Oncologic Applications of PET Scanning

Positron emission tomography (PET) scans are based on the use of positron-emitting radionuclide tracers coupled to organic molecules, such as glucose, ammonia, or water. The radionuclide tracers simultaneously emit 2 high-energy photons in opposite directions that can be simultaneously detected (referred to as coincidence detection) by a PET scanner, consisting of multiple stationary detectors that encircle the area of interest.

Related Policies

- Cardiac Applications of Positron Emission Tomography Scanning
- Interim PET Scanning in Oncology to Detect Early Response During Treatment
- Miscellaneous (Noncardiac, Nononcologic) Applications of Positron Emission Tomography

Policy

Notes:

1 - All policy statements apply to both positron emission tomography (PET) scans and PET/computed tomography (CT) scans (i.e., PET scans with or without PET/CT fusion).

2 - For the clinical situations indicated that may be considered medically necessary, this is with the assumption that the results of the PET scan will influence treatment decisions. If the results will not influence treatment decisions, these situations would be considered not medically necessary.

Bone Cancer:
PET scanning may be considered medically necessary in the staging of Ewing sarcoma and osteosarcoma.

PET scanning is considered investigational in the staging of chondrosarcoma.

Breast Cancer:
PET scanning may be considered medically necessary in the staging and restaging of breast cancer for the following application:

- Detecting locoregional or distant recurrence or metastasis (except axillary lymph nodes) when suspicion of disease is high and other imaging is inconclusive

PET scanning is considered investigational in the evaluation of breast cancer for all other applications, including but not limited to the following:

- Differential diagnosis in patients with suspicious breast lesions or an indeterminate/low suspicion finding on mammography
• Staging axillary lymph nodes
• Predicting pathologic response to neoadjuvant therapy for locally advanced disease

**Cervical Cancer:**
PET scanning may be considered *medically necessary* for either of the following:
- The initial staging of patients with locally advanced cervical cancer
- The evaluation of known or suspected recurrence

**Colorectal Cancer:**
PET scanning may be considered *medically necessary* as a technique for either of the following:
- Staging and restaging to detect and assess resectability of hepatic or extrahepatic metastases of colorectal cancer
- To evaluate a rising and persistently elevated carcinoembryonic antigen (CEA) level when standard imaging, including CT scan, is negative

PET scanning is considered *investigational* for either of the following:
- A technique to assess the presence of scarring versus local bowel recurrence in patients with previously resected colorectal cancer
- A technique contributing to radiotherapy treatment planning

**Esophageal Cancer:**
PET scanning may be considered *medically necessary* in either of the following:
- Staging of esophageal cancer
- Determining response to preoperative induction therapy

PET scanning is considered *investigational* in other aspects of the evaluation of esophageal cancer, including but not limited to the following applications:
- Detection of primary esophageal cancer

**Gastric Cancer:**
PET scanning may be considered *medically necessary* in either of the following:
- The initial diagnosis and staging of gastric cancer
- Evaluation for recurrent gastric cancer following surgical resection, when other imaging modalities are inconclusive

**Head and Neck Cancer:**
PET scanning may be considered *medically necessary* in any of the following:
- The diagnosis of suspected cancer
- Initial staging of disease
- Restaging of residual or recurrent disease during follow up

**Lung Cancer:**
PET scanning may be considered *medically necessary* for any of the following applications:
Patients with a solitary pulmonary nodule as a single scan technique (not dual-time) to distinguish between benign and malignant disease when prior CT scan and chest x-ray findings are inconclusive or discordant.

As a staging or restaging technique in those with known non-small-cell lung cancer.

To determine resectability for patients with a presumed solitary metastatic lesion from lung cancer.

PET scanning may be considered medically necessary to assess for distant metastases in small cell lung cancer when limited stage disease is suspected.

Except as noted above for suspected limited stage disease, PET scanning is considered investigational in staging of small cell lung cancer.

**Lymphoma, Including Hodgkin's Disease:**

PET scanning may be considered medically necessary as a technique for staging lymphoma either during initial staging or for restaging at follow-up.

**Melanoma:**

PET scanning may be considered medically necessary as a technique for assessing extranodal spread of malignant melanoma at initial staging or at restaging during follow-up treatment.

PET scanning may be considered medically necessary every 4-12 months to screen high-risk patients with stage IIB-IV melanomas for recurrent or metastatic disease for up to five years from the date of diagnosis.

PET scanning is considered investigational as a technique to detect regional lymph node metastases in patients with clinically localized melanoma who are candidates to undergo sentinel node biopsy.

**Neuroendocrine Tumors**

PET scanning may be considered medically necessary in the initial evaluation of poorly differentiated (high grade) neuroendocrine tumors when initial imaging (MRI or CT) is non-diagnostic.

PET scanning is considered investigational for subsequent imaging, including staging and restaging of neuroendocrine tumors.

**Ovarian Cancer:**

PET scanning may be considered medically necessary in the evaluation of patients with signs and/or symptoms of suspected ovarian cancer recurrence (restaging) when standard imaging, including CT scan, is inconclusive.

PET scanning is considered investigational in the initial evaluation of known or suspected ovarian cancer in all situations.

**Pancreatic Cancer:**

PET scanning may be considered medically necessary in the initial diagnosis and staging of pancreatic cancer when other imaging and biopsy are inconclusive.

PET scanning is considered investigational as a technique to evaluate other aspects of pancreatic cancer.
Soft Tissue Sarcoma:

PET scanning is considered investigative in evaluation of soft tissue sarcoma, including but not limited to the following applications:

- Distinguishing between benign lesions and malignant soft tissue sarcoma
- Distinguishing between low grade and high grade soft tissue sarcoma
- Detecting locoregional recurrence
- Detecting distant metastasis
- Evaluating response to imatinib and other treatments for gastrointestinal stromal tumors

Testicular Cancer:

PET scanning may be considered medically necessary in evaluation of residual mass following chemotherapy of stage IIB and III seminomas. (The PET scan should be completed not sooner than 6 weeks following chemotherapy.)

Except as noted above for seminoma, PET scanning is considered investigative in evaluation of testicular cancer, including but not limited to the following applications:

- Initial staging of testicular cancer
- Distinguishing between viable tumor and necrosis/fibrosis after treatment of testicular cancer
- Detection of recurrent disease after treatment of testicular cancer

Thyroid Cancer:

PET scanning may be considered medically necessary in the restaging of patients with differentiated thyroid cancer when thyroglobulin (Tg) levels are elevated and whole-body I-131 imaging is negative.

PET scanning is considered investigative in the evaluation of known or suspected differentiated or poorly differentiated thyroid cancer in all other situations.

Unknown Primary:

PET scanning may be considered medically necessary in patients with an unknown primary who meet all of the following criteria:

- In patients with a single site of disease outside the cervical lymph nodes
- Patient is considering local or regional treatment for a single site of metastatic disease
- After a negative workup for an occult primary tumor
- PET scan will be used to rule out or detect additional sites of disease that would eliminate the rationale for local or regional treatment

PET scanning is considered investigative for other indications in patients with an unknown primary, including, but not limited to the following:

- As part of the initial workup of an unknown primary
- As part of the workup of patients with multiple sites of disease
Medical Policy

Cancer Surveillance:
PET scanning is considered investigational when used as a surveillance tool for patients with cancer or with a history of cancer. A scan is considered surveillance if performed more than 6 months after completion of cancer therapy (12 months for lymphoma) in patients without objective signs or symptoms suggestive of cancer recurrence. (See Policy Guidelines)

Other Oncologic Applications:
Other oncologic applications of PET scanning, including but not limited to the following, are considered investigational:

- Diagnosis and management of known or suspected prostate cancer
- Diagnosis of brain tumors
- Staging of multiple myeloma
- Staging inguinal lymph nodes in patients with squamous cell carcinoma of the penis

Policy Guidelines

Patient Selection Issues
As with any imaging technique, the medical necessity of positron emission tomography (PET) scanning depends in part on what imaging techniques are used either before or after the PET scanning. Due to its expense, PET scanning is typically considered after other techniques, such as CT, MRI, or ultrasonography, provide inconclusive or discordant results. In patients with melanoma or lymphoma, PET scanning may be considered an initial imaging technique. If so, the medical necessity of subsequent imaging during the same diagnostic evaluation is unclear. Thus, PET should be considered for the medically necessary indications above only when standard imaging, such as CT or MRI, is inconclusive or not indicated.

The patient selection criteria for PET scanning may also be complex. For example, it may be difficult to determine from claims data whether a PET scan in a patient with malignant melanoma is being done primarily to evaluate extranodal disease or the regional lymph nodes. Similarly, it may be difficult to determine whether a PET scan in a patient with colorectal cancer is being performed to detect hepatic disease or evaluate local recurrence. Due to the complicated hierarchy of imaging options in patients with malignancy and complex patient selection criteria, 1 possible implementation strategy for this policy is its use for retrospective review, possibly focusing on cases with multiple imaging tests, including PET scans.

Use of PET scanning for surveillance as described in the policy statement and policy rationale refers to use of PET to detect disease in asymptomatic patients at various intervals. This is not the same as use of PET for detecting recurrent disease in symptomatic patients; these applications of PET are considered within tumor-specific categories of the policy statements.

Coding
A PET scan essentially involves 3 separate activities:
Manufacture of the radiopharmaceutical, which may be manufactured on site or manufactured at a regional delivery center with delivery to the institution performing PET

Actual performance of the PET scan

Interpretation of the results.

The following CPT codes and HCPCS codes are available to code for PET scans:

**CPT Codes:**

- **78811**: Positron emission tomography (PET) imaging; limited area (e.g., chest, head/neck)
- **78812**: Positron emission tomography (PET) imaging; skull base to mid-thigh
- **78813**: Positron emission tomography (PET) imaging; whole body

The following are CPT codes for concurrently acquired PET and computed tomography (CT):

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

When the radiopharmaceutical is provided by an outside distribution center, there may be an additional separate charge, or this charge may be passed through and included in the hospital bill. In addition, an extra transportation charge will be likely for radiopharmaceuticals that are not manufactured on site.

**HCPCS Codes:**

Centers for Medicare and Medicaid Services (CMS) maintained a couple of HCPCS codes for Medicare noncovered indications:

- **G0219**: PET imaging whole body; melanoma for noncovered indications
- **G0235**: PET imaging, any site not otherwise specified
- **G0252**: PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)

CMS added 2 new modifiers to facilitate the changes in the Medicare national coverage policy for PET. The modifiers are:

- **PI**: Positron emission tomography (PET) or PET/computed tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing, 1 per cancer diagnosis
- **PS**: Positron emission tomography (PET) or PET/computed tomography (CT) to inform the subsequent treatment strategy of cancerous tumors when the
beneficiary’s treating physician determines that the PET study is needed to inform subsequent anti-tumor strategy.

The following are HCPCS codes specific to a few of the radiotracers used for PET:

- **A9552**: Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries
- **A9526**: Nitrogen N-13 AMMONIA, diagnostic, per study dose, up to 40 millicuries
- **A9580**: Sodium fluoride F-18, diagnostic, per study dose, up to 30 millicuries

### Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

### Rationale

#### Background

A variety of tracers are used for PET scanning, including oxygen-15, nitrogen-13, carbon-11, and fluorine-18. Because of their short half-life, some tracers must be made locally using an onsite cyclotron. The radiotracer most commonly used in oncology imaging has been fluorine-18 coupled with fluorodeoxyglucose (FDG), which has a metabolism related to glucose metabolism. FDG has been considered useful in cancer imaging, because tumor cells show increased metabolism of glucose. The most common malignancies studied have been melanoma, lymphoma, lung, colorectal, and pancreatic cancer.

For this policy, PET scanning is discussed for the following 4 applications in oncology:

- **Diagnosis**: Diagnosis refers to use of PET as part of the testing used in establishing whether or not a patient has cancer.
- **Staging**: This refers to use of PET to determine the stage (extent) of the cancer at the time of diagnosis, before any treatment is given. Imaging at this time is generally to determine whether or not the cancer is localized. This may also be referred to as initial staging.
- **Restaging**: This refers to imaging following treatment in 2 situations. Restaging is part of the evaluation of a patient in whom a disease recurrence is suspected based on signs and/or symptoms. Restaging also includes determining the extent of malignancy following completion of a full course of treatment.
- **Surveillance**: This refers to use of imaging in asymptomatic patients (patients without objective signs or symptoms of recurrent disease). This imaging is
completed 6 months or more (12 months or more for lymphoma) following completion of treatment.

Important Note
This policy only addresses the use of radiotracers detected with the use of dedicated PET scanners. Radiotracers such as FDG may be detected using single-photon emission computerized tomography (SPECT) cameras, a technique that may be referred to as FDG-SPECT imaging. The use of SPECT cameras for PET radiotracers presents unique issues of diagnostic performance and is not considered in this policy.

Regulatory Status
In 1997, the FDA Modernization Act attempted to resolve the controversy regarding PET scans first by establishing FDA authority over the safety and effectiveness of locally manufactured radiotracers and second, by developing streamlined regulations for good manufacturing practices with which each PET facility must comply.

FDA issued a notice in the Federal Register on March 10, 2000, summarizing the regulatory history of PET radiotracers and highlighting its decisions on safety and effectiveness for certain uses of certain PET radiotracers. FDA conducted a literature review and Advisory Committee meetings to discuss the following uses:

- $^{18}$F-FDG for evaluation of glucose metabolism in oncology
- $^{18}$F-FDG for evaluation of myocardial hibernation
- $^{13}$N-ammonia for evaluation of myocardial blood flow
- $^{15}$O-water for assessment of cerebral perfusion

However, only the first 3 of these were subsequently approved by the FDA. There have been no additional approvals specific to oncologic PET.

A draft guidance document for Current Good Manufacturing Practice (CGMP) requirements was issued on April 1, 2002; though as of October 2003, regulatory procedures had not yet been finalized.


Literature Review
This policy is based on multiple evaluations of PET, including Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessments, other systematic reviews, meta-analyses, decision analyses, and cost-effectiveness analyses. From the perspective of evidence-based medicine, overall, the literature on use of PET scanning in oncology is quite limited. There are few rigorous studies that assess the impact of PET on clinical outcomes. Most of the studies that report on outcomes describe changes in staging and/or treatment that result from the PET scan; however, the studies do not evaluate whether or not these changes result in an improvement in the net health outcome.

A 1997 TEC Assessment considered the use of PET scanning in the evaluation of solitary pulmonary nodules and staging of known lung cancer.(1) A 2006 evidence report by TEC for the Agency for Healthcare Research and Quality (AHRQ) addressed use of PET for staging small cell lung cancer (SCLC).(2) Three 1999 TEC Assessments(3-5) and one 2000 TEC Assessment(6) considered the use of PET scanning in the evaluation of melanoma, lymphoma, colorectal, and head and neck cancer. TEC Assessments from 2000 and 2002 addressed unknown primaries.(6,7) One 2001 TEC Assessment, a 2002 decision analysis,
and a 2005 systematic review focused on esophageal cancer.(8-10) Pancreatic cancer was evaluated in a 1999 TEC Assessment and the 2004 AHRQ systematic review.(11,12) The 2004 AHRQ systematic review also focused on ovarian cancer, as well as testicular cancer. Soft tissue sarcoma was the subject of a 2002 AHRQ systematic review.(13) Breast cancer was the focus of 2 TEC Assessments from 2001 and 2003, a systematic review from 2005, a systematic review from 2007, and a cost-effectiveness analysis from 2005.(14-18) Several uses of PET were reviewed in National Comprehensive Cancer Network (NCCN) Task Force documents released in 2007 and 2009.(19,20) Another AHRQ systematic review evaluating use of PET for 9 cancers was published in 2008.(21) Systematic reviews and meta-analyses published in 2011 and 2012 address 10 indications for 9 malignancies (22, Barger, 2012 #12, 23-34). In the Assessments, PET scanning was considered an adjunct to other imaging methods (i.e., CT, MRI, ultrasonography) often used when previous imaging studies are inconclusive or provide discordant results. In this setting, the clinical value of PET scans is the rate of discordance among imaging techniques and the percentage of time that PET scanning results in the correct diagnosis, as confirmed by tissue biopsy. The Assessments and other reviews offered the following observations and conclusions:

**Bone Cancer**

A systematic review and meta-analysis of studies examining the diagnostic accuracy of PET in Ewing sarcoma showed very high estimates of sensitivity and specificity (pooled sensitivity 96%, pooled specificity 92%).(35) Another study of PET in pediatric sarcoma (Ewing sarcoma and osteosarcoma) patients in which PET was used in addition to conventional imaging showed that PET was superior to conventional imaging in detecting lymph node and bone involvement.(36) The most thorough assessment of cancer involvement involved using both PET and conventional tests and produced important changes in therapy decisions.

There are very few studies examining the utility of PET in chondrosarcoma.

**Brain Tumors**

A systematic review and meta-analysis addressed use of fluorine-18 fluoro-ethyl-tyrosine (FET) in detecting primary brain tumors.(22) While it used a sophisticated meta-analytic method, it did not compare use of 18F-FET PET with another imaging modality for diagnosis of brain tumors, so no conclusions can be reached about comparative effectiveness. A 2013 meta-analysis found limited utility for 18F-FDG-PET in differentiating brain tumors.(37) Diagnostic performance was better with 11C-methionine PET. However, another meta-analysis found dynamic susceptibility contrast-enhanced MRI performed better than 11C-methionine PET in glioma recurrence detection.(38)

**Breast Cancer**

The 2001 TEC Assessment(14) focused on multiple applications of PET scanning in breast cancer, including characterization of breast lesions, staging axillary lymph nodes, detection of recurrence, and evaluating response to treatment. The 2003 TEC Assessment(15) re-examined all of these indications except for its role in characterizing breast lesions.

- The bulk of the data regarding PET scanning for breast cancer focuses on its use as a technique to further characterize breast lesions such that patients could avoid biopsy of a mammographically indeterminate or suspicious lesion. The key statistic in this analysis is the false negative rate, because patients with a false negative result on a PET scan may inappropriately forego a biopsy and subsequent treatment. The false negative rate will vary with the underlying
prevalence of the disease, but may range from 5.5% to 8.5%. Given the relative ease of breast biopsy, this false negative rate may be considered unacceptable, and thus patients may undergo biopsy regardless of the results of a PET scan.

- A 2005 systematic review and meta-analysis(16) focused on use of PET for detecting recurrence and metastases. The report concluded that PET is a valuable tool; however, it did not compare PET performance with that of other diagnostic modalities, so it is unclear if PET results in different management decisions and health outcomes.

A systematic review published in 2007(18) on use of PET for staging axillary lymph nodes identified 20 studies. Of these, 3 studies were rated with the highest quality grade, corresponding to broad generalizability to a variety of patients and no significant flaws in research methods. The remaining studies were more flawed and/or were more narrowly generalizable. The review observed that there was great variability in estimates of sensitivity and specificity from the selected studies and that it is difficult to draw conclusions from the evidence.

A 2013 meta-analysis by Hong et al reported sensitivity and specificity of PET-CT in diagnosing distant metastases in breast cancer patients were 0.96 (95% confidence interval [CI], 0.90 to 0.98) and 0.95 (95% CI, 0.92 to 0.97) when 8 studies totaling 748 patients were evaluated.(39) When the meta-analysis was completed on 6 comparative studies totaling 664 patients, the sensitivity and specificity were 0.97 (95% CI, 0.84 to 0.99) and 0.95 (95% CI, 0.93 to 0.97), compared with 0.56 (95% CI, 0.38 to 0.74) and 0.91(95% CI, 0.78 to 0.97) with conventional imaging.

Rong et al in 2013 meta-analyzed 7 studies totaling 668 patients and reported PET-CT sensitivity and specificity were greater than bone scintigraphy for detecting bone metastasis in breast cancer patients.(40) PET-CT sensitivity and specificity were 0.93 (95% CI, 0.82 to 0.98) and 0.99 (95% CI, 0.95 to 1.00), compared with 0.81 (95% CI, 0.58 to 0.93) and 0.96 (95% CI, 0.76 to 1.00) with bone scintigraphy.

An NCCN review of PET(19) concluded that PET is optional and may be useful in staging and restaging regional or distant metastasis when the suspicion is high and other imaging is inconclusive. PET or PET-CT are not recommended by the NCCN for staging breast cancer due to high false negative rates in detecting lesions less than 1 cm or low grade, low sensitivity in detecting axillary node metastasis, the low prior probability of detectable metastases in these patients, and high false positive rates. Additionally, NCCN does not recommend the routine use of PET scans in asymptomatic patients for surveillance and follow-up after breast cancer treatment.

Two meta-analyses pooled studies on use of FDG PET to predict pathologic response to neoadjuvant therapy before surgery for locally advanced breast cancer.(24) These articles report similar pooled point estimates of both sensitivity and specificity. They both concluded that PET has reasonably high sensitivity and relatively low specificity. Neither article describes how PET should be used to influence patient management decisions and therefore whether health outcomes would be changed relative to decisions not based on PET results. Thus, it is unclear whether PET improves outcomes for predicting pathologic response to neoadjuvant therapy for locally advanced breast cancer.

Cervical Cancer

An AHRQ review published in 2008 identified several studies in which PET or PET/CT was used in the staging of advanced cervical cancer and for detection and staging of recurrent disease.(21) The report concluded that most studies supported enhanced diagnostic accuracy, which would improve the selection of appropriate treatment for
patients. For recurrent disease, PET identifies additional sites of metastasis which would alter treatment decisions in some cases. For example, in a study by Yen et al (41) of 55 patients whose recurrences were initially considered curable with radical surgical treatment, 27 instead underwent palliative therapy based on PET results. An NCCN Task Force Report on PET (20) also identifies several studies that support use of PET for initial staging and identification and staging of recurrent disease. NCCN guidelines indicate PET-CT “may aid in treatment planning but is not accepted for formal staging purposes.” (42)

In a 2013 meta-analysis of 9 cervical cancer recurrence studies, Meads et al reported sensitivity and specificity of PET-CT were 94.8 (95% CI, 91.2 to 96.9) and 86.9% (95% CI, 82.2 to 90.5), respectively. (40). The authors found the quality of studies on recurrence were average and had some limitations. For example, studies included mostly symptomatic women and did not differentiate between usage for diagnosis and surveillance. NCCN guidelines recommend only a single PET-CT be done at 3 to 6 months after therapy for locally advanced cervical cancer for detecting persistent or recurrent disease but PET-CT is not recommended for surveillance. (42)

Colorectal Cancer

- Two clinical applications of PET scanning were considered in the TEC Assessment: (1) To detect hepatic or extrahepatic metastases and to assess their resectability in patients with colorectal cancer, either as part of initial staging or after primary resection, and (2) to evaluate the presence of postoperative scar versus recurrent disease as a technique to determine the necessity of tissue biopsy.

- The body of evidence indicates that PET scanning adds useful information to conventional imaging in detecting hepatic and extrahepatic metastases. In particular, PET can detect additional metastases leading to more identification of nonresectable disease, allowing patients to avoid surgery. The strongest evidence comes from a study that directly assessed the additional value of PET. In a group of 37 patients thought to have solitary liver metastases by conventional imaging, PET correctly upstaged 4 patients and falsely overstaged 1 patient. This study and another further found that, when PET is discordant with conventional imaging, PET is correct in 88% and 97%, respectively, of patients. When PET affects management decisions, it is more often used to recommend against surgery.

- When used to distinguish between local recurrence and scar, the comparison is between performing histologic sampling in all patients with a suspected local recurrence and avoiding sampling in patients whose PET scans suggest the presence of postoperative scar. The key concern is whether the negative predictive value (NPV) for PET is sufficiently high to influence decision making, specifically to avoid tissue biopsy when the PET scan is negative. The available studies suggest a probability of false negative results of 8%, making it unlikely that patients and physicians would be willing to forgo histologic sampling and delay potentially curative repeat resection.

- A systematic review of different imaging techniques for radiotherapy treatment planning of rectal cancer concluded that additional studies are needed to validate the use of PET in this setting. (25)

In a 2013 meta-analysis, Lu et al evaluated 510 patients from 11 studies on PET for colorectal cancer tumor recurrence detection in patients with CEA elevation. (43) FDG-PET and PET-CT pooled estimate sensitivities were 90.3% (95% CI, 85.5% to 94.0%) and 94.1% (95% CI, 89.4% to 97.1%), while specificities were 80.0% (95% CI, 67.0% to 89.6%) and 77.2% (95% CI, 66.4% to 85.9%), respectively.
The NCCN guideline for colon cancer "strongly discourages the routine use of PET-CT scanning for staging, baseline imaging or routine follow-up and recommends consideration of a preoperative PET-CT scan at baseline only if prior anatomic imaging indicates the presence of potentially surgically curable M1 disease."(44) NCCN panel opinion is divided on appropriateness of PET-CT when CEA level is rising but indicate it may be considered when imaging study results (e.g., a good quality CT scan), are normal.

The NCCN guideline for rectal cancer indicates PET-CT is “not routinely indicated” and “should only be used to evaluate an equivocal finding on a contrast-enhanced CT scan.”(45)

**Esophageal Cancer**

- Regarding initial diagnosis, PET is generally not considered a test for detecting primary esophageal tumors, and evidence is lacking on its use to differentiate between esophageal cancer and benign conditions.

An NCCN Task Force report found studies showing that PET is more sensitive than other diagnostic imaging in detecting stage IV disease with distant lymph node involvement. A meta-analysis described in the report found a 67% pooled sensitivity, 97% specificity, and small added value after conventional staging in detecting distant metastasis.(20) In a 2013 meta-analysis of 245 patients with esophageal cancer from 6 studies, Shi et al reported that for detection of regional nodal metastases, FDG PET-CT had a sensitivity of 0.55 (95% CI, 0.34 to 0.74) and specificity of 0.76 (95% CI, 0.66 to 0.83).(46) The NCCN guideline on esophageal cancer indicates PET-CT may be considered if there is no evidence of M1 disease.(47)

Another use of PET in esophageal cancer is in determining whether to continue chemotherapy for potential curative resection. The NCCN Task Force Report describes several studies in which response to chemotherapy as defined as a decline in standardized uptake values correlated with long-term survival.(20) Patients who do not respond to chemotherapy may benefit by this test by being spared futile and toxic chemotherapy. However, this treatment strategy of PET-directed chemotherapy does not appear to have been validated with randomized controlled trials (RCTs) showing improved overall health outcomes. The NCCN guideline on esophageal cancer indicates PET-CT may be considered to assess treatment response 5-6 weeks after preoperative therapy.(47)

**Gastric Cancer**

A systematic review and meta-analysis pooled 9 studies on evaluating recurrent gastric cancer.(33) The meta-analysis used methods that do not adequately account for dependence of sensitivity and specificity, nor do they adequately handle covariates that might explain between-study heterogeneity. It concluded that PET combined with CT may be more effective than either modality alone, but the data presented do not support this conclusion. In a 2013 meta-analysis, the sensitivity of PET-CT for detecting recurrence of gastric cancer after surgical resection was 0.86 (95% CI, 0.71 to 0.94), and specificity was 0.88 (95% CI, 0.75 to 0.94).(48)

The NCCN guidelines on gastric cancer indicate PET-CT (but not PET alone) may be used as part of an initial workup if there is no evidence of metastatic disease.(49) The guidelines note the sensitivity of PET-CT is lower than CT, but the specificity is higher than CT and adds value to the diagnostic workup. The NCCN guidelines also indicate PET-CT may be used to evaluate response to treatment.
Head and Neck Cancer

- Among the 3 studies identified in the TEC Assessment that used other diagnostic modalities to attempt to identify a primary tumor in patients with positive cervical lymph nodes, PET found more primary tumors than other modalities in 2 studies and identified similar proportions in 1 study.\(^{(6)}\) When data from these 3 studies are pooled, PET was found to identify tumor in 38% of cases and other modalities found tumor in 21% of cases.

- When PET is used to initially stage the cervical lymph nodes (i.e., the status of the cervical nodes is unknown), the addition of PET to other imaging modalities increased the proportion of patients who were correctly staged, as confirmed histologically. When compared head to head with other imaging modalities, the pooled data from a variety of studies suggested that PET had a better diagnostic performance compared with CT and MRI.

- Of 8 studies focusing on the use of PET to detect residual or recurrent disease, 5 found PET to be more specific and sensitive, 2 reported mixed or equivalent results, and 1 reported worse results compared with CT.

Meta-analyses in 2013 have reported good sensitivities and specificities with PET-CT for detecting head and neck cancer metastases (better than bone scintigraphy \(^{(50)}\)) and recurrence.\(^{(51)}\) The NCCN guidelines on head and neck cancer indicate PET-CT may be appropriate for stage III-IV disease evaluation, for detection of metastases or recurrence, and for evaluation of response to treatment.\(^{(52)}\)

Lung Cancer

- PET scanning may have a clinical role in patients with solitary pulmonary lung nodules in whom the diagnosis is uncertain after prior CT scan and chest radiograph. Patients who are relatively young and have no smoking history are at a relatively low risk for lung cancer, and in this setting the NPV of a PET scan is relatively high. If presented with a negative PET scan and information about the very low probability of undetected malignancy, it is quite likely that some patients would choose to avoid the harms of an invasive sampling procedure (i.e., biopsy). A meta-analysis on evaluating pulmonary nodules using dual-time PET (a second scan added after a delay) found that its additive value relative to a single PET scan is questionable.\(^{(34)}\)

- In patients with known non-small-cell lung cancer, the clinical value of PET scanning relates to improved staging information regarding the involvement of mediastinal lymph nodes, which generally excludes patients from surgical excision. The TEC Assessment\(^{(1)}\) cited a decision-analysis study that suggested that the use of CT plus PET scanning in staging the mediastinal lymph nodes resulted in fewer surgeries and an average gain in life expectancy of 2.96 days. The gain in life expectancy suggests that avoidance of surgery was not harmful to the patients in that potentially beneficial surgery was not withheld on the basis of false positive imaging results.

- An NCCN report on the use of PET scanning\(^{(19)}\) supports an indication for patients who are suspected to have solitary metastases who may be candidates for surgical resection. In such patients, the test may detect additional metastases, which would rule out or change the extent of planned surgery.

- Six studies of patients with SCLC reported evidence suggesting that for nonbrain metastases, PET added to conventional staging is more sensitive in detecting disease than conventional staging alone.\(^{(2)}\) PET may correctly upstage and
downstage disease, and studies reported very high occurrence of patient management changes that were attributed to PET. However, the quality of these studies is consistently poor, and insufficient detail in reporting was the norm, especially with respect to the reference standard. A systematic review of staging SCLC found PET to be more effective than conventional staging methods; however, this review was heavily flawed by not conducting a quality assessment of individual studies, so its conclusions may not be sound. (27) It is not possible from the limited and poor quality evidence that is available to determine whether the use of PET adds value relative to conventional staging tests for SCLC.

• Meta-analyses in 2013 have reported good sensitivities and specificities in lung cancer detection with PET-CT. (53, 54)

The American College of Chest Physicians issued guidelines on the diagnosis and management of lung cancer in 2013. (55) The guidelines state that RCTs support the use of PET or PET-CT scanning as a component of lung cancer treatment and recommend PET or PET-CT for staging, detection of metastases, and avoidance of non-curative surgical resections.

The NCCN guidelines on non-small-cell lung cancer indicate PET may be used in the staging of disease, detection of metastases, treatment planning, and detection of disease recurrence. (56). However, PET is not recommended for detection of brain metastasis from lung cancers. The NCCN guidelines on SCLC indicate PET may be used in the staging of disease and treatment planning but “is not recommended for routine follow-up.” (57)

Lymphoma, Including Hodgkin Disease

• Of the 14 available studies reviewed in the TEC Assessment, (4) 3 compared PET with anatomic imaging in initial staging and restaging of patients with Hodgkin disease and non-Hodgkin lymphoma. Two of these studies included data from both diseased and nondiseased sites for PET and CT. Both studies found PET to have better overall diagnostic accuracy than CT. The third study addressed detection of diseased sites only and found PET to have the same sensitivity as use of CT or MRI. Among the 6 studies that reported on concordance between PET and other imaging modalities, PET was discordant with other modalities in 11% to 50%. PET was correct among discordances in 40% to 75%. PET has been reported to affect patient management decisions in 8% to 20% of patients in 5 studies mainly by correctly upstaging disease, but also by correctly downstaging disease. Thus when PET is added to conventional imaging, it can provide useful information for selective effective treatment that is appropriate to the correct stage of disease.

• Meta-analyses in 2013 have reported good sensitivities and specificities with PET-CT in the detection of newly diagnosed Hodgkin lymphoma (58) and diffuse large B cell lymphoma. (59)

The NCCN guidelines for non-Hodgkin lymphoma and Hodgkin lymphoma indicate PET-CT may be used in staging, restaging, and evaluating treatment response. (60, 61)

Melanoma

• Surgical resection for melanoma is limited to those with local disease. Patients with widespread disease are not candidates for resection. Frequently, there is microscopic spread to the proximal lymph nodes. Therefore, patients with a high risk of nodal spread, as assessed by the thickness of the primary melanoma, may be candidates for lymph node sampling, termed sentinel node biopsy. PET
scanning has been investigated both as a technique to detect widespread disease as part of an initial staging procedure, and also to evaluate the status of the local lymph nodes to determine the necessity of sentinel node biopsy.

- To consider PET a useful alternative to sentinel node biopsy, it must have high sensitivity and specificity when either sentinel node biopsy or lymph node dissection serves as the reference standard. In the only study of this kind, PET had a sensitivity of only 17%, suggesting that PET rarely detects small metastases that can be discovered by sentinel node biopsy. Thus the TEC Assessment concluded that PET is not as beneficial as sentinel node biopsy in assessing regional lymph nodes. (3)

- The intent of using PET to detect extranodal metastases is to aid in selecting treatment appropriate to the patient's extent of disease. For example, surgical resection is typically not appropriate for widespread disease. A prospective blinded study of 100 patients found that PET was much more sensitive and specific than conventional imaging. Another prospective study of 76 patients found that, compared with CT, PET had much higher sensitivity and equivalent specificity. A third comparative study of 35 patients found that PET was much more sensitive than CT. It may be inferred from these studies that PET was usually correct when discordant with other modalities. PET affects management in approximately 18% of patients.

The NCCN guidelines on melanoma indicate PET-CT may be used for staging and restaging for more advanced disease such as stage III. PET-CT is not recommended for stage I or II disease. (62) PET-CT is also listed as an option for surveillance screening for recurrence or metastatic disease.

Multiple Myeloma

Two systematic reviews, one of which also conducted a meta-analysis, addressed PET for staging of multiple myeloma. (26,32) Neither report compared the diagnostic performance of PET with other imaging modalities, so they do not support conclusions about comparative effectiveness.

Neuroendocrine Tumors

Two meta-analyses from the same investigators addressed use of PET in patients with neuroendocrine tumors (NETs). (29,30) One report included patients with thoracic and gastroenteropancreatic NETs who had imaging with PET using gallium 68 somatostatin receptor (SMSR) radiotracers. (29) The other article included studies of paragangliomas scanned by PET with fluorine-18 dihydroxyphenylalanine (DOPA). (30) Neither study compared PET with other imaging modalities, precluding conclusions about comparative diagnostic performance.

Ovarian Cancer

- For primary evaluation (i.e., in patients with suspected ovarian cancer), the ability to rule out malignancy with a high NPV would change management by avoiding unnecessary exploratory surgery. However, available studies suggest that PET scanning has poorer NPV compared with other options, including transvaginal ultrasound (TVUS), Doppler studies, or MRI. Adding PET scanning to TVUS or MRI did not improve results.

- Positive predictive value is of greatest importance in evaluating patients with known ovarian cancer, either to detect disease recurrence or progression or monitor response to treatment. While the 2004 AHRQ systematic review (12)
suggested that PET may have value for detecting recurrence when CA125 is elevated and conventional imaging does not clearly show recurrence, this had not been demonstrated in an adequately powered prospective study. A 2008 AHRQ systematic review found that the evidence supported the use of PET-CT in detecting recurrent ovarian cancer.(21) The evidence for initial diagnosis and staging of ovarian cancer was still inconclusive.

A 2013 meta-analysis found PET-CT was useful in detecting ovarian cancer recurrence. (63) American College of Radiology Appropriateness Criteria also issued in 2013 indicates PET-CT is appropriate for detecting and restaging ovarian cancer recurrence.(64) NCCN guidelines for ovarian cancer indicate PET-CT may be appropriate “for indeterminate lesions if results will alter management.”(65) PET-CT may also be appropriate if clinically indicated after complete remission for follow-up and monitoring for recurrence.

**Pancreatic Cancer**

- Both the 2004 AHRQ systematic review(12) and the 1999 TEC Assessment(11) focused on 2 clinical applications of PET scanning in patients with known or suspected pancreatic cancer: the use of PET to distinguish between benign or malignant pancreatic masses, and the use of PET as a staging technique in patients with known pancreatic cancer.

- In terms of distinguishing between benign and malignant disease, the criterion standard is percutaneous or open biopsy. If PET were to be used to allow patients with scans suggesting benign masses to avoid biopsy, a very high NPV would be required. The key statistic underlying the NPV is the false negative rate. Patients with false negative results are incorrectly assumed to have benign disease and are thus not promptly treated for pancreatic cancer. Based on the literature review, the NPV ranged between 75% and 92% depending on an underlying prevalence of disease ranging from 50% to 75%. The Assessment concluded that this level of diagnostic performance would not be adequate to recommend against biopsy. The 2004 AHRQ report found that PET was sometimes found to be more accurate than other modalities, but the meta-analysis stated that it is unclear whether PET’s diagnostic performance surpasses decision thresholds for biopsy or laparotomy.(12)

- In both the TEC Assessment and AHRQ systematic review, there were inadequate data to permit conclusions regarding the role of PET scanning as a technique to stage known pancreatic cancer.

- The AHRQ review published in 2008 and past NCCN guidelines on pancreatic carcinoma suggest that PET-CT may be useful for staging in certain patients when the standard staging protocol is inconclusive.(20,21) Recent NCCN guidelines indicate “the role of PET-CT remains unclear.”(66) The guidelines state PET-CT “may be considered after formal pancreatic CT protocol in high-risk patients to detect extra pancreatic metastasis.”

**Penile Cancer**

A systematic review and meta-analysis of PET focused on staging inguinal lymph nodes among patients with penile squamous cell carcinoma. No comparisons were made with other imaging modalities. The report found that PET had low sensitivity and authors concluded that PET is not suited for routine clinical use.(28)
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Prostate Cancer

Both an NCCN Task Force Report(20) and an AHRQ systematic review(21) did not find sufficient evidence to support use of PET for any indication in patients with prostate cancer. Reports show significant overlap between benign prostatic hyperplasia, malignant tumor, local recurrence, and postoperative scarring. PET may have limited sensitivity in detecting distant metastatic disease. The AHRQ report identified only 4 studies of PET for the indications of restaging and recurrence, none of which addressed the effect of PET on management decisions.

In a meta-analysis of 10 studies (n=637) by Umbehr et al on initial prostate cancer evaluation, pooled sensitivity was 84% (95% CI, 68% to 93%) and specificity was 79% (95% CI, 53% to 93%).(67) In the analysis of 12 studies (n=1055) on patients with biochemical failure after local treatment, the pooled sensitivity was 85% (95% CI, 79% to 89%) and specificity was 88% (95% CI, 73% to 95%).

In a meta-analysis by von Eyben and Kairemo, the pooled sensitivity and specificity of choline PET-CT for detecting prostate cancer recurrence in 609 patients was 0.62 (95% CI, 0.51 to 0.66) and 0.92 (95% CI, 0.89 to 0.94), respectively.(68) In an evaluation of 280 patients from head-to-head studies comparing choline PET-CT with bone scans, PET-CT identified metastasis significantly more often than bone scanning (127 [45%] vs 46 [16%], respectively; odds ratio, 2.8; 95% CI, 1.9 to 4.1; p<0.001). The authors also reported results of the choline PET-CT changed treatment in 381 (41%) of 938 patients. Complete prostate-specific antigen (PSA) response occurred in 101 of 404 (25%) patients.

Mohsen et al conducted a meta-analysis on 23 studies on C11-acetate PET imaging for primary or recurrent prostate cancer.(69) Pooled sensitivity for primary tumor evaluation was 75.1% (69.8% to 79.8%) and specificity was 75.8% (72.4% to 78.9%). For detection of recurrence, sensitivity was 64% (59% to 69%) and specificity was 93% (83% to 98%). While study quality was considered poor, low sensitivities and specificities appear to limit the utility of C11-acetate imaging.

NCCN guidelines on prostate cancer indicate C11-choline PET may be considered for biochemical failure after primary treatment (i.e., radiation therapy or radical prostatectomy).(70) NCCN considers PET investigational for initial diagnosis and staging and notes FDG or fluoride PET should not be used in the community setting outside of a registry. Additionally, the routine use of PET-CT is not recommended due to limited evidence on its utility.

The European Association of Urology guidelines on prostate cancer indicate C11-choline PET-CT has limited value unless PSA levels are greater than 1.0 ng/mL.(71)

Recent meta-analyses do not report strong evidence for the use of PET or PET-CT in the initial staging or management of prostate cancer or in the evaluation of possible recurrence related to biochemical failure. Studies evaluated contained large heterogeneity including the use of different radiotracers and PET with and without CT. Pooled sensitivities and specificities for the use of PET in initial prostate cancer treatment are generally low with wide ranges reported. While pooled sensitivities and specificities reported may be higher for PET for the detection of prostate cancer recurrence, further studies are needed for comparison of PET and PET-CT with other imaging techniques, such as MRI and radionuclide bone scan.

Soft Tissue Sarcoma

- A 2002 AHRQ systematic review on use of PET for soft tissue sarcoma(13) evaluated 5 applications: distinguishing between benign lesions and malignant soft tissue sarcoma, distinguishing between low-grade and high-grade soft tissue
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sarcoma, detecting locoregional recurrence, detecting distant metastases, and evaluating response to therapy.

- The review found that PET has low diagnostic accuracy in distinguishing low-grade tumors from benign lesions. PET performs better at differentiating high- or intermediate-grade tumors from low-grade tumors; however, it is unclear whether this will have an impact on management decisions and health outcomes. Evidence is insufficient on the comparative diagnostic performance of PET and alternative diagnostic modalities in the diagnosis of soft tissue sarcoma, detection of locoregional recurrence, detection of distant metastasis, and evaluating response to therapy.

- A systematic review looked at PET for evaluating response to imatinib and other treatments for gastrointestinal stromal tumors. The report lacked a fundamental feature of well-performed systematic review: appraisal of the methodologic quality of individual studies. The review also lacked comparison of decision making and outcomes of PET-guided management with management guided without PET.

Testicular Cancer

- The 2004 AHRQ systematic review found 1 prospective study and 4 retrospective studies that generally showed higher sensitivity and specificity for PET over CT. However these studies were small in size and failed to report separate results for patients with seminoma versus those with nonseminoma. Studies also failed to report separate results by clinical stage of disease. Thus, it is unclear whether this evidence translates to changes in patient management and improved health outcomes.

- Studies on distinguishing between viable tumor and necrosis/fibrosis after treatment of testicular cancer were flawed in 2 main ways. First, most studies did not compare the diagnostic accuracy of PET with other imaging modalities. Second, studies that did compare PET and CT did not state a clear threshold for a positive CT test, making study results difficult to interpret. Therefore, it is uncertain whether use of PET leads to different patient management decisions and health outcomes than other imaging modalities.

An AHRQ technology assessment published in 2008 and studies evaluating residual masses in patients after chemotherapy for seminoma support the use of PET. NCCN guidelines support the use of PET for this indication.

Thyroid Cancer, Differentiated

The NCCN Task Force Report on PET reviewed studies which showed that PET can localize recurrent disease when other imaging tests are negative. In addition, PET is a predictor of prognosis in this setting. More metabolically active lesions on PET are strongly correlated with survival. Current NCCN guidelines on thyroid cancer continue to support the use of PET in thyroid cancer evaluations such as when iodine 131 imaging is negative and stimulated thyroglobulin is greater than 2-5 ng/mL.

Thyroid Cancer, Poorly Differentiated

A meta-analysis of studies on detecting recurrent or metastatic medullary thyroid carcinoma did not compare PET with other imaging modalities and did not clearly perform quality assessment of individual studies or incorporate study quality concerns into conclusions.
**Unknown Primary**

- The 2002 TEC Assessment(7) concluded that the TEC criteria were met for the limited indication of the workup and management of patients with unknown primaries and a single site of metastatic disease. Specifically, local or regional therapy may be offered to these patients. In this setting, PET scanning may be used to verify the absence of disseminated disease.

- Regarding this application, the TEC Assessment identified 4 reports, including a total of 47 patients referred for imaging with a single known metastatic site from an unknown primary. In 13 (28%) of these patients, PET scanning identified previously undetected metastases that were confirmed by biopsy. Therefore, the use of PET can contribute to optimal decision making regarding the appropriateness of local or regional therapy.

**Cancer Surveillance**

The clinical utility for PET scanning in surveillance (i.e., in performing follow-up PET scans in asymptomatic patients to detect early disease recurrence), is not well-studied. (For this policy, a scan is considered a surveillance scan if performed more than 6 months following therapy, but 12 months for lymphoma.) The most recent NCCN publication(20) indicates, "The use of PET as a surveillance tool should only be used in clinical trials." In addition, the NCCN guidelines for various malignancies often note that PET scans are not recommended in asymptomatic patients. For example, the NCCN breast cancer guidelines comment that PET scans (as well as many other modalities) provide no advantage in survival or ability to palliate recurrent disease and are not recommended.(73)

**Other Malignancies**

There are inadequate scientific data to permit conclusions regarding the role of PET scanning in other malignancies.

**Summary**

The utility of positron emission tomography (PET) scanning for the diagnosis and staging of malignancies varies by specific type of cancer. In general, PET scanning can be useful for distinguishing benign from malignant masses in certain circumstances and for increasing the accuracy of staging by detecting additional disease not detected by other imaging modalities. Therefore, PET scanning for diagnosis and staging of malignancies can be considered medically necessary when specific criteria are met for specific cancers, as outlined in the policy statement. For follow-up after the initial diagnosis and staging has been performed, there are a few situations in which PET can improve detection of recurrence, which may lead to a change in management. For routine tumor surveillance, the clinical utility is uncertain and this use of PET scanning is considered investigational.

**Medicare National Coverage**

The Medicare coverage policy regarding PET scans(75) that was updated in 2009 is summarized in the Appendix Table.

**References**


**Documentation Required for Clinical Review**

- History and physical and/or consultation notes including:
  - Indication for PET scan
  - Previous treatment and response
- Previous Imaging reports (e.g., CT, MRI, SPECT)
- Pathology reports (if applicable)

**Post Service**

- PET report
This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**Coding**

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

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<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>78812</td>
<td>Positron emission tomography (PET) imaging; skull base to mid-thigh</td>
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<td>Positron emission tomography (PET) imaging; whole body</td>
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<td>Sodium fluoride f-18, diagnostic, per study dose, up to 30 millicuries</td>
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<tr>
<td></td>
<td>G0219</td>
<td>Pet imaging whole body; melanoma for non-covered indications</td>
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<td>G0235</td>
<td>Pet imaging, any site, not otherwise specified</td>
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<td>G0252</td>
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<td>Fluorine-18 fluorodeoxyglucose (f-18 FDG) imaging using dual-head coincidence detection system (non-dedicated PET scan)</td>
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**Medical Policy**

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<th>ICD-9 Procedure</th>
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**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.