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Clinical Policy Bulletin: Positron Emission Tomography (PET)

Number: 0071**Policy****I. Cardiac Indications:**

Aetna considers positron emission tomography (PET) medically necessary for the following cardiac indications:

A. Evaluation of Coronary Artery Disease:

PET scans using rubidium-82 (Rb-82) or N-13 ammonia done at rest or with pharmacological stress are considered medically necessary for noninvasive imaging of the perfusion of the heart for the diagnosis and management of members with known or suspected coronary artery disease, provided such scans meet *either* one of the two following criteria:

1. The PET scan is used in place of, but not in addition to, a single photon emission computed tomography (SPECT), in persons with conditions that may cause attenuation problems with SPECT (obesity (BMI greater than 40), large breasts, breast implants, mastectomy, chest wall deformity, pleural or pericardial effusion); *or*
2. The PET scan is used following an inconclusive SPECT scan (i.e., the results of the SPECT are equivocal, technically uninterpretable, or discordant with a member's other clinical data).

In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the member.

B. Assessment of Myocardial Viability:

FDG-PET scans are considered medically necessary for the determination of myocardial viability prior to revascularization, either as a primary or initial diagnostic study or following an inconclusive SPECT. The greater specificity of PET makes a SPECT following an inconclusive PET not medically necessary.

The identification of members with partial loss of heart muscle movement or hibernating myocardium is important in selecting candidates with compromised ventricular function to determine appropriateness for revascularization. Diagnostic tests such as FDG-PET distinguish

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 > [Review History](#)
 > [Definitions](#)

Additional Information

> [Clinical Policy Bulletin Notes](#)

between dysfunctional but viable myocardial tissue and scar tissue in order to affect the management decisions in members with ischemic cardiomyopathy and left ventricular dysfunction.

II. Oncologic indications:

Aetna considers PET medically necessary for the following oncologic indications, when the following general and disease-specific criteria for diagnosis, staging, restaging and monitoring are met:

- Brain tumors
- Breast cancer
- Cervical cancer
- Colorectal cancer
- Esophageal cancer
- Ewing sarcoma and osteosarcoma
- Fallopian tube cancer
- Gastric cancer
- Gastrointestinal stromal tumors
- Head and neck cancers (excluding cancers of the central nervous system)
- Lymphoma
- Melanoma
- Merkel cell carcinoma
- Multiple myeloma and plasmacytomas
- Neuroendocrine tumors
- Non-small cell lung carcinoma
- Occult primary cancers
- Ovarian cancer
- Pancreatic cancer
- Primary peritoneal cancer
- Small cell lung carcinoma
- Small bowel adenocarcinoma
- Soft tissue sarcoma
- Solitary pulmonary nodules
- Testicular cancer
- Thyroid cancer (excluding metastatic thyroid cancer).

PET-CT Fusion: The fusion of PET and CT imaging into a single system (PET/CT fusion) is considered medically necessary for any oncologic indication where PET scanning is considered medically necessary. PET-CT fusion is considered experimental and investigational for cardiac and neurologic indications; a PET scan without CT is adequate to evaluate the brain and myocardium (NIA, 2005).

A. General Criteria

1. Diagnosis: The PET results may assist in avoiding an invasive diagnostic procedure, or the PET results may assist in determining the optimal anatomic location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal carcinoma, colorectal cancers, and melanoma is rarely considered medically necessary.
2. Staging: PET is considered medically necessary in situations in which clinical management of the member would differ depending on the stage of the cancer identified and *either*.

- the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound); *or*
 - the use of PET would potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the member.
3. Restaging: PET is considered medically necessary for restaging after completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of recurrence. Use of PET is also considered medically necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the member.
 4. Monitoring: PET for monitoring tumor response during the planned course of therapy is not considered medically necessary except for breast cancer. Restaging occurs only after a course of treatment is completed.

B. Disease-Specific Criteria

1. *Characterization of Solitary Pulmonary Nodules (SPNs):*

FDG-PET is considered medically necessary for the characterization of suspected SPNs when the general medical necessity criteria for oncologic indications (above) are met *and* the following conditions are met:

- A concurrent thoracic CT has been performed, which is necessary to ensure that the PET scan is properly coordinated with other diagnostic modalities; *and*
- An indeterminate or possibly malignant lesion, more than 1 cm and not exceeding 4 cm in diameter, has been detected (usually by CT).

The primary purpose of the PET scan of SPN should be to determine the likelihood of malignancy in order to plan the management of the member.

Note: A biopsy is not considered medically necessary in the case of a negative PET scan for SPNs, because the member is presumed not to have a malignant lesion, based upon the PET scan results.

Note: In cases of serial evaluation of SPNs using both CT and regional PET chest scanning, such PET scans are not considered medically necessary if repeated within 90 days following a previous negative PET scan.

2. *Non-Small Cell Lung Carcinoma (NSCLC):*

FDG-PET scans are considered medically necessary for the diagnosis, staging and restaging of non-small cell lung carcinoma (NSLC) when the general medical necessity criteria for oncologic indications (II. A. listed above) are met.

3. *Small Cell Lung Carcinoma (SCLC):*

FDG-PET scans are considered medically necessary for staging of persons with SCLC that has been determined to be clinical stage I (T 1-2, N0) after standard staging evaluation (including CT of the chest and upper abdomen, bone scan, and brain imaging).

4. *Colorectal Cancer and Small Bowel Adenocarcinoma:*

FDG-PET scans are considered medically necessary for diagnosis*, staging, and restaging of colorectal cancer and small bowel adenocarcinoma when the general medical necessity criteria for oncologic indications (II. A. listed above) are met. According to CMS, medical evidence supports the use of FDG-PET as a useful tool in determining the presence of hepatic/extrahepatic metastases in the primary staging of colorectal carcinoma, prior to selecting the treatment regimen. Use of FDG-PET is also supported in evaluating recurrent colorectal cancer or small bowel adenocarcinoma where the member presents with clinical signs or symptoms of recurrence.

*Note: A diagnostic tissue sample is usually obtainable without PET localization. Therefore, PET for diagnosis of colorectal cancer is rarely considered medically necessary.

5. *Lymphoma:*

FDG-PET scans are considered medically necessary for the diagnosis*, staging and restaging of lymphoma when the general medical necessity criteria for oncologic indications (II. A. listed above) are met.

*Note: A diagnostic tissue sample is usually obtainable without PET localization. Therefore, PET for diagnosis of lymphoma is rarely considered medically necessary.

6. *Melanoma:*

FDG-PET scans are considered medically necessary for the diagnosis*, staging, and restaging of melanoma when the general medical necessity criteria for oncologic indications (II. A. listed above) are met. FDG-PET is considered experimental and investigational and not medically necessary for use in evaluating regional nodes in persons with melanoma.

*Note: A diagnostic tissue sample is usually obtainable without PET localization. Therefore, PET for diagnosis of melanoma is rarely considered medically necessary.

7. *Esophageal Cancer:*

FDG-PET is considered medically necessary for the diagnosis*, staging and re-staging of esophageal carcinoma when general medical necessity criteria for oncologic indications (II. A. listed above) are met. Medical evidence is present to support the use of FDG-PET in presurgical staging of esophageal cancer.

*Note: A diagnostic tissue sample is usually obtainable without PET localization. Therefore, PET for diagnosis of esophageal cancer is rarely considered medically necessary.

8. *Gastric cancer:*

FDG-PET is considered medically necessary for diagnosis,* staging and restaging of gastric carcinoma when general medical necessity criteria for oncologic indications (II. A. listed above) are met. Consensus guidelines support the use of FDG-PET in the presurgical staging of gastric cancer.

*Note: A diagnostic tissue sample is usually obtainable without PET localization. Therefore, PET for diagnosis of gastric cancer is rarely considered medically necessary.

9. *Gastrointestinal Stromal Tumors:*

FDG-PET is considered medically necessary for diagnosis*, staging and restaging of gastrointestinal stromal tumors (GIST) when general medical necessity criteria for oncologic indications (II. A. listed above) are met. Consensus guidelines support the use of FDG-PET in the presurgical staging of GIST.

*Note: A diagnostic tissue sample is usually obtainable without PET localization. Therefore, PET for diagnosis of GIST is rarely considered medically necessary.

10. *Head and Neck Cancers:*

FDG-PET scans are considered medically necessary for the diagnosis, staging, and restaging of head and neck cancers (excluding cancers of the central nervous system (CNS)) when general medical necessity criteria for oncologic indications (II.A. listed above) are met. The head and neck cancers encompass a diverse set of malignancies of which the majority is squamous cell carcinomas. Persons with head and neck cancers may present with metastases to cervical lymph nodes but conventional forms of diagnostic imaging fail to identify the primary tumor. Persons with cancer of the head and neck are left with two options, either to have a neck dissection or to have radiation of both sides of the neck with random biopsies. PET scanning attempts to reveal the site of primary tumor to prevent adverse effects of random biopsies or unneeded radiation.

PET scans of the CNS are considered experimental and investigational.

11. *Thyroid Cancer:*

FDG-PET scans are considered medically necessary when general medical necessity criteria for oncologic indications (II. A. listed above) are met, for staging of thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation with an elevated or rising serum thyroglobulin (Tg) greater than 10 ng/ml and negative I-131 whole body scintigraphy.

FDG-PET is considered not medically necessary for determining which members with metastatic thyroid cancer are at highest risk for death, because this information is for informational purposes only and has not been demonstrated to alter member management.

FDG-PET scans are considered experimental and investigational for other thyroid cancer indications, including:

- Use for the initial staging of post-surgical thyroid cancer of cell types that concentrate I-131 poorly; or
- Use of FDG-PET for re-staging of previously treated thyroid cancer of medullary cell origin in persons with an elevated serum calcitonin and negative standard imaging tests.

12. *Breast Cancer:*

FDG-PET scans are considered medically necessary for members with breast cancer for the following indications, where general medical necessity criteria for oncologic indications (II. A. listed above) are met:

- Monitoring tumor response to treatment for persons with locally advanced and metastatic breast cancer when a change in therapy is contemplated; or
- Staging members with distant metastases or restaging members with locoregional recurrence or metastases.

FDG-PET is considered experimental and investigational for the initial diagnosis of breast cancer and for the staging of axillary lymph nodes.

Positron emission mammography is considered experimental and investigational.

13. *Cervical Cancer:*

FDG-PET scans are considered medically necessary for the detection of pre-treatment metastases (staging) in women who are newly diagnosed with cervical cancer and have negative conventional imaging (CT or MRI), when general medical necessity criteria for oncologic indications (II. A. listed above) are met.

FDG-PET scans are considered experimental and investigational for the diagnosis and restaging of cervical cancer.

14. *Ovarian Cancer, Fallopian Tube Cancer and Primary Peritoneal Cancer:*

FDG-PET scans are considered medically necessary for restaging (detecting recurrence) of previously treated women with a rising CA-125 level who have negative or equivocal conventional imaging (CT or MRI) when general medical necessity criteria for oncologic indications (II.A listed above) are met.

FDG-PET scans are considered experimental and investigational for diagnosis, staging, and monitoring of ovarian cancer, fallopian tube cancer and primary peritoneal cancer.

15. *Testicular Cancer:*

FDG-PET scans are considered medically necessary for restaging (detecting recurrence) of testicular cancer in men with previously treated disease who have a residual mass with normal or persistently elevated serum markers (e.g., alpha fetoprotein or serum chorionic gonadotropin) when general medical necessity criteria for oncologic indications (II.A. listed above) are met.

FDG-PET scans are considered experimental and investigational for diagnosis, staging and monitoring of testicular cancer.

16. *Multiple Myeloma and Plasmacytomas:*

FDG-PET scans are considered medically necessary for evaluating suspected plasmacytomas (staging) in persons with multiple myeloma and for restaging of persons with solitary plasmacytomas.

17. *Ewing Sarcoma and Osteosarcoma:*

FDG-PET scans are considered medically necessary for staging and restaging of osteosarcoma and Ewing sarcoma family of tumors.

18. *Soft Tissue Sarcoma:*

FDG-PET scans are rarely medically necessary for soft tissue sarcomas. FDG-PET scans are considered medically necessary for staging prior to resection of an apparently solitary metastasis, or for grading unresectable lesions when the grade of the histopathological specimen is in doubt.

FDG-PET scans are considered experimental and investigational for restaging of soft tissue sarcomas.

19. *Neuroendocrine Tumors:*

FDG-PET scans are considered medically necessary for the diagnosis and staging of persons with neuroendocrine tumors when general medical necessity criteria for oncologic indications (II.A. listed above) are met.

20. *Pancreatic Tumors:*

FDG-PET scans are considered medically necessary for diagnosis and staging of pancreatic tumors where imaging tests (CT or MRI) are equivocal.

21. *Brain Cancer:*

FDG-PET scans are considered medically necessary for diagnosis and staging, where metastatic brain cancer lesions are identified but no primary is found, and for restaging, to distinguish recurrent tumor from radiation necrosis.

22. *Occult Primary:*

FDG-PET is considered medically necessary for staging in carcinomas of unknown primary site in tumors of indeterminate histology where the primary site cannot be identified by endoscopy or other imaging studies (CT, MRI) and where locoregional therapy for a single site of disease is being considered. FDG-PET scans are considered experimental and investigational for diagnosis or restaging of carcinomas of unknown primary.

23. *Merkel Cell Carcinoma:*

PET is considered medically necessary for evaluating (i) the possibility of a skin metastasis from a non-cutaneous carcinoma (e.g., small cell carcinoma of the lung), especially in cases where

CK20 is negative, and (ii) the extent of lymph node and/or visceral organ involvement.

24. *FDG-PET in Place of ^{99m}Tc Skeletal Scintigraphy:*

Due to an interruption in production, there is a temporary shortage of technetium 99-m (^{99m}Tc), which is used in nuclear medicine for skeletal scintigraphy (bone scans). During this shortage, Aetna will consider FDG-PET an acceptable alternative to bone scans for detecting skeletal abnormalities for medically necessary indications.

25. *Additional Experimental and Investigational Oncological Indications:*

Aetna considers PET scans experimental and investigational for the evaluation of bladder cancer, chondrosarcoma, endometrial cancer, gestational trophoblastic neoplasia, hepatobiliary cancer, ileal carcinoma, jejunal adenocarcinoma, kidney cancer, Langerhans cell histiocytosis, leukemia, lymphangiomatosis, malignant thymoma, mesothelioma, neurofibromatosis, Paget's disease (including extra-mammary Paget's disease), peri-ampullary cancer, prostate cancer, skin cancer, thymic carcinoma, vulvar cancer, or for other oncologic indications not listed as medically necessary in this policy.

III. Neurologic Indications:

Aetna considers FDG-PET medically necessary only for pre-surgical evaluation for the purpose of localization of a focus of refractory seizure activity.

Aetna considers PET scans experimental and investigational for Alzheimer disease, dementia, Parkinson's disease, Huntington disease, or for other neurologic indications not listed as medically necessary in this policy.

IV. Other Indications:

Aetna considers FDG-PET experimental and investigational for chronic osteomyelitis, coccidioidomycosis (also known as valley fever, San Joaquin Valley fever, California valley fever, and desert fever), fever of unknown origin, infection of hip arthroplasty, and other indications not listed as medically necessary in this policy.

Note: PET scans for routine screening of asymptomatic members are not considered medically necessary, regardless of the number and severity of risk factors applicable to the member.

Note: PET scanning with a gamma camera is considered experimental and investigational for all indications.

Background

Positron emission tomography also known as positron emission transverse tomography (PETT), or positron emission coincident imaging (PECI), is a non-invasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body. A positron camera (tomograph) is used to produce cross-sectional tomographic images, which are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as 2-[F-18] fluoro-d-glucose (FDG) that are administered intravenously to the member.

Although PET scans using the radioactive glucose analog FDG have proven to be a highly accurate imaging test for diagnosing and staging a variety of non-urolologic cancer types, its role in the management of prostate malignancies is still being defined. The use of PET scanning in the diagnosis and staging of prostate cancer is hampered by the generally low metabolic activity of most prostate tumors and their metastases. It has shown promise for staging and re-staging persons with advanced-stage disease and aggressive tumors suspected by a high tumor grade and high prostate-specific antigen velocity. Further investigations are needed to ascertain the eventual place of PET scans in prostate cancer.

Vees et al (2007) evaluated the value of positron emission tomography (PET)/computed tomography (CT) with either (18)F-choline and/or (11)C-acetate, of residual or recurrent tumor after radical prostatectomy (RP) in patients with a prostate-specific antigen (PSA) level of < 1 ng/ml and referred for adjuvant or salvage radiotherapy. In all, 22 PET/CT studies were performed, 11 with (18)F-choline (group A) and 11 with (11)C-acetate (group B), in 20 consecutive patients (2 undergoing PET/CT scans with both tracers). The median (range) PSA level before PET/CT was 0.33 (0.08 - 0.76) ng/ml. Endorectal-coil magnetic resonance imaging (MRI) was used in 18 patients. Nineteen patients were eligible for evaluation of biochemical response after salvage radiotherapy. There was abnormal local tracer uptake in 5 and 6 patients in group A and B, respectively. Except for a single positive obturator lymph node, there was no other site of metastasis. In the 2 patients evaluated with both tracers there was no pathological uptake. Endorectal MRI was locally positive in 15 of 18 patients; 12 of 19 responded with a marked decrease in PSA level (half or more from baseline) 6 months after salvage radiotherapy. The authors concluded that although (18)F-choline and (11)C-acetate PET/CT studies succeeded in detecting local residual or recurrent disease in about half the patients with PSA levels of <1 ng/ml after RP, these studies can not yet be recommended as a standard diagnostic tool for early relapse or suspicion of subclinical minimally persistent disease after surgery. Endorectal MRI might be more helpful, especially in patients with a low likelihood of distant metastases. Nevertheless, further research with (18)F-choline and/or (11)C-acetate PET with optimal spatial resolution might be needed for patients with a high risk of distant relapse after RP even at low PSA values.

Takahashi et al (2007) noted that 2-(18)F-fluoro-2-deoxy-D-glucose (FDG)-PET imaging in prostate cancer is challenging because glucose utilization in well-differentiated prostate cancer is often lower than in other tumor types. Nonetheless, FDG-PET has a high positive predictive value for untreated metastases in viscera, but not lymph nodes. A positive FDG-PET can provide useful information to aid the clinician's decision on future management in selected patients who have low PSA levels and visceral changes as a result of metastases. On the other hand, FDG-PET is limited in the identification of prostate tumors, as normal urinary excretion of radioisotope can mask pathological uptake. Moreover, there is an overlap in the degree of uptake between prostate cancer, benign prostatic hyperplasia and inflammation. The tracer choice is also important. (11)C-choline has the advantage of reduced urinary excretion, and thus (11)C-choline PET may provide more accurate information on the localization of main primary prostate cancer lesions than MRI or MR spectroscopy. (11)C-choline PET is sensitive and accurate in the pre-operative staging of pelvic lymph nodes in prostate cancer. A few studies are available but there were no PET or PET/CT studies with a large number of patients for tissue confirmation of prostate cancer; further investigations are required.

Greco et al (2008) stated that the patient population with a rising PSA post-therapy with no evidence of disease on standard imaging studies currently represents the second largest group of prostate cancer patients. Little information is still available regarding the specificity and sensitivity of PET tracers in the assessment of early biochemical recurrence. Ideally, PET imaging would allow one to accurately discriminate between local versus nodal versus distant relapse, thus enabling appropriate selection of

patients for salvage local therapy. The vast majority of studies show a relatively poor yield of positive scans with PSA values < 4 ng/ml. So far, no tracer has been shown to be able to detect local recurrence within the clinically useful 1 ng/ml PSA threshold, clearly limiting the use of PET imaging in the post-surgical setting. Preliminary evidence, however, suggested that ¹¹C-choline PET may be useful in selecting out patients with early biochemical relapse (PSA < 2 ng/ml) who have pelvic nodal oligometastasis potentially amenable to local treatment. The authors concluded that the role of PET imaging in prostate cancer is gradually evolving but still remains within the experimental realm. Well-conducted studies comparing the merits of different tracers are needed.

An assessment by the Blue Cross and Blue Shield Association Technology Evaluation Center on PET for breast cancer (2003) stated that FDG-PET for evaluating breast cancer does not meet its criteria for initial staging of axillary lymph nodes, for detection of locoregional recurrence or distant metastasis/recurrence, or for evaluating response to treatment.

CMS has released a decision memorandum on PET for suspected dementia. Although CMS has announced limited coverage of PET to distinguish Alzheimer's disease from frontotemporal dementia when the distinction is uncertain and other criteria are met, the decision memorandum recognized that there is no available literature that directly evaluated the impact on patient outcomes of adding PET in patients with early dementia who have undergone standard evaluation who do not meet the criteria for Alzheimer disease due to variations in the onset, presentation, or clinical course (suggesting other neurodegenerative causes for the disorder such as frontotemporal dementia). In addition, CMS found no trials that examined the impact of PET in changing the management as a surrogate for evaluating PET impact on health outcomes in patients with this sort of difficult differential diagnosis. The assessment also recognized that there are no established cures for either Alzheimer disease or frontotemporal dementia. A paucity of medications are available for Alzheimer's disease, which have a limited ability to decrease the rate of cognitive decline when administered early in the course of the disease. CMS coverage determination was primarily based on the value of PET in providing information useful in "non-medical decision-making." Aetna, however, does not consider non-medical decision-making a medically necessary indication for testing. Because of a lack of adequate evidence that PET scanning alters clinical management of such persons such that clinical outcomes are improved, Aetna considers PET scanning for differentiating Alzheimer disease from frontotemporal dementia experimental and investigational.

An assessment prepared for the California Technology Assessment Forum (CTAF) concluded that PET for Alzheimer's disease does not meet CTAF's criteria (Feldman, 2004). The assessment stated: "The critical question that remains unanswered by this and the other studies of PET in the evaluation of AD/dementia is: To what extent does PET improve diagnostic accuracy beyond what can be obtained with a thorough clinical evaluation? Given that the sensitivity of clinical criteria are reported to be about 80%-90%, it is difficult for any diagnostic test to significantly improve diagnostic accuracy. And given the fact that treatment of the most common non-AD dementias (e.g., Dementia of Lewy Bodies or vascular dementias) with cholinesterase inhibitor drugs is not likely to be harmful and in fact may be beneficial to these patients, it may be that an empirical approach of ruling out reversible causes of dementia and treating all others with cholinesterase inhibitor drugs is appropriate and cost effective."

The assessment noted that the greatest promise of PET in Alzheimer disease is likely to be in improving a clinician's ability to identify at-risk patients and to offer them treatment before they are significantly affected by Alzheimer disease. Few studies, however, have enrolled patients with mild symptoms or mild cognitive impairment so it is unclear what role PET is destined to play in identifying this subgroup of patients most likely to benefit from current and emerging therapies for Alzheimer's disease.

A proposed decision memo for FDG-PET for infection and inflammation from the CMS (Phurrough et al, 2007) stated that there is insufficient evidence to conclude that FDG-PET for chronic osteomyelitis, infection of hip arthroplasty and fever of unknown origin are reasonable and necessary. Thus, CMS proposed to continue national non-coverage for these indications.

Positron emission tomography has limited sensitivity for mesothelioma. Furthermore, current guidelines have not incorporated PET scanning into the management of persons with mesothelioma. The available literature on the effect of PET on clinical outcomes of malignant mesothelioma are limited. In a small feasibility study, Francis and colleagues (2007) evaluated the role of serial (18)F-FDG PET in the assessment of response to chemotherapy in patients with mesothelioma. Patients were prospectively recruited and underwent both (18)F-FDG PET and conventional radiological response assessment before and after 1 cycle of chemotherapy. Quantitative volume-based (18)F-FDG PET analysis was performed to obtain the total glycolytic volume (TGV) of the tumor. Survival outcomes were measured. A total of 23 patients were suitable for both radiological and (18)F-FDG PET analysis, of whom 20 had CT measurable disease. After 1 cycle of chemotherapy, 7 patients attained a partial response and 13 had stable disease on CT assessment by modified RECIST criteria. In the 7 patients with radiological partial response, the median TGV on quantitative PET analysis fell to 30 % of baseline (range of 11 % - 71 %). After 1 cycle of chemotherapy, Cox regression analysis demonstrated a statistically significant relationship between a fall in TGV and improved patient survival ($p = 0.015$). Neither a reduction in the maximum standardized uptake value ($p = 0.097$) nor CT ($p = 0.131$) demonstrated a statistically significant association with patient survival. The authors concluded that semi-quantitative (18)F-FDG PET using the volume-based parameter of TGV is feasible in mesothelioma and may predict response to chemotherapy and patient survival after 1 cycle of treatment. Therefore, metabolic imaging has the potential to improve the care of patients receiving chemotherapy for mesothelioma by the early identification of responding patients. This technology may also be useful in the assessment of new systemic treatments for mesothelioma.

Ceresoli et al (2007) noted that most patients with malignant pleural mesothelioma (MPM) are candidates for chemotherapy during the course of their disease. Assessment of the response with conventional criteria based on computed tomography (CT) measurements is challenging, due to the circumferential and axial pattern of growth of MPM. Such difficulties hinder an accurate evaluation of clinical study results and make the clinical management of patients critical. Several radiological response systems have been proposed, but neither WHO criteria nor the more recent RECIST (Response Evaluation Criteria in Solid Tumors) uni-dimensional criteria nor hybrid uni- and bi-dimensional criteria seem to apply to tumor measurement in this disease. Recently, modified RECIST criteria for MPM have been published. Although they are already being used in current clinical trials, they have been criticized based on the high grade of inter-observer variability and on theoretical studies of mesothelioma growth according to non-spherical models. Computer-assisted techniques for CT measurement are being developed. The use of FDG-PET for prediction of response and, more importantly, of survival outcomes of MPM patients is promising and warrants validation in large prospective series. New serum markers such as osteopontin and mesothelin-related proteins are under evaluation and in the future might play a role in assessing the response of MPM to treatment.

Spiro et al (2008) stated that guidelines issued by the National Institute for Clinical Excellence (NICE) in the England and Wales recommend that rapid access to (18)F-deoxyglucose positron emission tomography (FDG-PET) is made available to all appropriate patients with non-small-cell lung cancer (NSCLC). The clinical evidence for the benefits of PET scanning in NSCLC is substantial, showing that PET has high accuracy, sensitivity and specificity for disease staging, as well as pre-therapeutic assessment in candidates for surgery and radical radiotherapy. Moreover, PET

scanning can provide important information to assist in radiotherapy treatment planning, and has also been shown to correlate with responses to treatment and overall outcomes. If the government cancer waiting time targets are to be met, rapid referral from primary to secondary healthcare is essential, as is early diagnostic referral within secondary and tertiary care for techniques such as PET. Studies are also required to explore new areas in which PET may be of benefit, such as surveillance studies in high-risk patients to allow early diagnosis and optimal treatment, while PET scanning to identify treatment non-responders may help optimize therapy, with benefits both for patients and healthcare resource use. Further studies are needed into other forms of lung cancer, including small-cell lung cancer and mesothelioma. The authors concluded that PET scanning has the potential to improve the diagnosis and management of lung cancer for many patients. Further studies and refinement of guidelines and procedures will maximize the benefit of this important technique.

Sorensen et al (2008) stated that extrapleural pneumonectomy (EPP) in MPM may be confined with both morbidity and mortality, and careful pre-operative staging identifying resectable patients is important. Staging is difficult and the accuracy of pre-operative CT scan, 18F-FDG PET/CT scan (PET/CT), and mediastinoscopy is unclear. These investigators compared these staging techniques to each other and to surgical-pathological findings. Subjects were patients with epithelial subtype MPM, aged less than or equal to 70 years, and had lung function test allowing pneumonectomy. Pre-operative staging after 3 to 6 courses of induction chemotherapy included conventional CT scan, PET/CT, and mediastinoscopy. Surgical-pathological findings were compared to pre-operative findings. A total of 42 consecutive patients were without T4 or M on CT scan. PET/CT showed inoperability in 12 patients (29 %) due to T4 (7 patients) and M1 (7 patients). Among 30 patients with subsequent mediastinoscopy, including 10 with N2/N3 on PET/CT, N2 were histologically verified in 6 (20 %). Among 24 resected patients, T4 occurred in 2 patients (8 %), and N2 in 4 (17 %), all being PET/CT negative. The PET/CT accuracy of T4 and N2/N3 compared to combined histological results of mediastinoscopy and EPP showed sensitivity, specificity, positive predictive value, negative predictive value, and positive and negative likelihood ratios of 78 % and 50 %, 100 % and 75 %, 100 % and 50 %, 94 % and 75 %, not applicable and 5.0, and 0.22 and 0.67, respectively. The authors concluded that non-curative surgery is avoided in 29 % out of 42 MPM patients by pre-operative PET/CT and in further 14 % by mediastinoscopy. Even though both procedures are valuable, there are false negative findings with both, urging for even more accurate staging procedures.

CPT Codes / HCPCS Codes / ICD-9 Codes

Cardiac indications:

CPT codes covered if selection criteria are met:

78459

78491

78492

Other CPT codes related to the CPB:

78464

78465

HCPCS codes covered if selection criteria are met:

A9526	Nitrogen N-13 ammonia, diagnostic, per study dose, up to 40 millicuries
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A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries
A9555	Rubidium Rb-82, diagnostic, per study dose, up to 60 millicuries

ICD-9 codes covered if selection criteria are met (not all-inclusive):

410.00 - 410.92	Acute myocardial infarction
411.0 - 411.89	Other acute and subacute forms of ischemic heart disease
412	Old myocardial infarction
413.0 - 413.9	Angina pectoris
426.2 - 426.6	Atrioventricular, bundle branch, and other heart block
427.31	Atrial fibrillation
428.0 - 428.9	Heart failure

Other ICD-9 codes related to the CPB:

414.00 - 414.07	Coronary atherosclerosis
420 - 420.99	Pericarditis
423.8 - 423.9	Other and unspecified diseases of pericardium
511.1	Pleurisy with effusion, with mention of a bacterial cause other than tuberculosis
511.81	Malignant pleural effusion
511.89	Other specified forms of effusion, except tuberculous
511.9	Unspecified pleural effusion
611.1	Hypertrophy of breast [large breasts]
754.89	Other specified nonteratogenic anomalies [chest wall deformity]
V43.82	Organ or tissue replaced by other means, breast [breast implants]
V45.71	Acquired absence of breast [status post mastectomy]
V45.81	Aortocoronary bypass status
V45.82	Percutaneous transluminal coronary angioplasty status
V85.4	Body Mass Index 40 and over, adult

Oncologic indications and conditions other than cardiac and neurologic for PET and PET-CT Fusion:**CPT codes covered if selection criteria are met:**

78608
78609
78811

78812

78813

78814

78815

78816

Other CPT codes related to the CPB:

32095

32100

32405

38500 - 38530

61534

61536

82378

HCPCS codes covered if selection criteria are met:

A9552 Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries

G0235 PET imaging, any site, not otherwise specified

HCPCS codes not covered for indications listed in the CPB:

G0219 PET imaging whole body; melanoma for non-covered indications

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)

S8085 Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (non-dedicated PET scan) [when described as an FDG-SPECT scan]

Other HCPCS codes related to the CPB:

A4641 Radiopharmaceutical, diagnostic, not otherwise classified

ICD-9 codes covered if selection criteria are met:

140.0 - 154.8, Malignant neoplasm of lip, oral cavity, and pharynx, esophagus,
 157.0 - 157.9, stomach, small intestine, colon, rectum, rectosigmoid junction, and
 158.8 - 158.9, anus, pancreas, peritoneum, nasal cavities, middle ear, and
 160.0 - 163.9, accessory sinuses, mediastinum, respiratory system and other
 164.2 - 165.8, intrathoracic organs, bones of skull and face, mandible, connective
 170.0 - 172.9, tissue and other soft tissue, melanoma of skin, skin, breast, cervix
 174.0 - 175.9, uteri, ovary, fallopian tube, testis, eye, brain, thyroid gland, head,
 180.0 - 180.9, face, and neck
 183.0 - 183.9,
 186.0 - 186.9,
 190.0 - 191.9,
 193, 195.0

199.1	Other malignant neoplasm without specification of site [occult primary cancers]
200.00 - 202.48, 202.60 - 202.98	Malignant neoplasm of lymphatic and hematopoietic tissue
203.00 - 203.02	Multiple myeloma
209.00 - 209.69, 209.75	Neuroendocrine tumors
230.0 - 230.4, 231.0 - 231.9, 233.0, 234.0	Carcinoma in situ lip, oral cavity, and pharynx, esophagus, stomach, colon, rectum, respiratory system, breast, and eye
235.0 - 235.1, 235.6 - 235.9	Neoplasm of uncertain behavior of major salivary glands, lip, oral cavity, and pharynx, larynx, trachea, bronchus, and lung, pleura, thymus, and mediastinum, and other and unspecified respiratory organs
237.5 - 237.9	Neoplasm of uncertain behavior of brain and nervous system
345.00 - 345.91	Epilepsy and recurrent seizures [pre-surgical evaluation for localization of seizure focus]
492.8	Other emphysema
518.89	Other diseases of lung, not elsewhere classified
530.0	Achalasia and cardiospasm
530.89	Other specified disorders of esophagus
560.9	Unspecified intestinal obstruction
569.89	Other specified disorders of intestine
709.9	Unspecified disorder of skin and subcutaneous tissue
780.33	Post traumatic seizures
780.39	Other convulsions [pre-surgical evaluation for localization of seizure focus only]
784.2	Swelling, mass, or lump in head and neck
785.6	Enlargement of lymph nodes
793.1	Nonspecific abnormal findings on radiological and other examinations of lung field
990	Effects of radiation, unspecified [radiation necrosis]
V10.03 - V10.06, V10.11 - V10.12, V10.21 - V10.22, V10.3, V10.41, V10.43,	Personal history of malignant neoplasm of esophagus, large intestine, rectum, rectosigmoid junction, and anus, trachea, bronchus and lung, larynx, nasal cavities, middle ear, and accessory sinuses, breast, stomach, cervix uteri, ovary, testis, lymphosarcoma and reticulosarcoma, Hodgkin's disease, bone, melanoma of skin, eye, brain, thyroid and neuroendocrine tumor

V10.47,
 V10.71 -
 V10.72,
 V10.81 -
 V10.82,
 V10.84 -
 V10.85,
 V10.87,
 V10.91

ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

114.0 - 114.9	Coccidioidomycosis
155.0 - 156.9, 158.0	Malignant neoplasm of liver and intrahepatic bile ducts, gallbladder and extrahepatic bile ducts and retroperitoneum
164.0 - 164.1	Malignant neoplasm of thymus and heart
173.0 - 173.9	Malignant neoplasm of skin
176.0 - 179	Malignant neoplasm of Kaposi's sarcoma and uterus, part unspecified
181	Malignant neoplasm of placenta
182.0 - 182.8	Malignant neoplasm of body of uterus
184.0 - 184.9	Malignant neoplasm of other and unspecified female genital organs
185	Malignant neoplasm of prostate
187.1 - 189.9	Malignant neoplasm of penis and other male genital organs, bladder, and kidney and other and unspecified urinary organs
192.0 - 192.9	Malignant neoplasm of other and unspecified parts of nervous system
194.0 - 194.9	Malignant neoplasm of other endocrine glands and related structures
196.9	Secondary and unspecified malignant neoplasm of lymph nodes, site unspecified
197.2 - 197.3	Secondary malignant neoplasm of pleura and other respiratory organs
197.4	Secondary malignant neoplasm of small intestine, including duodenum [ileal carcinoma]
197.6 - 197.7	Secondary malignant neoplasm of retroperitoneum and peritoneum, and liver, specified as secondary
198.0 - 198.5	Secondary malignant neoplasm of kidney, other urinary organs, skin, brain and spinal cord, other parts of nervous system, and bone and bone marrow
198.7	Secondary malignant neoplasm of adrenal gland
198.82	Secondary malignant neoplasm of genital organs
198.89	Secondary malignant neoplasm of other specified sites

202.50 - 202.58	Letterer-Siwe disease [langerhans cell histiocytosis]
203.10 - 208.92	Plasma cell leukemia and immunoproliferative neoplasms, lymphoid leukemia, myeloid leukemia, monocytic leukemia, and other specified leukemia
210.0 - 229.9	Benign neoplasms
230.5 - 230.9	Carcinoma in situ of anal canal, anus, unspecified, other and unspecified parts of intestine, liver and biliary system, and other and unspecified digestive organs
232.0 - 232.9	Carcinoma in situ of skin
233.32	Carcinoma in situ of vulva
234.8 - 234.9	Carcinoma in situ of other and unspecified sites
235.3 - 235.4	Neoplasm of uncertain behavior of liver and biliary passages, and retroperitoneum and peritoneum
235.9 - 237.4	Neoplasm of uncertain behavior of other and unspecified respiratory organs, genitourinary organs, and endocrine glands
238.1	Neoplasm of uncertain behavior of connective and other soft tissue
238.3 - 238.79	Neoplasm of uncertain behavior of breast and other lymphatic and hematopoietic tissues
239.3 - 239.7	Neoplasm of uncertain behavior of breast, bladder, other genitourinary organs, brain, and endocrine glands and other parts of nervous system
239.9	Neoplasm of uncertain behavior, site unspecified
277.89	Other specified disorders of metabolism [langerhans cell histiocytosis]
290.0 - 319	Mental disorders
320 - 344.9, 346.00 - 389.9	Diseases of the nervous system and sense organs [except pre-surgical evaluation for localization of seizure focus]
390 - 429.9	Heart disease
630	Hydatidiform mole [gestational trophoblastic neoplasia]
711.95	Unspecified infective arthritis [infection of hip arthroplasty]
730.10 - 730.19	Chronic osteomyelitis
731.0	Osteitis deformans without mention of bone tumor [Paget's disease of bone]
780.01 - 780.09	Alteration of consciousness
780.1 - 780.2	Hallucinations and syncope and collapse
780.4	Dizziness and giddiness
780.60	Fever, unspecified [fever of unknown origin (FUO)]

780.93	Memory loss
780.99	Other general symptoms
781.0 - 781.99	Symptoms involving nervous and musculoskeletal systems
793.0	Nonspecific abnormal findings on radiological and other examination of skull and head
793.2	Nonspecific abnormal findings on radiological and other examination of other intrathoracic organ
794.00 - 794.19	Nonspecific abnormal results of function studies of brain and central nervous system and peripheral nervous system and special senses
794.30 - 794.39	Nonspecific abnormal results of function studies, cardiovascular
996.66	Infection and inflammatory reaction due to internal joint prosthesis [infection of hip arthroplasty]
998.59	Other postoperative infection [infection of hip arthroplasty]
V10.00 - V10.02	Personal history of malignant neoplasm of gastrointestinal tract, unspecified
V10.07 - V10.09	Personal history of malignant neoplasm of liver and of gastrointestinal tract, other
V10.29	Personal history of malignant neoplasm of other respiratory and intrathoracic organs
V10.42	Personal history of malignant neoplasm of other parts of uterus
V10.46	Personal history of malignant neoplasm of prostate
V10.48 - V10.60	Personal history of malignant neoplasm of epididymis, other male genital organs, urinary organs, and leukemia, unspecified
V10.62 - V10.69	Personal history of malignant neoplasm, myeloid, monocytic, and other leukemia
V10.79	Personal history of other lymphatic and hematopoietic neoplasms
V10.83	Personal history of other malignant neoplasm of skin
V10.86	Personal history of malignant neoplasm of other parts of nervous system
V10.88 - V10.90	Personal history of malignant neoplasm of other endocrine glands and related structures, other, and unspecified sites
V43.64	Hip joint replaced by other means [infection of hip arthroplasty]
V70.0 - V82.9	Persons without reported diagnosis encountered during examination and investigation of individuals and populations

Neurologic indications for PET:

CPT codes covered for indications listed in the CPB:

78608

78609

ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

290.0 - 290.9	Dementias
294.10 - 294.11	Dementia in conditions classified elsewhere
310.1	Personality change due to conditions classified elsewhere
331.0	Alzheimer's disease
332.0 - 332.1	Parkinson's disease
333.4	Huntington's chorea
780.93	Memory loss
781.1	Disturbances of sensation of smell and taste
V17.2	Family history of other neurological diseases
V80.0	Special screening for neurological conditions

The above policy is based on the following references:

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