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Title:

Positron Emission Tomography (PET)

Number:

RAD605.001

Effective Date:

03-01-2008

Legislation:

ILLINOIS: None

NEW MEXICO: None

OKLAHOMA: None

TEXAS: None

FEDERAL (applies to all Plans): None

Contract:

Each benefit plan or contract defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers have the responsibility for consulting the member's benefit plan or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between a Medical Policy and a member's benefit plan or contract, the benefit plan or contract will govern.

Coverage:

ONCOLOGIC APPLICATIONS:

Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) **may be considered medically necessary** for known or suspected malignancy (**except screening, surveillance, and those malignancies listed below**) when the:

- findings on other imaging modalities are inconclusive and/or discordant; AND
- results of PET or PET/CT will be the deciding factor in determining medical and/or surgical intervention.

Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) **is considered not medically necessary** for periodic surveillance in the absence of clinical evidence of recurrent or persistent disease.

Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) **is considered experimental, investigational and unproven** for screening.

Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) **is considered experimental, investigational and unproven** for the following types of malignancies:

- Ovarian,
- Pancreatic,
- Small cell lung,
- Soft tissue sarcoma.

CARDIAC APPLICATIONS

Myocardial perfusion

Cardiac PET scanning **may be considered medically necessary** as a technique to assess **myocardial perfusion** defects and thus diagnose coronary artery disease (CAD) when **BOTH** of the following criteria are met:

- Patient has at least intermediate risk for coronary artery disease, **AND**
- The PET scan is used in place of, but not in addition to a single photon emission computed tomography (SPECT), OR previous SPECT scan results are inconclusive.

Myocardial viability

Cardiac PET scanning **may be considered medically necessary** to assess the **myocardial viability** in patients with severe left ventricular dysfunction as a technique to determine candidacy for a revascularization procedure.

OTHER APPLICATIONS

Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) **may be considered medically necessary** for the following:

- Diagnosis of **chronic osteomyelitis**;
- Assessment of selected patients with **epileptic seizures** who are candidates for surgery

NOTE: Appropriate candidates are those patients who have complex partial seizures that have failed to respond to medical therapy and who have been advised to have a resection of a suspected epileptogenic focus located in a region of the brain accessible to surgery. Conventional techniques for seizure localization must have been tried and provided data that suggested a seizure focus, but were not sufficiently conclusive to permit surgery.

EEG's AND PET EXAMINATION: The purpose of the PET examination should be to avoid subjecting the patient to extended pre-operative electroencephalographic recording with implanted electrodes.

Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) **is considered experimental, investigational and unproven** for all other indications

Codes:

CPT Codes:	HCPCS Codes:
78459, 78491, 78492, 78608, 78609, 78811, 78812, 78813, 78814, 78815, 78816	G0235 , G0252, G0219

ICD-9 Diagnosis Codes:	ICD-9 Procedure Codes:
Refer to ICD-9-CM Manual	Refer to ICD-9-CM Manual

Description:

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 two 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.

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, tracers must be made locally, the majority requiring an on-site cyclotron.

This policy only addresses the use of radiotracers detected with the use of dedicated PET scanners. There is a similar procedure to PET that may be referred to as FDG-SPECT (fluorodeoxyglucose-single photon emission computed tomography), metabolic SPECT, or PET using a gamma camera. In this procedure radiotracers such as FDG may be detected using SPECT cameras.

Terminology for PET as related to malignancies

- **Diagnosis.** PET can be useful to avoid an invasive diagnostic procedure, or to determine the optimal anatomic location to perform an invasive procedure. In general, for most solid tumors, a tissue diagnosis is made prior to performing a PET scan. PET scans following a tissue diagnosis are generally performed for staging rather than diagnosis. PET should not be used as a screening test.
- **Staging.** PET is used for staging in clinical situations in which clinical management of the patient would differ depending on the stage of the cancer identified, and:
 - the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography [CT], magnetic resonance imaging [MRI], or ultrasound), or

- PET 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 patient.
- **Restaging.** Restaging applies to testing after a course of treatment is completed. PET is used for restaging:
 - after completion of treatment, for the purpose of detecting residual disease;
 - for detecting suspected recurrence or metastasis;
 - to determine the extent of a known recurrence; or
 - if PET 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 patient.
- **Monitoring.** This refers to use of PET to monitor tumor response to treatment during the planned course of therapy (i.e., when a change in therapy is anticipated).

PET/CT Fusion Imaging

PET/CT Fusion Imaging is a new diagnostic tool for the staging and restaging of cancer. Patients can be examined with both PET and CT in a single examination. This new technology correlates two simultaneous imaging modalities for a comprehensive examination that combines anatomic data with functional or metabolic information. The CT images are used for anatomic reference of the tracer uptake patterns images in PET, as well as for attenuation correction of the PET data.

Cardiac Pet Scan

In terms of myocardial perfusion studies, patient selection criteria for PET scans involve an individual assessment of the pretest probability of coronary artery disease (CAD), based on both patient symptoms and risk factors. Patients at low risk for CAD may be adequately evaluated with exercise electrocardiography. Patients at high risk for CAD may not benefit from a non-invasive assessment of myocardial perfusion, since, in this setting, a negative test may represent a false negative result. These patients may be immediately referred to coronary angiography.

Patient selection criteria for PET scans for myocardial viability are typically those patients with severe left ventricular dysfunction who are under consideration for a revascularization procedure. A PET scan may determine whether the left ventricular dysfunction is related to viable or nonviable myocardium. Patients with viable myocardium may benefit from revascularization, while those with non-viable myocardium will not. As an example, PET scans are commonly performed in potential heart transplant candidates to rule out the presence of viable myocardium.

For both perfusion and viability study indications, a variety of studies have suggested that the PET scans are only marginally more sensitive or specific than SPECT scans. Therefore the choice between a PET scan (which may not be available locally) and a SPECT scan represents another clinical issue. PET scans may provide the greatest advantage over SPECT scans in obese patients where tissue attenuation of tracer is of greater concern.

Rationale:

ONCOLOGIC APPLICATIONS

This policy is based on multiple evaluations of PET, including Blue Cross Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) Assessments, other systematic reviews, meta-analyses, decision analyses, and cost-effectiveness analyses. In the TEC 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 TEC Assessments and literature reviews offered the following observations and conclusions.

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 x-ray. Patients who are relatively young and have no smoking history are at a relatively low risk for lung cancer, and in this setting the negative predictive value 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).

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 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.

Six studies of patients with small cell lung cancer (SCLC) reported evidence suggesting that for non-brain metastases PET added to conventional staging is more sensitive in detecting disease than conventional staging alone. 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. From the limited and poor quality evidence that is available, it is not possible to determine whether the use of PET adds value relative to conventional staging tests for SCLC.

Pancreatic Cancer

The 2004 Agency for Healthcare Research and Quality (AHRQ) systematic review and the 1999 TEC Assessment both focused on two 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 gold 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 negative predictive value would be required. The key statistic underlying the negative predictive value 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 negative predictive value ranged between 75% and 92%, depending on an underlying prevalence of disease ranging from 50%–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. 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.

Ovarian Cancer

For primary evaluation, i.e., in patients with suspected ovarian cancer, the ability to rule out malignancy with a high negative predictive value would change management by avoiding unnecessary exploratory surgery. However, available studies suggest that PET scanning has poorer negative predictive value compared to 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 suggested that PET may have value for detecting recurrence when CA125 is elevated and conventional imaging does not clearly show recurrence, this has not been demonstrated in an adequately powered prospective study. There was insufficient evidence to permit scientific conclusions regarding this application.

Soft Tissue Sarcoma

A 2002 AHRQ systematic review on use of PET for soft tissue sarcoma evaluated five 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 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.

CARDIAC APPLICATIONS

In 2003, the American College of Cardiology (ACC) and the American Heart Association (AHA) published updated guidelines for cardiac radionuclide imaging. Cardiac applications of PET scanning were included in these guidelines. The ACC/AHA guidelines categorize specific indications for PET scanning:

- Class I is defined as conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.
- Class IIa is defined as conditions for which there is conflicting evidence or a divergence of opinion but the weight of evidence/opinion is in favor of usefulness/efficacy.
- Class IIb is similar to Class IIa except that the usefulness/efficacy is less well established by evidence/opinion.

The medically necessary indications for PET myocardial perfusion studies in this policy are consistent with Class I and Class IIa indications in the ACC guidelines.

Myocardial Viability

PET has perhaps been most thoroughly researched as a technique to assess myocardial viability to determine candidacy for a coronary revascularization procedure. For example, a patient with a severe stenosis identified by coronary angiography may not benefit from revascularization if the surrounding myocardium is non-viable. A fixed perfusion defect, as imaged on SPECT scanning or stress thallium echocardiography, may suggest non-viable myocardium. However a PET scan may reveal metabolically active myocardium, suggesting areas of hibernating myocardium that would indeed benefit from revascularization. The most common PET technique for this application consists of N-13 ammonia as a perfusion tracer and FDG as a metabolic marker of glucose utilization. A pattern FDG uptake in areas of hypoperfusion (referred to as FDG/blood flow mismatch) suggests viable, but hibernating myocardium. The ultimate clinical validation of this diagnostic test is the percentage of patients who experience improvement in left ventricular dysfunction after revascularization of hibernating myocardium, as identified by PET scanning.

SPECT scanning may also be used to assess myocardial viability. For example, while initial myocardial uptake of thallium-201 reflects myocardial perfusion, redistribution after prolonged periods can be used as a marker of myocardial viability. Initial protocols required redistribution imaging after 24 to 72 hours. While this technique was associated with a strong positive predictive value, there was a low negative predictive value, i.e., 40% of patients without redistribution nevertheless showed clinical improvement after revascularization. The negative predictive value has improved with the practice of thallium reinjection. Twenty-four to 72 hours after initial imaging, patients receive a reinjection of thallium and undergo redistribution imaging.

The ACC/AHA guidelines conclude that PET imaging "appears to have slightly better overall accuracy for predicting recovery of regional function after revascularization in patients with left ventricular (LV) dysfunction than single photon techniques (i.e., SPECT scans)." However, the ACC guidelines indicate that either PET or SPECT scans are Class I indications for predicting improvement in regional and global LV function and natural history after revascularization, and thus do not indicate a clear preference for either PET or SPECT scans in this situation.

Further supporting the equivalency of these two testing modalities, Siebelink and colleagues performed a prospective randomized study comparing management decisions and outcomes based on either PET imaging or SPECT imaging in 103 patients with chronic coronary artery disease and left ventricular dysfunction who were being evaluated for myocardial viability. Management decisions included drug therapy or revascularization with either angioplasty or coronary artery bypass grafting. This study is unique in that the diagnostic performance of the two studies was tied to the actual patient outcomes. No difference in patient management or cardiac event-free survival was demonstrated between management based on the two imaging techniques. The authors concluded that either technique could be used for management of patients considered for revascularization with suspicion of jeopardized myocardium.

Myocardial Perfusion

In patients with symptoms suggestive of CAD, a central clinical issue is to determine whether a coronary angiogram is necessary for further work-up. A variety of non-invasive imaging tests, including PET (using rubidium-82) and SPECT scans, have been investigated as a means of identifying reversible perfusion defects, which may reflect coronary artery disease, and thus identify patients who may benefit from further work-up with an angiogram. The following table summarizes the ACC guidelines for myocardial reperfusion for both SPECT

and PET scans in patients with an intermediate risk of coronary artery disease

Indication

SPECT/PET Class Class

Identify extent, severity, and location of ischemia (SPECT protocols vary according to whether patient can exercise).	I	IIA
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Repeat test after 3–5 years after revascularization in selected high-risk asymptomatic patients (SPECT protocols vary according to whether patients can exercise).	IIa	
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As initial test in patients who are considered to be at high risk (i.e., patients with diabetes or those with a more than 20% 10-year risk of a coronary disease event) (SPECT protocols vary according to whether patients can exercise).

Myocardial perfusion PET when prior SPECT study has been found to be equivocal for diagnostic or risk stratification purposes.	NA	I
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As noted in the table, the data and consensus opinion (as reflected by a Class I designation) favors limiting a PET scan to those situations in which a prior SPECT scan is inconclusive. In the text summary, the guidelines note, "Overall, because of the higher resolution of PET and the routine application of attenuation correction, it is probable that sensitivity and specificity are slightly higher for PET compared with SPECT, but there is not a robust database of head-to-head comparisons." The previous 1995 version of the guidelines stated, "PET is an expensive imaging modality, and whether the greater cost of PET is justified by a possible improvement in diagnostic accuracy requires further rigorous study. Thus, until data from large-scale, definitive studies are published, PET is considered an effective modality for the noninvasive diagnosis of coronary artery disease but should be considered for routine diagnostic purposes only if the costs of PET are equivalent to or less than the costs of SPECT imaging in the same community." This discussion of the relative costs of PET and SPECT has been eliminated in the 2003 version of the guidelines.

Studies continued to show the equivalence of SPECT and PET. As one example, Slart and colleagues concluded that there was overall good agreement between SPECT and PET for the assessment of myocardial viability in patients with severe LV dysfunction. Comparative studies reported on test accuracy and did not address impact on clinical outcomes.

While comparative studies were identified for SPECT compared to PET in the evaluation of CAD, the comparative data are still limited. Using a thorax-cardiac phantom, Knesaurek concluded that PET was better at detecting smaller defects. In this study, a 1 cm (centimeter) insert was not detectable by SPECT, yet it was detectable using PET. Merhige reported on outcomes of non-contemporaneous patients with similar probabilities of CAD who were evaluated by SPECT or PET. In this study involving PET scans done at one center compared to those evaluated by SPECT, those receiving PET evaluations had lower rates of angiography (13% versus 31%) and revascularization (6% versus 11%) with similar rates of death and MI at one year of follow-up. These results were viewed as preliminary and additional comparative studies showing impact on outcomes are needed.

OTHER APPLICATIONS

Recent review articles discuss the potential applications for PET in various neurological and psychological conditions. Henry and Van Heertum recently suggested that "interictal FDG PET can be used in presurgical epilepsy evaluations to reliably: 1) determine the side of anterior temporal lobectomy, and in children the area of multilobar resection, without intracranial electroencephalographic recording of seizures; 2) select high-probability sites of intracranial electrode placement for recording ictal onsets; and 3) determine the prognosis for complete seizure control following anterior temporal lobe resection." The performance data for PET localization of seizure foci has already been established. It is suggested that FDG PET might also be used to localize and minimize the placement of intracranial electrodes that could reduce the morbidity associated with intracranial monitoring, even if invasive monitoring was not avoided altogether.

Parsey and Mann state that "brain imaging is not yet part of clinical practice in psychiatry," and describe the various PET tracers and applications currently being investigated. PET radiotracers include the use of 18F-FDG to track metabolic activity, 15-O-water as a marker for cerebral blood flow, and a variety of 11-C tagged neuroreceptor markers to study serotonergic or dopaminergic activity as well as psychotropic drug effects.

The role of PET in dementia is an active area for research but is not yet clear. The Centers for Medicare and Medicaid Services (CMS) issued a decision memorandum on April 16, 2003, that would not support coverage of FDG PET in Alzheimer's disease (AD) because the evidence did not demonstrate its use for improved patient outcomes. This decision was based, in part, on a technology assessment conducted at Duke University through the AHRQ Evidence-based Practice Center. This assessment used decision-analysis modeling to examine whether the use of FDG PET would improve health outcomes when used for diagnosis of AD in three clinical populations: patients with dementia, patients with mild cognitive impairment, or subjects with no symptoms but a first-degree relative with AD. PET was considered to have an 88% sensitivity (79% to 94% = 95% confidence interval [CI]) and 87% specificity (77% to 93% = 95% CI) for diagnosing AD. The report concluded that outcomes for all three groups of patients were better if all patients were treated with agents such as cholinesterase inhibitors rather than using FDG PET to select patients for treatment based on PET results, since the complications of treatment were relatively mild and treatment was considered to have some degree of efficacy in delaying the progression of AD. Thus, the adverse effect of not treating subjects with AD who had false-negative PET results was influential in this analysis. However, this conclusion was sensitive to the toxicity associated with treatment.

In October 2003, CMS accepted a petition from the University of California at Los Angeles (UCLA) School of Medicine to reconsider its policy for "use of FDG PET to distinguish patients with AD from those with other causes of symptoms confounding the diagnosis of dementia or to assist with the diagnosis of early dementia in beneficiaries for whom the differential diagnosis included one or more kinds of neurodegenerative disease, in cases where specific criteria have been met." On September 15, 2004, Medicare made public its final decision memorandum announcing a positive national coverage decision for a subset of patients "with a recent diagnosis of dementia and documented cognitive decline of at least six months, who meet diagnostic criteria for both Alzheimer's disease (AD) and frontotemporal dementia (FTD), who have been evaluated for specific alternative neurodegenerative diseases or causative factors, and for whom the cause of the clinical symptoms remains uncertain."

For its reconsideration, CMS requested an update of the original AHRQ assessment. In addition, Medicare considered a consensus report by the Neuroimaging Work Group of the Alzheimer's Association and proceedings of an expert panel discussion of neuroimaging in AD, convened by the National Institute of Aging and Medicare.

The updated technology assessment concluded that no new publications provided direct evidence to evaluate the use of PET to either differentiate among different types of dementia or to identify those patients with mild cognitive impairment who were at greatest risk to progress to AD.

The additional sources considered by Medicare, i.e., a consensus report, and an expert panel discussion, acknowledged the lack of direct evidence. However, these sources also suggested that, based on expert opinion, PET scanning potentially provided additional information in the small subset of patients presenting with diagnostic uncertainties between AD and FTD. It should be noted that the experts also expressed serious concerns about the potential misuse of PET scanning in patients with dementia, leading to unnecessary radiation exposure and costs.

In their decision memorandum, Medicare notes that they had previously indicated that they would consider "evidence from structured expert decision analysis of clinical scenarios..." in supporting coverage of such clinical indications. The salient points of the specific coverage criteria are summarized as follows:

"The evidence is adequate to conclude that an FDG-PET scan is reasonable and necessary in patients with a recent diagnosis of dementia and documented cognitive decline of at least six months, who meet diagnostic criteria for both Alzheimer's disease (AD) and frontotemporal dementia (FTD), who have been evaluated for specific alternative neurodegenerative diseases or causative factors, and for whom the cause of the clinical symptoms remains uncertain. The following additional conditions must be met.

- The onset, clinical presentation or course of cognitive impairment is aberrant for AD and FTD is suspected as an alternative neurodegenerative cause of the cognitive decline.
- The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology [AAN] encompassing a medical history from the patient and well-acquainted informant (including assessment of activities of daily living, physical and mental status examination aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as MRI or CT scan)."

Medicare also notes that it intends to cover PET scans in "practical clinical trials" that are Medicare approved for studying the use of PET in dementia. Medicare indicated it will work with the National Institute on Aging (NIA), AHRQ, Alzheimer's Association (AA), and experts in AD and imaging to develop the trials.

In contrast to the CMS national policy, this medical policy continues to consider PET for AD and dementia as investigational, due to the lack of direct evidence that this imaging technique will result in a change in management that will improve patient outcomes.

A recent scientific statement from the AHA provides guidelines and recommendations for perfusion imaging in cerebral ischemia. The authors state that "although the development of these techniques has been fascinating, their role in evaluating a variety of diseases of the CNS [central nervous system] is controversial." This report mentions that "oxygen extraction fraction (OEF) as measured with PET scanning" is being used in a new national trial to help "define the patient population with occlusive vascular disease at risk for stroke and the potential of an EC-IC [extracranial-intracranial] bypass to decrease that risk." This report further states that "other types of perfusion imaging with challenge tests may act as surrogate techniques for the more elaborate and expensive PET-OEF technique."

Two additional studies were identified exploring the use of FDG PET to assist in the differential diagnosis of infection in musculoskeletal conditions. Schmitz et al. evaluated 16 consecutive subjects with suspected

spondylodiscitis on the basis of clinical and imaging findings who underwent surgical histopathological evaluation. Interpretation of FDG PET was blinded to clinical information and final diagnosis. This study reported that FDG PET was able to identify the presence of spondylodiscitis in all 12 subjects who had surgically proven infection (100% sensitivity). Among the four cases without evidence of infection at surgery, PET was truly negative in three cases with either degenerative changes or fracture and falsely positive in one patient who had a spinal sarcoma but no associated infection (75% specificity). A study by Manthey et al. explored the use of FDG-PET for differentiating synovitis, loosening, and infection in 23 patients who had 14 hip and 14 knee prostheses, but PET interpretations were not clearly blinded. Results found that PET identified four of four cases with periprosthetic infection and four of five cases with periprosthetic loosening, and there were true-negative PET results in three cases without evidence of infection, loosening, or synovitis. Confirmation of these favorable preliminary results in well-designed, prospective studies including larger numbers of patients is needed.

In a systematic review and meta-analysis of diagnostic imaging to assess chronic osteomyelitis, the authors reviewed studies through July 2003 on six imaging approaches to chronic osteomyelitis, including fluorodeoxyglucose PET. The study concluded that PET is the most accurate mode (pooled sensitivity=96% [95% CI: 88%-99%]; pooled specificity=91% [95% CI: 81%-95%]) for diagnosing chronic osteomyelitis. Leukocyte scintigraphy is adequate in the peripheral skeleton (sensitivity=84% [95% CI: 72%-91%]; specificity=80% [95%CI: 61%-91%]), but is inferior in the axial skeleton (sensitivity=21% [95% CI: 11%-38%]; specificity=60% [95%CI: 39%-78%]). The assessment of PET is based on four prospective, European studies published between 1998 and 2003, with a total of 1,660 patients. However, the study populations vary and include the following: 1) 57 patients with suspected spinal infection referred for FDG PET and who had previous spinal surgery, but not "recently;" 2) 22 trauma patients scheduled for surgery who had suspected metallic implant-associated infection; 3) 51 patients with recurrent osteomyelitis or osteomyelitis symptoms for more than six weeks, 36 in the peripheral skeleton and 15 in the central skeleton; and 4) 30 consecutive non-diabetic patients referred for possible chronic osteomyelitis. The results appear to be robust across fairly diverse clinical populations, which strengthen the conclusions. A clinical trial funded by the U.S. National Institutes of Health at the University of Pennsylvania to look at the use of FDG PET in the complicated diabetic foot started in 2002 and began enrolling patients in March 2007, toward a target of 240 patients. This trial may provide additional information on the use of PET in this specific population.

Pricing:

None

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Related Documents:

RAD604.005, FDG Using Camera Based Imaging (FDG-SPECT)

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