Positron Emission Tomography (PET) for Oncologic Applications

DESCRIPTION

Positron Emission Tomography (PET), also called PET imaging or a PET scan, is a form of nuclear medicine imaging. PET imaging is based on the use of positron emitting radionuclide tracers coupled to organic molecules such as glucose, ammonia, or water. The radionuclide tracers simultaneously emit two high-energy photons in opposite directions that can be simultaneously detected by a PET scanner. The PET scanner consists of multiple detectors that encircle the area of interest. A variety of tracers are used for PET scanning including oxygen-15, nitrogen-13, carbon-11, and fluorine-18. The most commonly used radiotracer in oncology imaging is fluorine-18 coupled with fluorodeoxyglucose (FDG). FDG has a metabolism related to glucose metabolism. It has been considered potentially useful in cancer imaging, since tumor cells show increased metabolism of glucose.

Proposal is to add words or statements in red and delete words or statements with strikethrough.

POLICY

- Positron emission tomography (PET) scans for the oncological applications listed below are considered medically necessary if the medical appropriateness criteria are met:
  - Adrenal Tumors
  - Anal Cancer
  - Bone Cancers
  - Breast Cancer
  - Castleman’s Disease
  - Central Nervous System Tumors
  - Cervical Cancer
  - Esophageal Cancer
  - Gastric Cancer
  - Gastrointestinal/Pancreatic Neuroendocrine Cancers
  - Gastrointestinal Stromal Tumor
  - Head and Neck Cancers
  - Hematopoietic Stem Cell Transplantation
  - Hepatocellular Carcinoma/Biliary Tumors
  - Langerhans Cell Histiocytosis (LCH)
  - Leukemia (Chronic Lymphocytic (CLL))
  - Lung Cancers
  - Lymphomas
  - Medulloblastoma, Supratentorial Primitive Neuroectodermal Tumors, and Pineoblastoma
  - Melanomas and other Skin Cancers
  - Metastatic Cancer, Carcinoma of Unknown Primary Site, & Other Types of Cancer
  - Multiple Myeloma and Plasmacytomas
  - Neuroblastoma
  - Ovarian Cancer
  - Pancreatic Cancer
  - Paraneoplastic Syndromes
  - Prostate Cancer
  - Rhabdomyosarcoma
  - Salivary Gland Cancer
  - Soft Tissue Sarcomas
Testicular and Nonepithelial Ovarian Cancer (Germ Cell Cancer)
Thoracic Cancers (Other than Esophageal and Lung)
Thyroid Cancers
Transitional Cell Cancer
Wilms Tumor

• Positron emission tomography (PET) scans for the following applications are considered investigational:
  - General Guidelines
    - When imaging lesions less than 8 mm in size
    - Surveillance imaging (unless specifically stated in the criteria)
    - Distant or diffuse metastatic disease
    - Metastatic disease in the central nervous system (CNS)
    - Follow-up after localized therapy (e.g., radiofrequency ablation, embolization, stereotactic radiation)
  - Breast
    - When used for non-invasive breast cancers
    - When obvious multi-organ metastatic disease is present
    - PET mammography
    - When used for surveillance
  - Esophageal
    - When used for surveillance
  - Gastrointestinal
    - Non-invasive carcinomas
    - Carcinomas contained within a polyp
    - Colon cancer that is completely resected and lymph node negative
    - Anal margin carcinomas
    - T1 gastric cancers
    - Following complete resection of gastrointestinal stromal tumor (GIST)
    - Liver lesions less than 1 cm in individuals without a prior history of confirmed malignancy
    - When used following interventional radiology procedures involving liver lesions, such as radiofrequency ablation (RFA)
    - When used following postoperative adjuvant chemotherapy with the following:
      ▪ Resection has removed all known gross disease
      ▪ Markers are not elevated
    - When used in the setting of obvious multi-organ metastatic disease
  - Gynecologic Cancers
    - Endometrial cancer
    - Vulvar cancer
    - Vaginal cancer
    - Uterine cancers
    - Non-invasive cervical cancer
    - External genitalia cancer
  - Head and Neck (Squamous cell carcinomas of the head and neck)
    - When used to determine the need for neck dissection for individual with newly diagnosed head and neck cancer
• When used for restaging of cancers of the head and neck when surgery is the primary treatment modality (e.g. complete resection/ radical neck dissection)
• When complete response or progression is clearly obvious on physical examination
• When used for salivary gland tumors
• When used as a substitute for panendoscopy

- Leukemia (acute lymphoblastic, acute myeloid, and chronic myeloid)

- Lungs
  • When using serial PET scans to evaluate lung nodules
  • When other imaging modalities have confirmed skeletal disease metastasis from other primary sites (i.e. lung, breast, prostate, renal cell and other urogenital cancers)
  • Metastatic non-small cell disease outside chest cavity (e.g., malignant pleural/pericardial effusion)
  • When other imaging shows extensive staged disease in small cell carcinoma
  • For restaging for the following:
    ▪ When surgery was the primary treatment and all known tumor was resected
    ▪ When tumors were initially treated with radiation therapy as the only treatment modality

- Melanoma and Other Skin Cancers
  • For routine surveillance in all skin cancers (including melanoma) for asymptomatic individuals

- Miscellaneous (Carcinomas of unknown primary site, soft tissue sarcoma, generalized lymphadenopathy and mediastinal abnormalities/ lymphadenopathy, liver lesions, adrenal lesions and neuroendocrine lesions)
  • When used for surveillance and for routine body imaging of lymph nodes
  • When used following complete resection
  • When used for generalized lymphadenopathy and mediastinal abnormalities prior to histologic diagnosis

- Prostate Cancer

- Primary brain tumors
  • For detection, initial work up or staging for primary brain tumors
  • For the use of FDG-PET in the evaluation of metastatic deposits and well-differentiated brain tumors

- Salivary Gland Cancers

- Renal Cell Cancer

- Skin Cancers (Non-Melanoma)
  • Unless specifically addressed within the policy criteria (e.g., Merkel cell carcinoma)

- Uterine Cancer

MEDICAL APPROPRIATENESS

• Positron emission tomography (PET) for oncological applications is considered medically appropriate if ANY ONE of the following are met:
  • Adrenal Tumors with ANY ONE of the following met:
    ▪ Initial workup or initial staging with ALL of the following met:
• Pheochromocytoma, parangangioma, or paragangliomeuroma or adrenocortical carcinoma
• Continued suspicion with negative or inconclusive imaging
• PET results will direct immediate care decisions
  ▪ Restaging or recurrence with ALL of the following met:
    • Continued suspicion with negative or inconclusive imaging

  o Anal Cancer with ANY ONE of the following met:
    ▪ Initial workup or initial staging with ALL of the following met:
      • Stage II - IV squamous cell carcinoma of the anal canal
    ▪ Restaging or recurrence with ALL of the following met:
      • Stage III or IV squamous cell carcinoma of the anal canal
      • Biopsy proven recurrence
      • Inconclusive conventional imaging

  o Hepatocellular Carcinoma (HCC) / Biliary Tumors (Primary) with ANY ONE of the following met:
    ▪ Initial workup or initial staging with ALL of the following met:
      • Primary biliary carcinoma (biopsy is not required; liver lesion with AFP >20 is adequate for imaging)
      • No evidence of metastatic disease by conventional imaging
      • To determine if individual is a surgical candidate

  o Bone Sarcoma – Chordoma with ANY ONE of the following met:
    ▪ Initial workup or initial staging with inconclusive conventional imaging
    ▪ Restaging or recurrence with ALL of the following met:
      • Completion of radiotherapy or every 2 cycles of chemotherapy
      • Inconclusive conventional imaging

  o Bone Cancer - Ewing Sarcoma and Primitive Neuroectodermal Tumors with ANY ONE of the following met:
    ▪ Initial staging with ALL of the following met:
      • Plain X-ray has been performed
      • Histologic diagnosis has been established
    ▪ Treatment response with ALL of the following met:
      • Distant bone metastasis with ANY ONE of the following met:
        o After every 2 cycles of chemotherapy
        o End of planned chemotherapy
    ▪ Restaging with ANY ONE of the following met:
      • After approximately 12 weeks of neoadjuvant chemotherapy and prior to local control surgery to confirm the absence of disease progression
      • Following local control surgery and planned chemotherapy
    ▪ Surveillance with ALL ANY ONE of the following met:
      • Conventional imaging inconclusive or suspicious for recurrence and PET avidity will determine whether biopsy or continued observation is appropriate
      • PET will determine whether biopsy or continued observation is appropriate
      • Obvious clinical symptoms show strong evidence suggesting recurrence (PET could replace conventional imaging)
      • Restaging after biopsy-confirmed recurrence

  o Bone Cancer - Osteogenic Sarcoma with ANY ONE of the following met:
    ▪ Initial staging with ALL of the following met:
      • Plain X-ray has been performed

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Histologic diagnosis has been established

Treatment response with ANY ONE of the following met:
- Distant bone metastasis with ANY ONE of the following met:
  - After every 2 cycles of chemotherapy
  - End of planned chemotherapy
- Restaging with ANY ONE of the following met:
  - After 10-12 weeks of neoadjuvant chemotherapy and prior to local control surgery to confirm absence of disease progression
  - Distant bone metastasis with ANY ONE of the following met:
    - Following local control surgery, whole body PET/CT every 4 months
    - End of planned chemotherapy

- **Breast Cancer** with ANY ONE of the following met:
  - Initial workup or initial staging when CT and/or bone scan are inconclusive
  - Restaging or recurrence with ALL of the following met:
    - Inconclusive CT, MRI, and/or bone scan for suspected recurrence
    - Further characterization is needed to make treatment decisions
  - Stage IV disease with ALL of the following met:
    - Bone metastasis only site of Stage IV disease (excluding brain mets)
    - Prior bone scan has not been performed for serial comparison

- **Carcinoma of Unknown Primary Site** with ANY ONE of the following met:
  - Carcinoma found in lymph node or organ known not to be primary and ANY ONE of the following studies have failed to demonstrate site of primary:
    - CT Chest and Abdomen/Pelvis with contrast
    - CT Neck with contrast if cervical or supraclavicular involvement
    - CT with contrast of any other symptomatic site
    - MRI with and without contrast of any other symptomatic site
    - Diagnostic (not screening) mammogram and full pelvic exam
    - MRI bilateral breasts if pathology consistent with breast primary and mammogram is inconclusive
  - Sebaceous carcinoma of the skin and ANY ONE of the following studies have failed to demonstrate site of primary:
    - CT Chest and Abdomen/Pelvis with contrast
    - CT Neck with contrast if cervical or supraclavicular involvement
    - CT with contrast of any other symptomatic site
    - MRI with and without contrast of any other symptomatic site
    - Diagnostic (not screening) mammogram and full pelvic exam
    - MRI bilateral breasts if pathology consistent with breast primary and mammogram is inconclusive

- **Castleman’s Disease** with ANY ONE of the following met:
  - Initial staging with ALL of the following met:
    - Prior CT suggests unicentric disease
    - Surgical resection being considered
    - PET/CT to confirm unicentric disease
  - Restaging or recurrence with ANY ONE ALL of the following met:
    - Indicated for ANY ONE of the following:
• Multicentric disease
• Surgically unresected unicentric disease after every 2 cycles of chemotherapy
  • Surgically non-resected unicentric disease being treated with chemotherapy every 2 cycles with
Indicated for ANY ONE of the following:
  o Suspected recurrence
  o Recurrent B symptoms
  o Rising LDH/IL-6/VEGF levels

  o Central Nervous System Tumors - Low Grade Glioma (WHO histologic grade of I or II) with ALL of the
    following met:
    ▪ Initial staging with PET brain metabolic imaging with ANY ONE of the following met:
      • Transformation to high grade glioma is suspected based on symptoms or recent MRI findings
      • Evaluate a brain lesion of indeterminate nature

  o Central Nervous System Tumors – High Grade Glioma (WHO histologic grade of III or IV) with ALL of
    the following met:
    ▪ Initial staging with PET brain metabolic imaging with ANY ONE of the following met:
      • To distinguish radiation-induced tumor necrosis from progressive disease within 18-months of
        completing radiotherapy
      • To evaluate inconclusive MRI findings to determine need for biopsy or change in therapy, including
        a change from active therapy to surveillance
      • To evaluate a brain lesion of indeterminate nature

  o Cervical Cancer with ANY ONE of the following met:
    ▪ Initial workup or initial staging with ANY ONE of the following met:
      • Stage IB1 or less (<4 cm confined to the cervix) if other advanced imaging studies inconclusive
      • Stage IB2 or higher if radiation therapy is to be primary treatment modality
      • Any size cervical cancer with ALL of the following met:
        o Incidentally found in a hysterectomy specimen
        o Inconclusive conventional imaging
    ▪ Restaging or recurrence with ALL ANY ONE of the following met:
      • Inconclusive conventional imaging with ANY ONE of the following:
        o Difficult or abnormal examination
        o Elevated LFTs
        o Signs or symptoms of recurrence
      • Radiation or chemotherapy is primary therapy and surgical salvage is treatment option

  o Colorectal Cancer
    ▪ Initial workup or initial staging with ANY ONE of the following met:
      • Isolated metastatic lesion(s) on other imaging and individual is ANY ONE of the following:
        o Candidate for aggressive surgical resection
        o Candidate for other localized treatment of metastasis for curative intent
      • Inconclusive conventional imaging
    ▪ Restaging or recurrence with ANY ONE of the following met:
      • Postoperative elevated or rising CEA or LFTs with negative recent conventional imaging
      • Isolated metastatic lesion(s) on conventional imaging and individual is ANY ONE of the following:
        o Candidate for aggressive surgical resection
        o Candidate for localized treatment to metastasis with curative intent
      • Differentiate local tumor recurrence from postoperative and/or post-radiation scarring

  o Esophageal Cancer

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Initial workup or initial staging with ALL of the following met:

- Biopsy proven
- Prior to start of neoadjuvant therapy in preparation for surgery
- No evidence of metastatic disease by conventional imaging

Restaging or recurrence with ANY ONE of the following met:

- Conventional imaging is inconclusive
- Salvage surgical candidate with recurrence and no metastatic disease documented by conventional imaging
- After completion of radiation therapy with ALL of the following:
  - Recent CT findings are inconclusive
  - PET findings will alter immediate care decision making
  - PET imaging done as early as 6 weeks after completion of radiation therapy

- Extrathoracic Small Cell Carcinoma Metastases with ANY ONE of the following met:
  - Initial staging with ALL ANY ONE of the following met:
    - No evidence of metastatic disease
    - Conventional imaging is inconclusive for determining localized vs distant metastatic disease

- Gastric Cancers with ANY ONE of the following met:
  - Initial workup or initial staging with ALL of the following met:
    - Stage equal to or greater than T2
    - No metastatic disease by conventional imaging
  - Restaging or recurrence with inconclusive findings on conventional imaging

- Gastrointestinal Stromal Tumor (GIST) with ANY ONE of the following met:
  - Initial workup or initial staging with inconclusive conventional imaging
  - Restaging or recurrence with inconclusive conventional imaging
  - Treatment response with inconclusive conventional imaging

- Head and Neck Cancer – Squamous Cell Carcinoma with ANY ONE of the following met:
  - Squamous Cell Carcinoma Suspected diagnosis with ANY ONE of the following met:
    - To determine a more favorable site for biopsy when prior biopsy was nondiagnostic
    - To determine a more favorable site for biopsy when a relatively inaccessible site is contemplated which would require invasive surgical intervention for biopsy attempt
  - Nasopharyngeal (NPC) Cancer Initial workup or initial staging with ANY ONE of the following met:
    - Known stage III or IV disease
    - Nasopharyngeal primary site
    - Inconclusive conventional imaging (CT, MRI)
    - Prior to start of primary chemoradiotherapy and have not undergone definitive surgical resection
    - To direct laryngoscope/exam under anesthesia for biopsy
    - Pulmonary nodule(s) ≥8 mm in size
    - Cervical lymph node biopsy positive for squamous cell carcinoma and no primary site identified on CT or MRI
    - Inconclusive findings suggestive of disease outside the head and neck area
  - Restaging or recurrence with ALL ANY ONE of the following met:
    - Following primary chemoradiotherapy for Stage III or IV disease (no sooner than 12 weeks following radiation therapy) with ANY ONE of the following met:
      - Evaluation for salvage surgery/radical neck dissection in individuals with measurable residual disease on physical exam or on recent CT or MRI
      - Distinguish active tumor from radiation fibrosis
    - Inconclusive conventional imaging (CT or MRI)
- Biopsy proven local recurrence

- **Hematopoietic Stem Cell Transplantation** with ANY ONE of the following met:
  - Post-Transplant with ANY ONE of the following met:
    - Inconclusive conventional imaging at Day +100
    - Tandem autologous transplants (2-4 autologous transplants back-to-back, spaced 6-8 weeks apart)
    - PET permitted following each separate transplant

- **Langerhans Cell Histiocytosis (LCH)** with ANY ONE of the following met:
  - Multifocal bone involvement observed on skeletal survey
  - Bone pain and negative skeletal survey
  - Other clinical symptoms suggesting multisite disease
  - Recurrence evaluation

- **Leukemia (Chronic Lymphocytic (CLL) and Small Lymphocytic Lymphoma (SLL))** with ALL of the following met:
  - Suspected transformation (Richter’s) from a low grade lymphoma to a more aggressive type with ANY ONE of the following met:
    - New B symptoms (e.g., fever, night sweats, unintended weight loss of > 10%)
    - Rapidly growing lymph nodes
    - Extranodal disease develops
    - Significant recent rise in LDH above normal range

- **Lung Cancer – Non-Small Cell (NSCLC)** with ANY ONE of the following met:
  - Evaluate pulmonary nodule measuring 8 mm (0.8 cm) to 30 mm (3 cm) seen on CT or MRI
  - Evaluate pulmonary mass measuring 31 mm (3.1 cm) or greater seen on CT or MRI with ANY ONE of the following met:
    - Prior to biopsy when resection will be performed instead of biopsy if PET confirms limited disease
    - Prior to biopsy if multiple possible biopsy options are present to determine most favorable site
  - Initial workup or initial staging with ANY ONE of the following met:
    - PET was not performed prior to histological diagnosis
    - Indicated for ANY ONE of the following:
      - All Stage I - IIIB disease
      - Stage IV disease confined to the chest region (pleura/pericardium or solitary site including lung nodules)
      - Conventional imaging is inconclusive
    - To confirm solitary focus of metastatic disease (i.e., brain or adrenal) if being considered for aggressive surgical management
  - Restaging or recurrence with ANY ONE of the following met:
    - Suspected or biopsy proven recurrence localized to the chest cavity
    - Newly identified abnormalities localized to chest cavity on conventional imaging
    - Inconclusive findings on conventional imaging
    - Differentiate tumor from radiation scar/fibrosis

- **Lung Cancer – Small Cell (SCLC)** with ANY ONE of the following met:
  - Early staging with ALL of the following met:
    - Confirm limited stage disease (non-metastatic)
    - Initial staging imaging (CT and MRI) showed disease limited to the thorax
Lymphoma – Anaplastic Large Cell with ANY ONE of the following met:
- Initial staging or initial diagnosis
- Clinical suspicion of skull or distal lower extremity involvement
- Treatment response as often as every 2 cycles of chemotherapy
- Clarify inconclusive findings detected on conventional imaging

Lymphoma – Burkitt's with ANY ONE of the following met:
- Initial staging or initial diagnosis
- Clinical suspicion of skull or distal lower extremity involvement
- Evaluate treatment response, as often as every cycle of chemotherapy
- End of chemotherapy and/or end of radiation therapy evaluation
- Evaluate suspected recurrence with inconclusive conventional imaging

Lymphoma - Central Nervous System (also known as Microglioma) with ANY ONE of the following met:
- Initial staging to confirm CNS primary when CT results are inconclusive

Lymphoma – Cutaneous (includes Peripheral T-Cell, Primary Cutaneous B Cell, Mycosis Fungoides/Sézary Syndrome, Primary Cutaneous CD30+T Cell Lymphoproliferative Disorders) with ANY ONE of the following met:
- Initial staging or initial diagnosis
- End of chemotherapy and/or radiation evaluation

Lymphoma – Diffuse Large B Cell (DLBCL), Grade 3 Follicular, Grey Zone, Primary Mediastinal B Cell, Post-Transplant Lymphoproliferative Disorder and Viral-Associated Lymphoproliferative Disorder with ANY ONE of the following met:
- Clinical suspicion of skull or distal lower extremity involvement
- Treatment response as frequently as every two cycles
- End of chemotherapy and/or radiation therapy evaluation
- Suspected or biopsy-confirmed recurrence
- Clarify inconclusive findings on conventional imaging

Lymphoma – Follicular (WHO Grade 1 - 2) with ANY ONE of the following met:
- Initial staging or initial diagnosis
- End of therapy evaluation
- Suspected transformation (Richter's) from a low grade lymphoma to a more aggressive type with ANY ONE of the following met:
  - New B symptoms (e.g., fever, night sweats, unintended weight loss of > 10%)
  - Rapidly growing lymph nodes
  - Extramedial disease develops
  - Significant recent rise in LDH above normal range

Lymphoma – Hodgkin with ANY ONE of the following:
- Classical Hodgkin lymphoma with ANY ONE of the following met:
  - Initial staging or initial diagnosis
  - Whole body PET/CT when there is clinical suspicion of skull or distal lower extremity involvement
  - To determine a more favorable site for biopsy when a relatively inaccessible site is contemplated
  - Treatment response as frequently as every 2 cycles
  - Treatment response with low risk (stage IA or IIA) mixed cellularity Hodgkin lymphoma after cycles 1 and 3
End of chemotherapy evaluation
End of radiation therapy evaluation (after 12 weeks of completion of radiation therapy)
Surveillance with a single follow-up PET/CT when end of therapy PET/CT documents Deauville 4 or 5 FDG avidity

**Nodular Lymphocyte-Predominant Hodgkin** with ANY ONE of the following met:
- Initial staging or initial diagnosis
- Treatment response as frequently as every 2 cycles
- End of chemotherapy evaluation
- End of radiotherapy evaluation (after 12 weeks of completion of radiation therapy)
- Suspected recurrence
- Suspected transformation (Richter’s) from a low grade lymphoma to a more aggressive type with ANY ONE of the following met:
  - New B symptoms (e.g., fever, night sweats, unintended weight loss of > 10%)
  - Rapidly growing lymph nodes
  - Extranodal disease develops
  - Significant recent rise in LDH above normal range
- Surveillance with a single follow-up PET/CT if the end of therapy PET/CT documents Deauville 4 or 5 FDG avidity

**Lymphoma – Mantle Cell** with ANY ONE of the following met:
- Initial staging or initial diagnosis if radiation therapy is being considered for Stage I or II disease
- End of therapy evaluation

**Lymphoma – Marginal Zone & MALT Lymphomas (Mucosa Associated Lymphoid Tissue)** with ANY ONE of the following met:
- Initial staging or initial diagnosis if radiation therapy is being considered for Stage I or II disease
- End of therapy evaluation

**Medulloblastoma, Supratentorial Primitive Neuroectodermal Tumors, and Pineoblastoma** with ANY ONE of the following:
- PET Brain Metabolic Imaging with ANY ONE of the following are met:
  - Distinguish radiation-induced tumor necrosis from progressive disease within 18 months of completing radiotherapy
  - Evaluate inconclusive MRI findings if ALL ANY ONE of the following are met:
    - To determine need for biopsy
    - To determine need for change in therapy, including a change from active therapy to surveillance
  - Evaluate a brain lesion of indeterminate nature to determine whether biopsy/resection can be safely postponed

**Melanomas and Other Skin Cancers** with ANY ONE of the following met:
- **Melanoma** initial work-up or initial staging with ANY ONE of the following met:
  - Stage III (sentinel node positive, palpable regional nodes)
  - Stage IV (metastatic)
  - Mucosal, including lip primary
  - Ocular/orbital primary site
  - Primary melanoma site unknown with ALL of the following met:
    - CT Chest negative
    - CT Abdomen/Pelvis negative
- **Melanoma** restaging or recurrence with ALL ANY ONE of the following met:
  - Documented or clinically suspected recurrence at ANY ONE of the following:
Primary site
In-transit disease
Regional lymph nodes
Metastatic site
- Inconclusive conventional imaging
- Isolated metastatic disease based on results of initial conventional imaging
- **Merkel Cell carcinoma** initial work-up or initial staging with **ALL** of the following met:
  - No metastatic disease identified on conventional imaging
- **Merkel Cell carcinoma** restaging or recurrence with **ALL** of the following met:
  - No metastatic disease on any of the previous imaging studies
- **Other Non-melanoma Skin Cancers** initial work-up or initial staging with **ALL ANY ONE** of the following met:
  - Perineural invasion or local regional extension (i.e., bone, deep soft tissue) involvement with **ALL** of the following met:
    - PET performed on primary site
    - Regional staging of large squamous cell or basal cell carcinomas prior to operative treatment
    - Normal size nodes are visualized but may harbor metastatic tumor
  - Skin lesion potentially a dermal metastasis from distant primary when conventional imaging (CT or MRI) is unable to identify a primary site
- **Other Non-melanoma Skin Cancers** restaging or recurrence with **ALL** of the following met:
  - Recurrence where planned therapy is more extensive than simple wide local excision with **ALL** of the following met:
    - Regional staging of large squamous cell or basal cell carcinomas prior to operative treatment
    - Normal size nodes are visualized but may harbor metastatic tumor
- **Metastatic Cancer** with **ANY ONE** of the following met: *(when primary cancer is known, PET request should be reviewed by primary cancer guideline)*
  - **Adrenal Gland Metastases** with **ALL** of the following met:
    - To confirm isolated adrenal lesion with **ALL** of the following are met:
      - No diagnosis-specific guideline available regarding PET imaging
    - To confirm solitary isolated adrenal metastasis
    - Conventional imaging does not reveal other metastatic disease
    - Primary tumor site controlled
    - Surgical resection or radiotherapy of adrenal metastasis is potentially curative
  - **Bone Metastases** *(including Vertebral)*
    - F-FDG-PET/CT on a case-by-case basis with **ALL** of the following are met:
      - Bone pain
      - Negative bone scan
      - Negative CT or MRI
  - **Brain Metastases** when **ANY ONE ALL** of the following are met:
    - Indicated for **ANY ONE** of the following:
      - Solitary Suspected brain metastasis suspected with prior diagnosis of cancer
    - Brain metastasis and no known primary tumor
    - Indicated for **ANY ONE** of the following:
      - Inconclusive conventional imaging
      - Confirm stable systemic disease or absence of other metastatic disease
  - **Liver Metastases** with **ANY ONE** of the following met:
To confirm solitary metastasis amenable to resection on conventional imaging
LFT’s and/or tumor markers continue to rise with negative CT and MRI results

**Lung Metastases with ANY ONE of the following met:**
- Lung nodule(s) greater than or equal to 8 mm
- To confirm solitary metastasis amenable to resection on conventional imaging

- **Multiple Myeloma and Plasmacytomas** with ANY ONE of the following met:
  - Initial workup or initial staging with ANY ONE ALL of the following met:
    - Negative or inconclusive conventional imaging
    - Indicated for ANY ONE of the following:
      - Determine if a plasmacytoma is solitary
      - Suspicion of extraosseous plasmacytomas
      - Suspected progression of malignancy for ANY ONE of the following:
        - Monoclonal Gammopathy of Unknown Significance (MGUS)
        - Smoldering Myeloma (SMM) Ensure member has Stage I (“smoldering”) and not a higher stage
  - Restaging or recurrence with ANY ONE of the following met:
    - MGUS disease with signs/symptoms or labs studies suggesting progression
    - Negative PET will allow change in management from active treatment to maintenance or surveillance
    - To determine additional therapies in refractory disease or non-secretory disease

- **Neuroblastoma** with ANY ONE of the following met:
  - MIBG-negativity documented at initial diagnosis
  - At major decision points such as hematopoietic stem cell transplantation or surgery if MIBG and CT/MRI are inconclusive
    - Individuals currently receiving medications that may interfere with MIBG uptake that cannot safely be discontinued prior to imaging, including:
      - Tricyclic antidepressants
      - Selective serotonin reuptake inhibitors (SSRI’s)
      - Neuroleptics
      - Antihypertensive drugs
      - Decongestants
      - Stimulants

- **Neuroendocrine Cancers** with ANY ONE of the following met:
  - **Bronchopulmonary or Thymic Carcinoid** with ANY ONE of the following met:
    - Initial workup or initial staging with ANY ONE of the following met:
      - Inconclusive CT or MRI
      - After complete resection if ALL of the following are met:
        - Resection fails to resolve secretion of pathologic levels of hormones or neurotransmitter compounds
        - Nuclear imaging (MIBG, Octreotide, or Somatostatin scintigraphy) is negative
    - Restaging or recurrence with negative or inconclusive conventional imaging
  - **Gastrointestinal/Pancreatic Neuroendocrine Cancers** with ANY ONE of the following met:
    - Suspected/Diagnosis with ALL of the following met:
      - Conventional imaging negative or inconclusive
      - Systemic symptoms strongly suggestive of functioning neuroendocrine tumor
    - Initial workup or initial staging with ALL ANY ONE of the following met:
      - Inconclusive CT or MRI
After complete resection if ALL of the following met:
- Resection fails to resolve secretion of pathologic levels of hormones or neurotransmitter compounds
- Negative nuclear imaging (MIBG, Octreotide, or Somatostatin scintigraphy)
- Restaging/recurrence with inconclusive conventional imaging

Ovarian Cancer with ANY ONE of the following met:
- Initial workup or initial staging with ANY ONE of the following met:
  - Primary peritoneal disease with biopsy-proven malignancy consistent with ovarian carcinoma
  - Elevated tumor markers with negative or inconclusive CT imaging
- Restaging or recurrence with ALL ANY ONE of the following met:
  - CT negative or inconclusive and ANY ONE of the following
    - CA-125 continues to rise
    - Elevated LFTs
  - Conventional imaging failed to demonstrate tumor or if persistent radiographic mass with rising tumor markers

Pancreatic Cancer with ANY ONE of the following met:
- Initial workup or initial staging if no evidence of metastatic disease on CT or MRI
- Restaging or recurrence with ALL of the following met:
  - Inconclusive conventional imaging post neoadjuvant chemoradiation (if given as curative therapy)
  - Suspected recurrence

Paraneoplastic Syndromes with ANY ONE of the following met:
- Abnormality on conventional imaging difficult to biopsy
- Inconclusive conventional imaging

Primary Peritoneal Mesothelioma with ANY ONE of the following met:
- Initial staging with ANY ONE of the following met:
  - No evidence of metastatic disease
  - Inconclusive finding on conventional imaging
- Recurrence or restaging with inconclusive finding on conventional imaging

Prostate Cancer with ALL of the following met:
- Recurrence or restaging with ALL of the following met:
  - CT, MRI and bone scan negative for metastasis
  - C Choline PET/CT scan is requested
- Indicated for ANY ONE of the following:
  - Individual with prior radical prostatectomy and ANY ONE of the following:
    - Palpable anastomotic recurrence
    - PSA remains greater than 0.2 after at least 2 PSAs
    - Initial undetectable PSA increasing on 2 consecutive PSAs
  - Individual with prior radiation therapy and ANY ONE of the following:
    - Clinical suspicion of relapsed disease
    - PSA increasing on at least 2 consecutive values above post-therapy baseline

Rhabdomyosarcoma with ANY ONE of the following met:
- Initial staging after histologic confirmation of diagnosis
- Treatment response with ANY ONE of the following met:
  - Response assessment prior to local control surgery
  - Response assessment prior to radiation therapy
Evaluation of residual mass visible on conventional imaging as part of end of therapy evaluation

Response assessment of disease visible on PET but not conventional imaging

- When results are likely to result in a treatment change, including a change from active treatment to surveillance.

  - Surveillance with ANY ONE, ALL of the following met:
    - Conventional imaging (CT, MRI, US, plain film) inconclusive for recurrence
    - PET avidity will determine whether biopsy or continued observation is appropriate
    - Obvious clinical symptoms show strong evidence suggesting recurrence

- **Salivary Gland** with ANY ONE of the following met:
  - Initial workup or initial staging with ALL of the following met:
    - Biopsy-proven malignancy
    - Suspicious lung abnormality is found on CT chest

- **Soft Tissue Sarcomas** with ANY ONE of the following met:
  - Initial workup or initial staging with ANY ONE of the following met:
    - Grade of tumor in doubt following biopsy
    - Conventional imaging suggests solitary metastasis amenable to surgical resection
    - Conventional imaging inconclusive
    - Planning neoadjuvant therapy
    - Prior to surgical resection for tumors greater than 3cm (30mm)
    - Clinical suspicion of skull or distal lower extremity involvement
  - Treatment response with ANY ONE of the following met:
    - Assess response prior to local control surgery or radiation therapy
    - Evaluation of residual mass visible on conventional imaging as part of end of therapy evaluation
    - Assess response of disease visible on PET but not conventional imaging
  - Recurrence or restaging with ANY ONE of the following met:
    - Differentiate tumor from radiation or surgical fibrosis
    - Determine response to neoadjuvant therapy
    - Confirm oligometastatic disease prior to curative intent surgical resection
  - Surveillance with ALL of the following met:
    - Conventional imaging inclusive or suspicious for recurrence
    - PET avidity will determine if biopsy is appropriate

- **Testicular, Ovarian and Extragonadal Germ Cell Tumors** with ANY ONE of the following:
  - Restaging or recurrence with ALL of the following met:
    - Seminoma with residual mass greater than 3 cm (30mm)
    - CT findings are inconclusive
    - PET findings will alter immediate care decision making (can be performed as early as 6 weeks after completion of radiation therapy)

- **Thoracic Cancers (Other than Esophageal and Lung)** with ANY ONE of the following met:
  - **Malignant Pleural Mesothelioma** with ANY ONE of the following:
    - Initial workup or initial staging with ALL of the following met:
      - Cytologically or pathologically proven
      - No evidence of metastatic disease or inconclusive conventional imaging
    - Restaging with ALL of the following met:
      - Treatment with Following induction chemotherapy prior to surgical resection
      - Every 2 cycles following chemotherapy induction, prior to surgical resection
      - No evidence of metastatic disease
Thymic Carcinoma with ANY ONE of the following:
- Suspected or actual diagnosis with ANY ONE of the following met
  - Pulmonary nodule 8 mm (0.8 cm) to 30 mm (3 cm) seen on CT Chest or MRI Chest
  - Pulmonary mass 31 mm (3.1 cm) or greater seen on CT or MRI
- When resection will be performed instead of biopsy if PET confirms limited disease
- If multiple possible biopsy options are present and PET will be used to determine most favorable site
- Initial workup or initial staging with ANY ONE of the following met:
  - All Stage I-IIIB disease
  - Stage IV disease confined to chest region (pleura/pericardium or solitary site including lung nodules)
  - Inconclusive conventional imaging
- Restaging or recurrence with ANY ONE of the following met:
  - Newly identified abnormalities localized to chest cavity on conventional imaging
  - Suspected or biopsy proven recurrence localized to the chest cavity
  - Inconclusive conventional imaging
  - To differentiate tumor from radiation scar/fibrosis

Thymoma with ANY ONE of the following:
- Initial workup or initial staging if inconclusive finding on CT
- Restaging with ANY ONE of the following met:
  - Inconclusive finding on CT
  - Extensive disease on Following induction chemotherapy prior to surgical resection, if no evidence of metastatic disease

Thyroid Cancer with ANY ONE of the following met:
- Anaplastic and Medullary Thyroid Carcinomas with ANY ONE of the following met:
  - Initial workup or initial staging if conventional imaging inconclusive
  - Restaging or recurrence if conventional imaging inconclusive
- Follicular, Papillary and Hürthle Cell Carcinomas
  - Restaging or recurrence with ANY ONE of the following met:
    - Negative radiiodine scan and rising thyroglobulin level
    - Inconclusive findings on conventional imaging
    - Metastatic disease that is ALL of the following:
      - RAI refractory
      - conventional imaging is inconclusive

Transitional Cell Cancer with ANY ONE of the following met:
- Initial workup or initial staging with ALL of the following met:
  - Used to determine neoadjuvant therapy vs surgery as initial treatment
  - Conventional imaging negative or inconclusive

Wilms Tumor (unilateral and bilateral) with ANY ONE of the following met:
- For treatment response with ALL of the following met:
  - To establish the presence of active disease
  - A major therapeutic decision depends on PET avidity

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.
We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

SOURCES


**EFFECTIVE DATE**

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This document has been classified as public information.