Clinical Appropriateness Guidelines: Advanced Imaging

Appropriate Use Criteria: Positron Emission Testing, Other PET Applications, including Oncologic Tumor Imaging

Effective Date: March 12, 2018

Proprietary

Date of Origin: 03/30/2005
Last revised: 09/07/2017
Last reviewed: 09/07/2017

8600 W Bryn Mawr Avenue
South Tower - Suite 800
Chicago, IL 60631
P. 773.864.4600
www.aimspecialtyhealth.com

Table of Contents

Description and Application of the Guidelines

AIM's Clinical Appropriateness Guidelines (hereinafter "AIM's Clinical Appropriateness Guidelines" or the "Guidelines") are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. As used by AIM, the Guidelines establish objective and evidence-based, where possible, criteria for medical necessity determinations. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To advocate for patient safety concerns
- To enhance the quality of healthcare
- To promote the most efficient and cost-effective use of services

AIM's guideline development process complies with applicable accreditation standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up to date clinical principles and best practices. Relevant citations are included in the "References" section attached to each Guideline. AIM reviews all of its Guidelines at least annually.

AIM makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of AIM's Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, AIM considers the Guidelines to be important, proprietary information of AIM, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of AIM.

AIM applies objective and evidence-based criteria and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The AIM Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. If requested by a health plan, AIM will review requests based on health plan medical policy/guidelines in lieu of AIM's Guidelines.

The Guidelines may also be used by the health plan or by AIM for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

Administrative Guideline: Ordering of Multiple Studies

Requests for multiple imaging studies to evaluate a suspected or identified condition and requests for repeated imaging of the same anatomic area are subject to additional review to avoid unnecessary or inappropriate imaging.

Simultaneous Ordering of Multiple Studies

In many situations, ordering multiple imaging studies at the same time is not clinically appropriate because:

- Current literature and/or standards of medical practice support that one of the requested imaging studies is more appropriate in the clinical situation presented; or
- One of the imaging studies requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice; or
- Appropriateness of additional imaging is dependent on the results of the lead study.

When multiple imaging studies are ordered, the request will often require a peer-to-peer conversation to understand the individual circumstances that support the medically necessity of performing all imaging studies simultaneously.

Examples of multiple imaging studies that may require a peer-to-peer conversation include:

- CT brain and CT sinus for headache
- MRI brain and MRA brain for headache
- MRI cervical spine and MRI shoulder for pain indications
- MRI lumbar spine and MRI hip for pain indications
- MRI or CT of multiple spine levels for pain or radicular indications
- MRI foot and MRI ankle for pain indications
- Bilateral exams, particularly comparison studies

There are certain clinical scenarios where simultaneous ordering of multiple imaging studies is consistent with current literature and/or standards of medical practice. These include:

- Oncologic imaging – Considerations include the type of malignancy and the point along the care continuum at which imaging is requested
- Conditions which span multiple anatomic regions – Examples include certain gastrointestinal indications or congenital spinal anomalies

Repeated Imaging

In general, repeated imaging of the same anatomic area should be limited to evaluation following an intervention, or when there is a change in clinical status such that imaging is required to determine next steps in management. At times, repeated imaging done with different techniques or contrast regimens may be necessary to clarify a finding seen on the original study.

Repeated imaging of the same anatomic area (with same or similar technology) may be subject to additional review in the following scenarios:

- Repeated imaging at the same facility due to motion artifact or other technical issues
- Repeated imaging requested at a different facility due to provider preference or quality concerns
- Repeated imaging of the same anatomic area (MRI or CT) based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated imaging of the same anatomical area by different providers for the same member over a short period of time

Administrative Guideline: Pre-Test Requirements

Critical to any finding of clinical appropriateness under the guidelines for specific imaging exams is a determination that the following are true with respect to the imaging request:

- A clinical evaluation has been performed prior to the imaging request (which should include a complete history and physical exam and review of results from relevant laboratory studies, prior imaging and supplementary testing) to identify suspected or established diseases or conditions.
- **For suspected diseases or conditions:**
  - Based on the clinical evaluation, there is a reasonable likelihood of disease prior to imaging; and
  - Current literature and standards of medical practice support that the requested imaging study is the most appropriate method of narrowing the differential diagnosis generated through the clinical evaluation and can be reasonably expected to lead to a change in management of the patient; and
  - The imaging requested is reasonably expected to improve patient outcomes based on current literature and standards of medical practice.
- **For established diseases or conditions:**
  - Advanced imaging is needed to determine whether the extent or nature of the disease or condition has changed; and
  - Current literature and standards of medical practice support that the requested imaging study is the most appropriate method of determining this and can be reasonably expected to lead to a change in management of the patient; and
  - The imaging requested is reasonably expected to improve patient outcomes based on current literature and standards of medical practice.
- If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the pre-test requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Positron Emission Tomography (PET) PET Applications including Oncologic Tumor Imaging

CPT Codes

Dedicated PET Imaging:

78811..... PET imaging, limited area

78812..... PET imaging, skull to mid-thigh

78813..... PET imaging, whole body

PET/CT Imaging:

78814..... PET imaging, with concurrently acquired CT for attenuation correction and anatomic localization; limited area

78815..... PET imaging, with concurrently acquired CT for attenuation correction and anatomic localization; skull base to mid-thigh

78816..... PET imaging, with concurrently acquired CT for attenuation correction and anatomic localization; whole body

Commonly Used Radiopharmaceutical/Scanner

- 2-(fluorine-18) fluoro-2-deoxy-d-glucose (FDG), performed on a dedicated PET or integrated (hybrid) PET/CT scanner
- Radiopharmaceuticals other than 2-(fluorine-18) fluoro-2-deoxy-d-glucose (FDG) are still under active investigation.

Technology Considerations

The use of PET is generally limited to clinical situations in which tissue confirmation of malignancy has been established and standard imaging has not provided sufficient information to guide treatment decisions.

Standard imaging usually consists of CT or MRI, but may include xray, bone scan or ultrasound. In the majority of situations where residual or recurrent disease is of concern, biopsy remains the most reliable method of confirmation. In addition, timing of PET with regard to radiation treatment and other forms of therapy is critical, as the inflammatory response may lead to false positive findings.

For situations where standard imaging with contrast is recommended but a contraindication to contrast administration exists, special consideration for PET imaging will be given when the results of the study are needed to guide treatment.

Based on these considerations and the considerable nuance that exists across tumor types, peer-to-peer discussions will often be necessary to determine appropriateness of PET imaging.

Routine surveillance with PET or other imaging studies in asymptomatic patients has not been shown to improve survival or impact the ability to palliate recurrent disease, and is therefore not recommended.

Common Diagnostic Indications

Note: Initial treatment strategy refers to staging.

Anal cancer

- Initial treatment strategy
  - Standard imaging studies are equivocal or non-diagnostic for the extent of metastatic disease
- Radiation planning
  - For definitive treatment only
- Subsequent treatment strategy
  - Standard imaging studies are equivocal or non-diagnostic
  - Restaging of local recurrence when salvage surgery is planned
- Surveillance
  - Not indicated for surveillance

Bladder, renal pelvis and ureter

- Initial treatment strategy
  - Evaluation of stage II or stage III bladder cancer prior to surgery
  - When bone metastasis is suspected based on signs and symptoms and standard imaging has not demonstrated bone lesions

  Note: *PET is not indicated in bladder tumors which have not invaded the muscle (stage < cT2).*
- Subsequent treatment strategy
  - Assessment of treatment response when standard imaging is not indicated or inconclusive
  - Evaluation of objective signs or symptoms of disease when CT or MRI has not clearly demonstrated recurrence or progression
- Surveillance
  - Not indicated for surveillance

Bone/cartilage and connective/other soft tissue

- Initial treatment strategy
  - Standard imaging studies are equivocal or non-diagnostic for the extent of metastatic disease
  - Standard imaging suggests a resectable solitary metastasis
  - As a baseline prior to neoadjuvant chemotherapy for deep tumors larger than 3 cm
- Subsequent treatment strategy
  - After completion of neoadjuvant chemotherapy for deep lesions larger than 3 cm
- Surveillance
  - Not indicated for surveillance

Common Diagnostic Indications

Breast cancer, invasive (male and female)

- Initial treatment strategy when a diagnosis of invasive breast cancer has been established and **any of the following** apply:
  - Locally advanced disease (stage IIIA-IIIC) has been established and standard imaging does not clearly demonstrate metastatic disease
  - Symptom-directed staging has been performed and is equivocal or suspicious for metastatic disease
  - Standard imaging studies are equivocal or non-diagnostic for the extent of known metastatic disease
- Subsequent treatment strategy
  - Detection of recurrent or progressive disease, when standard imaging is equivocal or non-diagnostic
  - Suspected worsening of disease based on objective signs or symptoms (such as rising tumor markers), when standard imaging has been performed and does not clearly identify site of recurrence or progression
- Surveillance
  - Not indicated for surveillance

Note: *Standard imaging includes CT or MRI and bone scan, and may also include ultrasound when liver involvement is suspected. In the setting of bone-only metastatic disease, evaluation for progression or regression may be best imaged by PET.*

Central nervous system (CNS) cancers (primary malignancies of the brain and spinal cord)

- Initial treatment strategy
  - To evaluate possible systemic disease in proven CNS lymphoma
- Subsequent treatment strategy
  - Not indicated
- Surveillance
  - Not indicated for surveillance

Note: *Standard PET (body) imaging is sometimes used as staging, particularly for CNS lymphoma, or metastatic disease detected in the central nervous system. Primary brain tumors traditionally are imaged utilizing metabolic Brain FDG-PET scanning.*

Cervical cancer

- Initial treatment strategy
  - After definitive diagnosis of stage IB2 or higher cervical cancer
- Subsequent treatment strategy
  - Assessment of response to definitive chemoradiation when performed at least 12 weeks following therapy
  - Detection of recurrent or progressive disease, when standard imaging is equivocal or non-diagnostic
- Surveillance
  - Not indicated for surveillance

Common Diagnostic Indications

Colorectal cancer

- Initial treatment strategy—Detection of metastatic disease when the following are true:
  - Standard imaging has been performed (CT or ultrasound) and suggests resectable metastatic disease, **AND**
  - Confirmation of metastatic disease will impact the decision to proceed with curative surgery;

  OR

  - Lesion(s) is/are greater than 1 cm in diameter, **AND**
  - Lesion(s) is/are in a location not amenable to biopsy, or biopsy is considered high risk.

  Note: *A negative standard workup is considered sufficient for staging. In patients who cannot undergo contrast-enhanced CT due to contrast allergy or renal disease, PET may be utilized if the patient has potentially curable disease.*
- Radiation planning—Rectal cancer only
  - For preoperative treatment only
- Subsequent treatment strategy
  - CT is equivocal for metastatic disease and lesion(s) is/are greater than 1 cm in diameter
  - CT demonstrates potentially surgically curable recurrence
  - CT does not demonstrate a focus of recurrence but CEA level is rising
  - Signs or symptoms are suggestive of recurrence and CT with contrast is contraindicated.

  Note: *PET is not appropriate to assess response to chemotherapy due to an unacceptably high rate of false positive and false negative studies*
- Surveillance
  - Not indicated for surveillance

Esophageal and gastroesophageal junction cancers

- Initial treatment strategy
  - Standard imaging has been performed and has not demonstrated metastatic disease
- Radiation planning
  - For preoperative or definitive treatment only
- Subsequent treatment strategy
  - Assessment of response to chemoradiation, (as definitive treatment or prior to surgery) when performed at least 5 weeks after completion of therapy; **OR**,
  - Evaluation of suspected recurrence based on signs or symptoms, when standard modalities are equivocal for recurrent disease
- Surveillance
  - Not indicated for surveillance

Gastric cancer

- Initial treatment strategy—Detection of metastatic disease in tumors initially staged **1B or higher** when **all of the following** are true:
  - Standard imaging has been performed and has not clearly demonstrated metastatic disease.
  - Patient is a candidate for curative surgery.
- Radiation planning
  - For preoperative or definitive treatment only
- Subsequent treatment strategy
  - To determine resectability of residual disease following completion of primary (neoadjuvant) treatment, when follow-up evaluation with standard modalities does not demonstrate metastatic disease
  - Evaluation of suspected recurrence based on signs or symptoms, when standard modalities are equivocal for recurrent disease
- Surveillance
  - Not indicated for surveillance

Common Diagnostic Indications

Germ cell tumors of the ovary and testis

- Initial treatment strategy
  - Standard imaging studies are equivocal or non-diagnostic for the extent of metastatic disease.
- Subsequent treatment strategy
  - Standard imaging studies are equivocal or non-diagnostic
  - Residual mass >3 cm and normal markers
- Surveillance
  - Not indicated for surveillance

Head and neck, including lip, oral cavity, pharynx, larynx, nasal cavity, ear, sinuses, eye, or occult head and neck primary

- Initial treatment strategy
  - Evaluation of Stage III and IV cancers (tumors greater than 4 cm in size, or any evidence of regional node involvement) of the oral cavity, oropharynx, hypopharynx, nasopharynx, larynx and sinus
  - Following biopsy suggestive of a head and neck primary tumor (squamous cell cancer, adenocarcinoma, or anaplastic undifferentiated epithelial tumor) when CT or MRI evaluation of the neck has not detected a primary site of tumor
- Radiation planning
  - For preoperative or definitive treatment only
- Subsequent treatment strategy
  - Evaluation of disease following clinical response to treatment, no sooner than 12 weeks after completion of therapy
  - Evaluation of suspected recurrence based on signs or symptoms, when CT or MRI is equivocal or non-diagnostic for recurrent disease
  - Follow up of an equivocal post-treatment PET scan, no sooner than 4 weeks after the study, to determine need for further intervention such as neck dissection
- Surveillance
  - Not indicated for surveillance

Note: *PET is not generally indicated for initial evaluation of lip and salivary gland cancers, regardless of stage.*

Kidney cancer

- Initial treatment strategy
  - Evaluation of the extent of disease when curative resection of primary tumor or limited metastatic disease is planned, and standard imaging is equivocal for additional sites of disease.
- Subsequent treatment strategy—Evaluation of suspected recurrence when **all of the following** are true:
  - Standard imaging is equivocal for recurrent disease.
  - Biopsy cannot be performed.
  - Tumor has been shown to be PET avid (if a prior PET scan has been performed).
- Surveillance
  - Not indicated for surveillance

Note: *Bone scan and brain MRI should be performed for clinical suspicion of metastatic disease in renal cell carcinoma, as false negative PET results are commonly reported for this tumor type.*

Common Diagnostic Indications

Lung cancer

Pulmonary nodule

- Evaluation of a solitary pulmonary nodule when **all of the following** features are present:
  - Nodule is well-demarcated, solid or part solid, and lacks a benign calcification pattern.
  - Size is greater than 8 mm but less than 3 cm in greatest diameter
  - Nodule is surrounded by aerated lung parenchyma
  - There is no associated adenopathy, atelectasis or pleural effusion

Non-small cell lung cancer

- Initial treatment strategy
  - Diagnosis in patients with a strong clinical or radiographic suspicion of non-small cell lung cancer
  - Evaluation of the extent of disease following biopsy confirmation of non-small cell lung cancer
- Radiation planning
  - For preoperative or definitive treatment only
- Subsequent treatment strategy
  - Evaluation following induction or neoadjuvant therapy to determine eligibility for resection
  - Assessment of response to definitive chemoradiation when performed at least 12 weeks following therapy
  - Evaluation of signs or symptoms of disease when CT or MRI has not clearly demonstrated recurrence or progression
  - Differentiation of tumor from benign conditions (atelectasis, consolidation, or radiation fibrosis) when CT clearly delineates the abnormal findings
- Surveillance
  - Not indicated for surveillance

Note: *Areas previously treated with radiation therapy can remain FDG avid for up to 2 years.*

Small cell lung cancer

- Initial treatment strategy
  - Prior to definitive therapy when standard imaging suggests limited stage disease
- Radiation planning
  - Prior to initiation of radiation therapy
- Subsequent treatment strategy
  - Not routinely indicated
- Surveillance
  - Not indicated for surveillance

Lymphoma

Suspected lymphoma

- Initial evaluation of suspected lymphoma when lymph nodes are not amenable to biopsy

Note: *PET scan prior to histologic determination is not routinely recommended, as PET-avid lymphadenopathy can result from both benign and other malignant processes.*

Chronic lymphocytic leukemia (CLL) or Small lymphocytic lymphoma (SLL)

- Suspicion of Richter's transformation when PET is utilized to direct biopsy

Note: *Suspicion of Richter's transformation is most commonly based on a presentation of rapidly enlarging lymph nodes, onset of B symptoms, hepatosplenomegaly, and elevated serum lactate dehydrogenase (LDH) levels.*

Common Diagnostic Indications

Hodgkin's lymphoma

- Initial treatment strategy (often performed as an adjunct to CT chest/abdomen/pelvis)
- Radiation planning
  - Definitive or consolidative treatment
- Subsequent treatment strategy
  - Evaluation of response following 2–4 cycles of treatment
  - Post-treatment evaluation
  - Evaluation of suspected recurrence or progression of disease based on standard imaging or objective signs/ symptoms
- Surveillance
  - Not indicated for surveillance

Note: *For post-treatment evaluation, PET should not be performed sooner than 3 weeks following completion of all cycles of chemotherapy, or sooner than 12 weeks following completion of radiation therapy.*

Low grade/indolent non-Hodgkin's lymphoma or lymphoproliferative disorders (other than CLL/SLL)

- Initial treatment strategy
  - Evaluation of suspected transformation to a more aggressive lymphoma based on clinical signs or symptoms
  - Prior to initiation of therapy
- Radiation planning
  - Definitive or consolidative treatment
- Subsequent treatment strategy
  - Post-treatment response evaluation, when initial PET scan has demonstrated FDG uptake
  - Evaluation of suspected recurrence or progression of disease based on standard imaging, when there is an indication to resume systemic treatment
  - Evaluation of suspected transformation to a more aggressive lymphoma based on clinical signs or symptoms
- Surveillance
  - Not indicated for surveillance

Note: *For post-treatment evaluation, PET should not be performed sooner than 3 weeks following completion of all cycles of chemotherapy, or sooner than 12 weeks following completion of radiation therapy.*

Intermediate or High grade (aggressive) non-Hodgkin's lymphoma and other subtypes

- Initial treatment strategy (often performed as an adjunct to CT chest/abdomen/pelvis)
- Radiation planning
  - Definitive or consolidative treatment
- Subsequent treatment strategy
  - Evaluation of response following 2–4 cycles of treatment of stage III and IV disease, when standard imaging has not clearly demonstrated progression or regression of disease
  - Post-treatment evaluation
  - Evaluation of suspected recurrence or progression of disease based on standard imaging or objective signs/ symptoms
- Surveillance
  - Not indicated for surveillance

Common Diagnostic Indications

Myeloma

- Initial treatment strategy
  - Differentiation of smoldering myeloma from active myeloma when skeletal survey and/or whole body MRI is negative for bone involvement
- Subsequent treatment strategy
  - When routine evaluation with laboratory findings or bone survey suggests recurrence or progression of disease
- Surveillance
  - Not indicated for surveillance

Note: *Routine follow-up evaluation includes quantitative immunoglobulins and M protein (serum and urine), routine CBC, kidney function, and calcium levels, and bone surveys. Additional evaluation may also include bone marrow aspirate and biopsy, serum free light chain assays, MRI, and flow cytometry.*

Neuroendocrine tumor, particularly poorly differentiated disease

- Initial treatment strategy
  - Standard imaging studies are equivocal or non-diagnostic for the extent of metastatic disease
- Subsequent treatment strategy
- Surveillance
  - Not indicated for surveillance

Note: *Somatostatin receptor imaging should be considered in those tumors for which falsely negative FDG PET or PET/CT results are commonly reported, including well-differentiated neuroendocrine tumors.*

Other cancers not listed

- Initial treatment strategy
  - Standard imaging studies are equivocal or non-diagnostic regarding the extent of disease
- Subsequent treatment strategy
  - Detection of recurrent or progressive disease, when standard imaging is equivocal or non-diagnostic
- Surveillance
  - Not indicated for surveillance

Ovarian cancer (epithelial)

- Initial treatment strategy
  - Evaluation of indeterminate lesions detected by other imaging modalities, including ultrasound and CT or MRI, when additional information is required to guide management
- Subsequent treatment strategy
  - Evaluation of objective evidence of recurrent disease (such as rising tumor markers or increasing ascites) when CT or MRI does not clearly demonstrate recurrence or progression
- Surveillance
  - Not indicated for surveillance

Common Diagnostic Indications

Pancreatic adenocarcinoma

- Initial treatment strategy—Detection of extra-pancreatic disease in patients who are candidates for resection when **all of the following** are true:
  - Dedicated, high quality imaging of the pancreas has been performed (see Note below)
  - Extra-pancreatic disease has not been clearly identified
  - **Any of the following** high-risk features are present
    - CA 19-9 level greater than 100 U/ml
    - Primary tumor greater than 2 cm in size
    - Enlarged regional nodes
    - Tumor is considered borderline resectable
- Radiation planning
  - For preoperative or definitive treatment in patients without distant metastasis
- Subsequent treatment strategy
  - Detection of recurrent or progressive disease, when standard imaging is equivocal or non-diagnostic
- Surveillance
  - Not indicated for surveillance

Note: *Standard, high quality dedicated imaging evaluation of the pancreas includes a dedicated pancreatic protocol CT scan (multi-detector computed tomography angiography using a dual-phase pancreatic protocol, with images obtained in the pancreatic and portal venous phase of contrast enhancement) or MRI if CT is contraindicated. MRI may also be used to clarify CT-indeterminate liver lesions or suspected pancreatic tumors not visible on CT.*

Paraneoplastic syndrome including neurologic syndrome

- PET or PET/CT is indicated for initial evaluation of individuals with paraneoplastic syndrome

Prostate adenocarcinoma

Not medically necessary for any indication

Note: *FDG-PET/CT is not recommended for routine use for prostate cancer management because data remain insufficient. Furthermore, further study is needed to determine the best use of choline PET/CT in men with prostate cancer.*

Skin cancer, including:

Melanoma

- Initial treatment strategy—Evaluation for metastatic disease when **any of the following** are true:
  - To determine the extent of involvement in stage III and IV disease when used instead of CT chest, abdomen and pelvis
  - Standard imaging studies are equivocal or non-diagnostic for the extent of known metastatic disease
  - When the primary site is unknown and standard imaging is negative
- Radiation planning
  - For definitive treatment only
- Subsequent treatment strategy
  - Evaluation of objective signs or symptoms of metastatic disease when CT or MRI has not clearly demonstrated recurrence or progression
  - To assess treatment response in unresectable stage III and IV disease when used instead of CT chest, abdomen and pelvis
- Surveillance
  - Not indicated for surveillance

Note: *An isolated finding of a new skin lesion is not sufficient evidence of systemic recurrence.*

Common Diagnostic Indications

Mucosal Melanoma

- Initial treatment strategy
  - Detection of metastatic disease
- Radiation planning
  - For pre-operative or definitive treatment only
- Subsequent treatment strategy
  - Evaluation of disease following clinical response to treatment, no sooner than 12 weeks after completion of therapy
  - Evaluation of signs or symptoms of metastatic disease when CT or MRI has not clearly demonstrated recurrence or progression
- Surveillance
  - Not indicated for surveillance

Note: *An isolated finding of a new mucosal lesion is not sufficient evidence of systemic recurrence.*

Merkel cell carcinoma

- Initial treatment strategy
- Subsequent treatment strategy
- Surveillance
  - Not indicated for surveillance

Thorax, other than lung cancer, including pleural malignancies, cancers of the thymus, heart, and mediastinum

- Initial treatment strategy
  - For initial staging when surgical resection is being considered and there is no known metastatic disease
- Subsequent treatment strategy
  - For restaging after induction chemotherapy, if patient is medically operable
- Surveillance
  - Not indicated for surveillance

Common Diagnostic Indications

Thyroid

- Initial treatment strategy
  - Poorly differentiated papillary
  - Anaplastic
  - Medullary
  - Hurthle Cell
- Subsequent treatment strategy
  - Poorly differentiated papillary
  - Anaplastic
  - Medullary
  - Hurthle Cell
  - Well-differentiated papillary or follicular thyroid cancer
    - For evaluation of suspected recurrence when **both of the following** are met:
      - With negative I131 scan, or a history of a negative I131 scan
      - Stimulated thyroglobulin level greater than two (2) ng/dL in the absence of antibodies.
- Surveillance
  - Not indicated for surveillance

Note: *PET is most useful for non-iodine avid thyroid cancer. Furthermore, alternative imaging modalities should be considered in those tumor types for which falsely negative PET or PET/CT results are commonly reported, including medullary thyroid carcinoma. PET should be used with caution unless disease is known to be FDG-avid.*

Uterine cancer

- Initial treatment strategy
  - Standard imaging studies are equivocal or non-diagnostic for the extent of metastatic disease
- Subsequent treatment strategy
  - Standard imaging studies are equivocal or non-diagnostic
- Surveillance
  - Not indicated for surveillance

Vaginal, vulvar and penile cancers

- Initial treatment strategy
  - Standard imaging studies are equivocal or non-diagnostic for the extent of metastatic disease
  - Staging of penile cancer when pelvic lymph nodes are enlarged on CT or MRI and needle biopsy is not technically feasible
- Subsequent treatment strategy
  - Standard imaging studies are equivocal or non-diagnostic
  - Restaging of local recurrence when exenterative surgery is planned
- Surveillance
  - Not indicated for surveillance

Note: *Alternative imaging modalities should be considered in those tumor types for which falsely negative PET or PET/CT results are commonly reported, including many renal cell (kidney) carcinomas. PET should be used with caution.*

Screening: PET or PET/CT is considered not medically necessary as a screening test (i.e., for evaluation of patients without specific signs and symptoms of disease).

PET for screening or diagnosis of breast cancer is not a covered benefit by the Centers for Medicare & Medicaid Services and multiple health plans.

Other Considerations

PET mammography is an evolving technology under clinical development. This technology and its impact on health outcomes will continue to undergo review as new evidence-based studies are published. Interval routine coverage for PET mammography is not generally available and is not considered medically appropriate at this time.

PET bone scanning is currently only a covered benefit by the Centers for Medicare & Medicaid Services with CED. PET bone scanning is an evolving technology under clinical development. This technology and its impact on health outcomes will continue to undergo review as new evidence-based studies are published.

PET bone scan is considered not medically necessary.

PET Imaging of Infectious Processes

For diagnosis of chronic osteomyelitis involving the axial skeleton

References

1. Alpert JB, Lowry CM, Ko JP. Imaging the Solitary Pulmonary Nodule. *Clin Chest Med.* 2015;36(2):161-178.
2. American Society of Clinical Oncology. Choosing Wisely: Monitoring for cancer recurrence. ABIM Foundation; October 29, 2013. Available at http://www.choosingwisely.org/clinician-lists/american-society-clinical-oncology-monitoring-for-cancer-recurrence/ Accessed on January 29, 2018.
3. American Society of Clinical Oncology. Choosing Wisely: PET CT and radionuclide bone scans in staging early breast cancer. ABIM Foundation; April 4, 2012. Available at http://www.choosingwisely.org/clinician-lists/american-society-clinical-oncology-pet-ct-radionuclide-bone-scans-in-staging-early-breast-cancer/ Accessed on January 29, 2018.
4. American Society of Clinical Oncology. Choosing Wisely: PET CT and radionuclide bone scans in staging early prostate cancer. ABIM Foundation; April 4, 2012. Available at http://www.choosingwisely.org/clinician-lists/american-society-clinical-oncology-pet-ct-radionuclide-bone-scans-in-staging-early-prostate-cancer/ Accessed on January 29, 2018.
5. American Society of Clinical Oncology. Choosing Wisely: Surveillance testing imaging for breast cancer. ABIM Foundation; April 4, 2012. Available at http://www.choosingwisely.org/clinician-lists/american-society-clinical-oncology-surveillance-testing-imaging-for-breast-cancer/ Accessed on January 29, 2018.
6. Atri M, Zhang Z, Dehdashti F, et al. Utility of PET/CT to evaluate retroperitoneal lymph node metastasis in high-risk endometrial cancer: Results of ACRIN 6671/GOG 0233 trial. *Radiology* 2017;283(2):450-459. doi: 10.1148/radiol.2016160200. Epub 2017 Jan 3.
7. Bradley JD, Dehdashti F, Mintun MA, Govindan R, Trinkaus K, Siegel BA. Positron emission tomography in limited-stage small-cell lung cancer: a prospective study. *J Clin Oncol.* 2004;22(16): 3248-3254.
8. Brink I, Schumacher T, Mix M, et al. Impact of [18F]FDG-PET on the primary staging of small-cell lung cancer. *Eur J Nucl Med Mol Imaging.* 2004;31(12):1614-1620.
9. Bruzzi, JF, Swisher SG, Truong MT, et al. Detection of interval distant metastases: Clinical utility of integrated CT-PET imaging in patients with esophageal carcinoma after neoadjuvant therapy. *Cancer*. 2007;109(1):125-134.
10. Caroline I, Rosenthal MA. Imaging modalities in high-grade gliomas: pseudoprogression, recurrence, or necrosis? *J Clin Neurosci.* 2012;19(5):633-637.
11. Cayvarli H, Bekiş R, Akman T, Altun D. The Role of 18F-FDG PET/CT in the evaluation of gastric cancer recurrence. *Mol Imaging Radionucl Ther*. 2014;23(3):76-83.
12. Cerfolio RJ, Bryant AS, Ojha B. Restaging patients with N2 (stage IIIa) non-small cell lung cancer after neoadjuvant chemoradiotherapy: a prospective study. *J Thorac Cardiovasc Surg*. 2006;131(6):1229-1235.
13. Chang MC, Chen JH, Liang JA, Yang KT, Cheng KY, Kao CH. 18F-FDG PET or PET/CT for detection of metastatic lymph nodes in patients with endometrial cancer: a systematic review and meta-analysis. *Eur J Radiol*. 2012;81(11):3511-3517.
14. Chen J, Cheong JH, Yun MJ, et al. Improvement in preoperative staging of gastric adenocarcinoma with positron

emission tomography. *Cancer*. 2005;103(11):2383-2390.

15. Christensen JA, Nathan MA, Mullan BP, Hartman TE, Swensen SJ, Lowe VJ. Characterization of the solitary pulmonary nodule: 18F-FDG PET versus nodule-enhancement CT. *AJR Am J Roentgenol.* 2006;187(5):1361-1367.
16. De Santis M, Becherer A, Bokemeyer C, et al. 2-18fluoro-deoxy-D-glucose positron emission tomography is a reliable predictor for viable tumor in postchemotherapy seminoma: an update of the prospective multicentric SEMPET trial. *J Clin Oncol*. 2004;22(6):1034-1039.
17. Farma JM, Santillan AA, Melis M, et al. PET/CT fusion scan enhances CT staging in patients with pancreatic neoplasms. *Ann Surg Oncol*. 2008;15(9):2465-2471.
18. Fischer B, Lassen U, Mortensen J, et al. Preoperative staging of lung cancer with combined PET-CT. *N Engl J Med*. 2009;361(1):32-39.
19. Fletcher JW, Djulbegovic B, Soares HP, et al. Recommendations on the use of (18F) FDG PET in oncology. *J Nucl Med.* 2008;49:480-508.
20. Furukawa H, Ikuma H, Seki A, et al. Positron emission tomography scanning is not superior to whole body multidetector helical computed tomography in the preoperative staging of colorectal cancer. *Gut*. 2006;55(7):1007-1011.
21. Ghaneh P, Wong WL, Titman A, et al. PET-PANC: Multi-centre prospective diagnostic accuracy and clinical value trial of FDG PET/CT in the diagnosis and management of suspected pancreatic cancer (abstract). *J Clin Oncol.* 2016;34(15_ suppl):4008.
22. Gould MK, Donington J, Lynch WR, et al. Evaluation of individuals with pulmonary nodules: when is it lung cancer? Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest*. 2013;143(5 Suppl):e93S-120S.
23. Gould MK, Maclean CC, Kuschner WG, Rydzak CE, Owens DK. Accuracy of positron emission tomography for diagnosis of pulmonary nodules and mass lesions: a meta-analysis. *JAMA*. 2001;285(7):914-924.
24. Kollberg P, Almquist H, Blackberg M, et al. [(18)F]Fluorodeoxyglucose–positron emission tomography/computed tomography improves staging in patients with high-risk muscle-invasive bladder cancer scheduled for radical cystectomy. *Scand J Urol*. 2015;49(4):296-301.
25. Lim JS, Yun MJ, Kim MJ, et al. CT and PET in stomach cancer: preoperative staging and monitoring of response to therapy. *Radiographics*. 2006;26(1):143-156.
26. Lind P, Kohlfürst S. Respective roles of thyroglobulin, radioiodine imaging, and positron emission tomography in the assessment of thyroid cancer. *Semin Nucl Med*. 2006;36(3):194-205.
27. Lu YY, Chen JH, Chien CR, et al. Use of FDG-PET or PET/CT to detect recurrent colorectal cancer in patients with elevated CEA: a systematic review and meta-analysis. *Int J Colorectal Dis*. 2013;28(8):1039-1047.
28. Lu YY, Chen JH, Liang JA, et al. Clinical value of FDG PET or PET/CT in urinary bladder cancer: a systemic review and meta-analysis. *Eur J Radiol.* 2012;81(9):2411-2416.
29. MacManus M, Nestle U, Rosenzweig KE, et al. Use of PET and PET/CT for radiation therapy planning: IAEA expert report 2006–2007. *Radiother Oncol*. 2009;91(1):85-94.
30. Maziak DE, Darling GE, Inculet RI, et al. Positron emission tomography in staging early lung cancer: a randomized trial. *Ann Intern Med*. 2009;151(4):221-228.
31. Meyers BF, Downey RJ, Decker PA, et al; American College of Surgeons Oncology Group Z0060. The utility of positron emission tomography in staging of potentially operable carcinoma of the thoracic esophagus: results of the American College of Surgeons Oncology Group Z0060 trial. J Thorac Cardiovasc Surg. 2007; 133(3):738-745.
32. Mohile NA, DeAngelis LM, Abrey LE. The utility of body FDG PET in staging primary central nervous system lymphoma. *Neuro Oncol*. 2008;10(2):223-228.
33. Mosci C, Iagaru A. PET/CT imaging of thyroid cancer. *Clin Nucl Med*. 2011;36(12):e180-e185.
34. Moulton CA, Gu CS, Law CH, et al. Effect of PET before liver resection on surgical management for colorectal adenocarcinoma metastases: a randomized clinical trial. *JAMA*. 2014;311(18):1863-1869.
35. Muros MA, Llamas-Elvira JM, Ramírez-Navarro A, et al. Utility of fluorine-18-fluorodeoxyglucose positron emission tomography in differentiated thyroid carcinoma with negative radioiodine scans and elevated serum thyroglobulin levels. *Am J Surg.* 2000;179(6):457-461.
36. National Comprehensive Cancer Network, Inc.: NCCN Imaging Appropriate Use Criteria Compendium: Clinical Practice Guidelines for Anal Carcinoma; Bladder Cancer; Bone Cancer; Breast Cancer; Central Nervous System Cancers; Cervical Cancer; Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma; Colon Cancer; Esophageal and Esophagogastric Junction Cancers; Gastric Cancer; Head and Neck Cancers; Hodgkin Lymphoma; Kidney Cancer; Melanoma; Merkel; Multiple Myeloma; Neuroendocrine Tumors; Non-Small Cell Lung Cancer; Ovarian Cancer

Including Fallopian Tube Cancer and Primary Peritoneal Cancer; Pancreatic Adenocarcinoma; Penile Cancer; Prostate Cancer; Rectal Cancer; Small Cell Lung Cancer; Soft Tissue Sarcoma; Testicular Cancer; Thyroid Carcinoma; Uterine Neoplasms; Vulvar Cancer. Referenced with permission. To view the most recent and complete version of the NCCN Guidelines, go online to www.nccn.org.

37. Ozkan E, Aras G, Kucuk NO. Correlation of 18F-FDG PET/CT findings with histopathological results in differentiated thyroid cancer patients who have increased thyroglobulin or antithyroglobulin antibody levels and negative 131I whole-body scan results. *Clin Nucl Med*. 2013;38(5):326-331.
38. Ozkan E, Soydal C, Araz M, Aras G, Ibis E. The additive clinical value of 18F-FDG PET/CT in defining the recurrence of disease in patients with differentiated thyroid cancer who have isolated increased antithyroglobulin antibody levels. *Clin Nucl Med.* 2012;37(8):755-758.
39. Park JW, Jo MK, Lee HM. Significance of 18F-fluorodeoxyglucose positron-emission tomography/computed tomography for the postoperative surveillance of advanced renal cell carcinoma. *BJU Int*. 2009;103(5):615-619.
40. Pastorino U, Veronesi G, Landoni C, et al. Fluorodeoxyglucose positron emission tomography improves preoperative staging of resectable lung metastasis. *J Thoracic Cardiovasc Surg*. 2003; 126(6):1906-1910.
41. Patel K, Hadar N, Lee J, Siegel BA, Hillner BE, Lau J. The lack of evidence for PET or PET/CT surveillance of patients with treated lymphoma, colorectal cancer, and head and neck cancer: a systematic review. *J Nucl Med*. 2013; 54(9):1518-1527.
42. Rajkumar SV, Dimopoulos MA, Palumbo A, et al. International Myeloma Working Group updated criteria for the diagnosis of multiple myeloma. *Lancet Oncol*. 2014 Nov;15(12):e538-48.
43. Rijkers AP, Valkema R, Duivenvoorden HJ, van Eijck CH. Usefulness of F-18-fluorodeoxyglucose positron emission tomography to confirm suspected pancreatic cancer: a meta-analysis. *Eur J Surg Oncol*. 2014;40(7):794-804.
44. Risum S, Høgdall C, Loft A, et al. The diagnostic value of PET/CT for primary ovarian cancer—a prospective study. *Gynecol Oncol*. 2007;105(1):145-149.
45. Risum S, Høgdall C, Markova E, et al. Influence of 2-(18F) fluoro-2-deoxy-D-glucose positron emission tomography/computed tomography on recurrent ovarian cancer diagnosis and on selection of patients for secondary cytoreductive surgery. *Int J Gynecol Cancer*. 2009;19(4):600-604.
46. Robertson NL, Hricak H, Sonoda Y, et al. The impact of FDG-PET/CT in the management of patients with vulvar and vaginal cancer. *Gynecol Oncol*. 2016;140(3):420-424.
47. Rodriguez Rivera AM, Alabbas H, Ramjaun A, Meguerditchian AN. Value of positron emission tomography scan in stage III cutaneous melanoma: a systematic review and meta-analysis. *Surg Oncol*. 2014;23(1):11-16.
48. Salani R, Backes FJ, Fung MF, et al. Posttreatment surveillance and diagnosis of recurrence in women with gynecologic malignancies: Society of Gynecologic Oncologists recommendations. *Am J Obstet Gynecol*. 2011; 204(6):466-478.
49. Salvatore B, Paone G, Klain M, et al. Fluorodeoxyglucose PET/CT in patients with differentiated thyroid cancer and elevated thyroglobulin after total thyroidectomy and (131)I ablation. *Q J Nucl Med Mol imaging. Off Publ Ital Assoc Nucl Med [and] Int Assoc Radiopharmacol (IAR), [and] Sect Soc Radiopharm*. 2008;52(1):2-8.
50. Schröer-Günther MA, Wolff RF, Westwood ME, et al. F-18-fluoro-2-deoxyglucose positron emission tomography (PET) and PET/computed tomography imaging in primary staging of patients with malignant melanoma: a systematic review. *Syst Rev*. 2012;1:62.
51. Schuetze SM, Rubin BP, Vernon C, et al. Use of positron emission tomography in localized extremity soft tissue sarcoma treated with neoadjuvant chemotherapy. *Cancer*. 2005;103(2):339-348.
52. Sim YT, Goh YG, Dempsey MF, Han S, Poon FW. PET-CT evaluation of solitary pulmonary nodules: correlation with maximum standardized uptake value and pathology. *Lung*. 2013;191(6):625-632.
53. Siva S, Byrne K, Seel M, et al. 18F-FDG PET provides high-impact and powerful prognostic stratification in the staging of Merkel cell carcinoma: a 15-year institutional experience. *J Nucl Med*. 2013;54(8):1223-1229.
54. Treglia G, Kakhki VR, Giovanella L, Sadeghi R. Diagnostic performance of fluorine-18-fluorodeoxyglucose positron emission tomography in patients with Merkel cell carcinoma: a systematic review and meta-analysis. *Am J Clin Dermatol*. 2013;14(6):437-447.
55. Vural GU, Akkas BE, Ercakmak N, Basu S, Alavi A. Prognostic significance of FDG PET/CT on the follow-up of patients of differentiated thyroid carcinoma with negative 131I whole-body scan andelevated thyroglobulin levels: correlation with clinical and histopathologic characteristics and long-term follow-up data. *Clin Nucl Med.* 2012;37(10):953-959.
56. Xing Y, Bronstein Y, Ross MI, et al. Contemporary diagnostic imaging modalities for the staging and surveillance of melanoma patients: a meta-analysis. *J Natl Cancer Inst*. 2011;103(2):129-142.