicated after prior inconclusive imaging (NCCN 2019/2020)~~
	  ○ ~~Removed for resectable disease in Colorectal cancer~~
	  ○ ~~Removed for if candidate for surgery/locoregional therapy for endometrial cancer~~
	  ○ ~~Specified Ewings sarcoma-osseous~~
	  ○ ~~Added Extrahepatic Cholangiocarcinoma (previously not indicated)~~
	  ○ ~~Added Gallbladder carcinoma (previously not indicated)~~
	  ○ ~~Changed Gastric Cancer to prior inconclusive imaging or if radiation planning considered (previously indicated if no metastasis or early disease)~~
	  ○ ~~Added Gestational trophoblastic disease~~

	~~○ Added Hepatocellular/Intrahepatic Cholangiocarcinoma (previously not included)~~ ~~○ Changed Ovarian cancer (previously indicated for greater than Stage I)~~ ~~○ Added Fallopian tube and all stages of primary peritoneal cancer~~ ~~○ Added Osteosarcoma- osseous~~ ~~○ Added that for pheochromocytoma/ paraganglioma, extrapulmonary large/small cell, restaging FDG PET/CT can be done after inconclusive CT~~ ~~○ Modified Seminoma with residual mass >3cm or 6 weeks post chemotherapy (previously indicated)~~ ~~○ Added Uveal melanoma~~ ~~• Restaging NOT indicated (NCCN 2019/2020)~~ ~~○ Added AIDS related Kaposi sarcoma~~ ~~○ Changed Testicular non seminoma (previously indicated)~~ ~~○ Added Langerhans Cell Histiocytosis predominantly non-osseous disease (previously not included)~~ ~~• Added CT face/neck may be done in conjunction with PET when surgery or radiation is planned~~ ~~• Added to head and neck cancer that if a final PET is equivocal or borderline for residual disease PET, a repeat PET/CT a ≥ 6 weeks may help identify those that can be safely observed without additional surgery~~ ~~• Medullary thyroid: added FDG restaging indicated when CEA >5ng/ml post-surgery and after prior insufficient Dotatate scan~~ ~~• Modified pancreatic cancer symptoms to excessive weight loss~~ ~~• Added to Seminoma: if final PET is equivocal or borderline for residual disease PET, a repeat PET/CT a ≥ 6 weeks may help identify those that can be safely observed without additional surgery)~~ ~~• Thyroid FDG- changed serum thyroglobulin level to >2ng/ml (previously >5ng/ml) and added 'current OR two prior stimulated whole body I-131/ I-123 scans are negative (a current scan is needed if on radioiodine sensitizing medications)'~~ ~~• GA^{68} Dotatate- added restaging calcitonin levels ≥ 150 pg/ml or CEA levels >5 ng/ml post-surgery~~ ~~• F18 Fluciclovine (Axumin)~~ ~~○ Initial staging changed to: With prior inconclusive bone scan with no CT/MRI correlate; or inconclusive bone SPECT/CT~~

	○ Restaging changed to with rising/persistent PSA and after CT/MRI has been performed and is insufficient for detection of metastases • Added Inconclusive imaging features to background as noted in NCCN 2020 • Added Disease progression to Background as noted in NCCN 2020 • Added Section of Langerhans Cell Histiocytosis to background section
September 2019	• Removed Introduction section • Removed "Important Note" • Changed title "The following are noncovered for all other indications including (but not limited to):" to "The following are noncovered for F^{18} FDG, Ga^{68} Dotatate, F^{18} Fluciclovine (NCCN 2019):" • Under noncovered for F^{18} FDG, Ga^{68} Dotatate, F^{18} Fluciclovine section, added the following: ○ Breast cancer - Initial Staging for Stage I and II Breast Cancer ○ Melanoma - Initial and Restaging for Stage I and II Melanoma (NCCN 2016) ○ Bladder Cancer - non muscle invasive (by imaging or tissue sample) ○ Vulvar Cancer < T2 or no suspicion of metastatic disease ○ Prostate Cancer – Initial or Restaging ○ Small cell lung cancer – Staging (Initial or Restaging) for extensive disease ○ Ovarian Cancer - Restaging if stage I ○ Pancreatic Cancer – Restaging ○ Renal Cancer - Initial and Restaging ○ Skin Squamous Cell Carcinoma - Restaging ○ Gastric Cancer - Initial staging if there is evidence of metastases (M1), or very early disease (T1) ○ Malignant Pleural Mesothelioma - Initial staging except if stage I-IIIA and pre-surgical ○ Hepatocellular / Intrahepatic Cholangiocarcinoma - Initial and Restaging ○ Gallbladder/ Extrahepatic Cholangiocarcinoma - Restaging ○ Small bowel adenocarcinoma – Initial Staging ○ Chordoma – Restaging

	~~○ Adrenal (except pheochromocytoma/ paraganglioma) - Initial or Restaging~~ ~~○ Smoldering Myeloma - except to discern smoldering from active myeloma with negative skeletal survey~~ ~~○ ALL (Acute Lymphoblastic Leukemia)/ AML (Acute Myelogenous Leukemia) - Unless prior imaging suggests lymphomatous involvement~~ ~~○ BCC (Basal Cell Carcinoma (of the skin))~~ ~~○ Infection and/or Inflammation: removed "- PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin."~~ ~~• Under indications for oncological PET heading, added: "Note: for radiation treatment planning, contact health plan directly"~~ ~~• Under Initial Treatment Strategy, the first sentence now specifies "active myeloma" instead of "myeloma" previously~~ ~~• Under Initial Treatment Strategy, the last sentence now replaces "after a" with "AND": "To determine the optimal anatomic location for an invasive procedure AND prior imaging insufficient"~~ ~~• "CLL – chronic lymphocytic leukemia (PET/CT is generally not useful in CLL/SLL but may be necessary to direct nodal tissue sampling when high-grade histologic transformation is suspected) (NCCN, 2018)." has been changed to "CLL (Chronic Lymphocytic Leukemia): only when high-grade histologic transformation is suspected (NCCN, 2018)"~~ ~~• Changed references for SPN to "(Bueno, 2018; MacMahon, 2017)" from previous "(Vansteenkiste, 2006)"~~ ~~• Removed the section:~~ ~~" Excluding~~ ~~• ALL- acute lymphoblastic leukemia~~ ~~o Unless prior CT imaging suggest lymphomatous involvement~~ ~~• AML – acute myelogenous leukemia~~ ~~o Unless clinical suspicion for extramedullary disease~~ ~~• BCC – basal cell carcinoma (of the skin)~~ ~~• Prostate cancer (NCCN, 2018)"~~ ~~• Added "EXCEPT for the following, which are only indicated after prior inconclusive imaging (NCCN 2019):~~ ~~○ Colorectal~~ ~~○ Ovarian/ fallopian~~ ~~○ Sarcoma/ GIST/ Uterine/Rhabdomyosarcoma~~ ~~○ Chordoma~~

	~~○ Muscle-invasive bladder cancer~~ ~~○ Endometrial Cancer~~ ~~○ Penile (for palpable nodes only)~~ ~~○ Occult Primary~~ ~~○ Pancreatic Cancer (unless high-risk features: borderline resectable, markedly elevated CA19-9 > 180 U/ml, large primary tumor/ lymph nodes)~~ ~~○ Skin squamous Cell Carcinoma~~ ~~○ Gallbladder/ Extrahepatic Cholangiocarcinoma~~ ~~○ Poorly differentiated neuroendocrine tumors with prior negative Ga68 Dotatate/ MIBG/Octreotide scan (includes Pheochromocytoma/ paraganglioma, extrapulmonary large/small cell)"~~ ~~• Under subsequent Treatment Strategy, first line has been modified by adding parenthesis as follows: Restaging or monitoring response to active treatment (including immunotherapy)"~~ ~~• Under subsequent Treatment Strategy, changed "not to be performed within 4 weeks of completion of therapy (ideally F^{18} FDG, Ga^{68} Dotatate, F^{18} Fluciclovine PET is delayed 2 - 3months after surgical therapy, 2 - 3 months after radiation therapy if locoregional assessment is the imaging goal), and/or evaluation for suspicion of recurrence due to new or changing signs/symptoms. (Asymptomatic surveillance is not approvable) (NCCN, 2018)." to "The interval should ideally be 6 – 12 weeks after surgery, and 12 weeks after radiation. PET can be performed 1-3 weeks after neoadjuvant chemotherapy or neoadjuvant chemoradiation to assess stage for surgery. PET evaluation can also be done for suspicion of recurrence due to new or changing signs/symptoms or rising tumor markers, or inconclusive findings on CT. Asymptomatic surveillance is not approvable. (NCCN 2018, 2019)"~~ ~~• List of cancers under subsequent imaging (without needing prior inconclusive imaging) has been changed. The following were removed: Breast cancer (female and males), colorectal cancer (including colon, rectal, appendiceal or anal cancer), ovarian cancer. The following were changed as follows:~~ ~~• "Lung cancer - Non-small cell" to "Lung cancer - Non-small cell and limited stage - small cell cancer"~~ ~~• "Esophageal cancer" to "Esophageal and esophagogastric cancer"~~

	• ~~"Melanoma" to Melanoma- only stage III, IV (excludes uveal melanoma)~~ • ~~"Myeloma to "Active Myeloma/plasmacytoma"~~ • ~~Added for Soft tissue sarcoma: "only stage II/III for response to neoadjuvant Rx"~~ • ~~Added Merkel cell carcinoma~~ • ~~Added "Mesothelioma, if also presurgical"~~ • ~~Individual References were removed for soft tissue sarcoma and vulvar/ vaginal cancer.~~ • ~~Statement regarding subsequent PET scans needing prior inconclusive imaging has been modified from "only" if other imaging (ie. US, CT, MRI, NM) is inconclusive in determining a treatment plan or unable to be performed " to " only if other imaging (ie. US, CT, MRI, NM) is inconclusive/ insufficient in determining a treatment plan or unable to be performed or with rising tumor markers and negative/ insufficient other imaging. PETCT is to be used only if the cancer is known to be generally F^{18} FDG, Ga^{68} Dotatate, F^{18} Fluciclovine avid. It may be indicated if iodinated and gadolinium contrast are both contraindicated due to significant allergy or chronic renal failure without dialysis (NCCN 2019). "~~ • ~~Under subsequent PET scans needing prior inconclusive imaging, the following were changed:~~ ○ ~~Added: Breast cancer (female and males), Bladder cancer, only if metastatic, Colorectal Cancer – resectable metastatic disease only, Anal/ Vulvar/ Penile Carcinoma, Bone Sarcoma, Sarcoma/ GIST/ Uterine/Rhabdomyosarcoma, Ovarian/ malignant germ cell tumors/primary peritoneal cancer – Stage II-IV, Endometrial cancer if candidate for surgery/locoregional therapy; Poorly differentiated Cancers, or Dedifferentiated neuroendocrine tumors with prior negative Ga68 Dotatate/ MIBG/Octreotide scan~~ • ~~Removed: prostate cancer, pancreatic cancer, individual references for cancers~~ • ~~Changed: "Lung cancer -Small cell" to "Extensive small cell lung cancer"; "Tumor of unknown Origin" to "Occult primary"; "Neuroendocrine cancer (e.g. carcinoid, pheochromocytoma, etc)" to "Poorly differentiated or dedifferentiated neuroendocrine tumors with prior negative Ga68 Dotatate/ MIBG/Octreotide scan (includes Pheochromocytoma/ paraganglioma, extrapulmonary large/small cell)".~~

	• ~~Last sentence has been changed from "Other malignancies where the tumor has been shown to be F^{18} FDG, Ga^{68} Dotatate, F^{18} Fluciclovineavid on prior PET/CT imaging if done, and other imaging (ie: US, CT, MRI, NM) is inconclusive in determining a treatment plan or unable to be performed " to "Other malignancies where other imaging (i.e., US, CT, MRI, NM) is inconclusive in determining a treatment plan or unable to be performed."~~ • ~~Under thyroid Cancer,~~ ○ ~~Added references "(NCCN 2019, ATA 2015)" to subsequent treatment strategy for papillary/follicular/ hurthle cancers~~ ▪ ~~Changed "Stimulated serum thyroglobulin > 2 ng/ml" to "Stimulated serum thyroglobulin > 5 ng/ml or high anti- thyroglobulin antibody (anti-Tg Ab) > 1 year after treatment (Na SJ 2012)"~~ ▪ ~~Changed "Current whole body I-131 scan is negative (Kloos, 2005)" to "Current stimulated whole body I-131/ I-123 scan is negative (Alzahranj 2012)"~~ ○ ~~Changed "Medullary thyroid cancer when calcitonin levels > 150 pg/ml post-operatively (Wells, 2015)" to "Medullary thyroid cancer when calcitonin levels ≥ 150 pg/ml post primary treatment (NCCN 2019, Souteiro 2019)"~~ ○ ~~Changed "Anaplastic 3-6 months after initial treatment, 3-6 month interval if persistent structural disease (Smallridge, 2012)" to "Anaplastic: Initial and Restaging after prior inconclusive/ insufficient CT/MRI (NCCN 2019)"~~ • ~~Added pediatric cancers section as follows: "PEDIATRIC CANCERS (for indications different from adult guidelines):~~ ○ ~~Sarcoma - Initial and Restaging (Quartuccio 2015)~~ ○ ~~Neuroblastoma/ other cancers under Ga68 imaging: only with prior negative/ inconclusive MIBG/ Octreotide/ Ga68 PETCT (Uslu 2015, Alexander 2018, Kong 2016, Li 2018, Elkhatib 2017)~~ ○ ~~Nasopharyngeal Cancer- Initial staging after inconclusive/ insufficient MRI; Restaging. (Cheuk 2012)~~ • ~~For Gallium 68 Dotatate PET:~~

	~~○ Added references for initial or subsequent treatment strategy: (NCCN 2019, Deppen, 2016 a, b)~~ ~~○ Added under neuroendocrine tumors: "Medullary Thyroid Cancer for Initial staging; and Restaging when calcitonin ≥ 150 pg/ml"~~ ~~○ Modified last part of the last sentence as follows: "and rising biomarkers (asymptomatic surveillance is not approvable). "~~ ~~• Under 18F-Fluciclovine PET/CT SCAN:~~ ~~○ Added "(Axumin)" after 18F-Fluciclovine~~ ~~○ Removed reference "(Bach-Gansmo, 2017)"~~ ~~○ Changed "18F-Fluciclovine PET/CT scans should be performed only if other imaging (CT, MRI, US, NM) is inconclusive/insufficient AND the patient has not already been evaluated with an F18 FDG, Ga68 Dotatate, F18 Fluciclovine PET/CT Scan" to "Known prostate cancer for workup of recurrence and response to treatment, only if other imaging (CT, MRI) AND Bone scan is inconclusive/insufficient. (NCCN 2019, Andriole 2019, Bach-Gansmo 2017)"~~ ~~○ Removed:" Known prostate cancer for workup of recurrence and response to treatment:"~~ ~~○ "Initial treatment by radical prostatectomy with" was replaced by "Post radical prostatectomy with"~~ ~~○ "Initial treatment radiation therapy with" was replaced by "Post radiation therapy with"~~ ~~○ "Post-RT rising PSA or positive digital exam and is candidate for local therapy" was replaced by "rising/persistent PSA (increase should be >2ng/ml unless doubling time ≤ 8 months or pt is a candidate for local salvage therapy)"~~ ~~• Removed: "NOTE: Not all plans cover 18F-Fluciclovine (A9588), such as Magellan Complete Care of Florida and Magellan Complete Care of Arizona. If you are unsure, you should check with the Health Plan prior to requesting a PET with Fluciclovine from NIA."~~ ~~• Added Background section as follows:~~ ~~"BACKGROUND:~~ ~~Positron emission tomography (PET) is a rapidly developing and changing technology that is able to detect biochemical reactions, e.g., metabolism, or abnormal distribution of cell receptors within body tissues. A radioactive tracer is used~~

	~~during the procedure. Unlike other nuclear medicine examinations, PET can measure metabolic activity of the cells of body tissues, providing information about the functionality and structure of the particular organ or tissue examined. PET may also detect biochemical changes that help to evaluate malignant tumors and other lesions.~~ ~~The degree of radioactive tracer uptake may indicate increased metabolism in the cells of body tissues or an abnormal distribution of cell receptors. Cancer cells may show increased radioactive tracer relative to tissue not involved with tumor. Radioactive tracer uptake is often higher in fast-growing tumors; PET is often not as beneficial for slow growing tumors. Radioactive tracer uptake may occur in various types of active inflammation and is not specific for cancer."~~

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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

	▪ 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

Reviewed / Approved by NIA Clinical Guideline Committee

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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.