MP 6.01.18  
FDG Using Camera-Based Imaging (FDG-SPECT)

Medical Policy

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Description

FDG-SPECT, also referred to as metabolic SPECT (single photon emission computed tomography), or PET using a gamma camera, is a general term describing imaging techniques in which a SPECT gamma camera is used to detect the paired 511 keV photons emitted from decaying positrons associated with the metabolism of radiolabeled 2-fluoro-2 deoxy-D-glucose (FDG), a radiotracer commonly used in PET (positron emission tomography) imaging. SPECT cameras are conventionally used to provide scintigraphic studies such as bone scans or cardiac thallium studies. When used in conjunction with FDG, specially equipped SPECT cameras can provide images reflecting the metabolic activity of tissues, similar to PET scanning.

Dedicated PET scanners consist of multiple detectors arranged in a full or partial ring around the patient, permitting the simultaneous detection of the high-energy paired photons that are emitted at 180 degrees from one another. The clinical value of PET scans is related both to the ability to image the relative metabolic activity of target tissues and the resolution associated with PET scanners. The expense of on-site manufacture of the FDG is prohibitive for most facilities; that coupled with the expense of the PET scanner itself has limited the widespread availability of PET scanning. However, radiolabeled FDG has a relatively long half-life of 110 minutes, permitting off-site manufacture at distribution centers with transport to nearby facilities. Thus, the lack of PET scanners may be emerging as the critical limiting factor to further diffusion of PET imaging. In response, researchers have begun to investigate whether the more readily available SPECT cameras, routinely used to detect low-energy photons, could be adapted for use to detect higher energy photons emitted from positrons.

FDG-SPECT imaging describes 2 general techniques. In 1 technique SPECT cameras are adapted with collimators that screen out the lower energy photons and thus only detect the high-energy 511 keV photons. For the purposes of this policy, this technique will be referred to as FDG-collimated-SPECT. However, this approach decreases the sensitivity and resolution compared to that associated with PET scanners. In a second technique, a dual-headed rotating SPECT camera can be operated in the “coincidence mode,” meaning that the camera will only count those photons that are simultaneously detected at 180 degrees from one another. For the
purposes of this assessment, this technique will be referred to as FDG-DHC (dual-head coincidence)-SPECT. PET scanners also rely on coincidence detection, and thus FDG-DHC-SPECT more closely resembles a PET scanner. However, the lower number of detectors in the SPECT approach compared to the full or partial ring of detectors used in PET imaging will result in a relative loss of sensitivity and resolution. An additional technical challenge is the use of sodium iodide crystals, which scintillate in response to bombardment by photons. In SPECT cameras these crystals have been optimized to detect lower energy photons used in routine nuclear medicine studies and not the high-energy photons associated with FDG. These technical issues raise questions regarding the diagnostic performance of FDG-SPECT in comparison to PET scanning. Oncologic and cardiac applications have been most thoroughly studied.

**Note:** Conventional PET scanning is considered separately in policy Nos. 6.01.20, 6.01.26, and 6.01.06, addressing the cardiac, oncologic, and other applications of PET scans, respectively.

**Policy**

FDG-SPECT may be considered medically necessary as a technique to evaluate myocardial viability in patients with known coronary artery disease.

Other cardiac applications of FDG-SPECT are considered investigational, including, but not limited to, evaluation of coronary artery perfusion defects.

FDG-SPECT is considered investigational as a technique to evaluate patients with known or suspected malignancies.

Other applications of FDG-SPECT are considered investigational, including, but not limited to, evaluation of neurological disorders, dementias, psychiatric disorders, or motor neuron disorders.

**Policy Guidelines**

*Patient selection criteria for evaluation of myocardial viability*

Candidates for assessment of myocardial viability are typically those patients with severe left ventricular dysfunction who are under consideration for a revascularization procedure. A PET, FDG-SPECT, or thallium SPECT scan may determine whether the left ventricular dysfunction is related to viable or non-viable myocardium. Patients with viable myocardium may benefit from revascularization, while those with non-viable myocardium will not.

**Coding Issues**

In 2005, CMS discontinued the HCPCS G codes that explicitly identified PET scans using gamma cameras. At that time, CMS indicated that a CPT code should be used for these services. There is no specific CPT code and the Society of Nuclear Medicine recommends using 78999 – unlisted miscellaneous procedure, diagnostic nuclear medicine.

The following HCPCS S code may be used:

**Note:** Conventional PET scanning is considered separately in policy Nos. 6.01.20, 6.01.26, and 6.01.06, addressing the cardiac, oncologic, and other applications of PET scans, respectively.
S8085 Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (non-dedicated PET scan)

It is possible that institutions and providers may code for FDG-PET scans as if they were PET scans. PET scanning consists of 3 components: 1. preparation of the radiopharmaceutical; 2. the actual scan itself; and 3. physician interpretation.

The following CPT code describes PET as a technique to assess myocardial viability (i.e., metabolic imaging)

CPT code:

78459: Myocardial imaging, positron emission tomography (PET) metabolic evaluation.

The above CPT code essentially describes the physician work (i.e., interpretation component) of the PET scan. Institutions may code for the preparation of the radiopharmaceutical and the scan itself by using the “TC” modifier (i.e., technical component modifier) in conjunction with the above CPT code. However, if the radiopharmaceutical is supplied by an outside distribution center, there may be a separate charge for this component, distinct from the scan itself. In addition, there may be an additional transportation cost if the radiopharmaceutical is not manufactured on the premises. When charged separately, the radiopharmaceutical may be coded using the appropriate HCPCS code for the supply.

Specific coding for FDG-SPECT would require coding for the SPECT scan in conjunction with distinct coding for the radiopharmaceutical separate from the scan itself. However, all CPT codes describing SPECT scans include their clinical use (i.e., studies of wall motion, etc.), and no code describes the use of a SPECT scan to determine metabolic activity.

In 2006, a specific HCPCS code for FDG was added:

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

Rationale

FDG-SPECT imaging has been most extensively studied in 2 settings where conventional PET scanning has accepted clinical applications; oncologic applications, and assessment of myocardial viability. (See policy Nos. 6.01.26 and 6.01.20 for cardiac and oncologic applications of PET scanning, respectively.) For oncologic applications, the diagnostic performance of FDG-SPECT scanning must be evaluated in 2 settings; i.e., first, as an alternative to conventional PET scanning when PET facilities are locally available, and second, as an alternative to anatomic imaging techniques (typically CT scanning or MRI) when conventional PET scanning is not locally available. In assessing myocardial viability, FDG-SPECT scans must be compared to PET scans or conventional SPECT scans. Conventional thallium SPECT scanning reflects myocardial viability on the basis of cell membrane integrity, while, in contrast, PET scanning assesses myocardial viability on the basis of metabolic integrity. However, as discussed in a separate policy on cardiac applications of PET scanning (policy No. 6.01.20), the diagnostic performance of conventional PET and SPECT are considered clinically equivalent in the majority of cases.
Oncologic Applications

Both FDG-collimated-SPECT and FDG-DHC-SPECT have been evaluated in oncology patients. However, the early experience with FDG-collimated-SPECT suggested a significantly inferior performance of FDG-collimated-SPECT compared to PET scanning, and thus this technique has largely been abandoned in favor of FDG-DHC-SPECT. (1, 2) Representative studies using FDG-DHC-SPECT are reviewed here.

Tatsumi and colleagues reported on a study of 23 patients with newly diagnosed lung cancer who were examined with both conventional PET and FDG-DHC-SPECT on the same day. Although FDG-DHC-SPECT detected 22 of the 23 lung nodules, since this study only included patients with known lung cancer, it does not duplicate the typical clinical application of PET as a technique to evaluate an indeterminate pulmonary nodule. (3) Weber and colleagues reported on a case series of 96 patients who underwent FDG-DHC-SPECT scanning to evaluate pulmonary lesions with a mean size of 3.44 cm based on chest x-ray or CT scan. (4) Patients were selected for the study only if they were scheduled to undergo biopsy. Therefore, while the FDG-DHC-SPECT studies were compared to histopathologic diagnosis, the patient population had a higher prevalence of malignancy (90%), compared to the usual 40%–60% prevalence of malignancy in patients presenting with indeterminate lung lesions undergoing conventional PET scanning. The overall sensitivity and specificity of FDG-DHC-SPECT in diagnosing malignant lesions was 97% and 80%, respectively. CT scans were performed in 93 of the 96 patients; the sensitivity and specificity of CT scans in detecting malignancy was 99%–100% and 29%–38%, respectively, suggesting that compared to CT scanning, FDG-DHC-SPECT may have increased specificity. However, the authors note that the specificity of CT in this study is considerably lower than the 60% that is reported in the literature. The small number of benign lesions may explain the lower specificity in this series.

Delbeke and colleagues reported on a case series of 26 patients, 19 of whom had known or suspected malignancies in various sites. (5) All patients underwent both FDG-DHC-SPECT and conventional PET within one half hour of each other. Among the 19 oncology patients, FDG-DHC-SPECT identified only 28 of the 38 lesions identified by conventional PET scanning. Shreve and colleagues reported on a case series of 31 patients with known or suspected malignancies who underwent imaging with both conventional PET and FDG-DHC-SPECT. (6) All images were read blindly; PET results were considered the gold standard. Of a total of 109 discrete lesions depicted by conventional PET scanning, only 60 were identified by FDG-DHC-SPECT for a relative sensitivity of 55%. The relative sensitivity of FDG-DHC-SPECT was highest in the lung (FDG-DHC-SPECT correctly identified 13 of 14 lesions) and lowest in the abdomen (FDG-DHC-SPECT correctly identified only 6 of 23 lesions). The superior performance of FDG-DHC-SPECT in the lung compared to other sites may be related to the relatively low background noise in the lungs, which maximize contrast for pulmonary nodules. When background noise is higher, detection of small nodules (less than 1.5 cm) was clearly inferior for FDG-DHC-SPECT compared to conventional PET. The authors concluded that FDG-DHC-SPECT cannot be considered comparable to conventional PET for oncologic diagnosis. Other case series of FDG-DHC-SPECT report similar results, i.e., an inferior diagnostic performance of FDG-DHC-SPECT compared to PET, particularly for smaller lesions, or those located outside the lungs. (7-10)

Conclusion
Regarding oncologic applications, the data suggest that FDG-SPECT cannot be considered an equivalent diagnostic modality compared to conventional PET scanning, particularly for small lesions. There are inadequate data regarding the diagnostic performance of FDG-SPECT compared to other anatomic imaging techniques, such as CT or MRI scan.

**Cardiac Applications**

Both FDG-collimated and FDG-DHC-SPECT have been studied as techniques to evaluate myocardial viability. Srinivasan and colleagues reported on a case series of 28 patients with chronic coronary artery disease and left ventricular dysfunction. (11) All patients underwent FDG-collimated-SPECT, conventional PET, and thallium SPECT studies. Conventional PET served as the gold standard. The authors reported excellent overall correlation among all 3 techniques, although differences emerged on subset analysis. For example, for those with severe left ventricular dysfunction (i.e., ejection fraction less than 25%), conventional thallium SPECT tended to underestimate myocardial viability compared to FDG-collimated-SPECT and conventional PET. However, the majority of discordant lesions were located in the inferior wall, and the poorer performance of SPECT in this region may not be related to any limitation in thallium delivery or uptake, but instead due to the physical property of attenuation of the lower energy photons (compared to FDG) as they traverse the thorax. This limitation in thallium SPECT scanning may be corrected by attenuation correction. (12) More recently, Hasegawa and colleagues compared FDG-DHC-SPECT, FDG-collimated SPECT, and PET scanning as techniques to evaluate myocardial viability in 25 patients. (13) The authors reported that the image quality of FDG-DHC-SPECT was superior to that of FDG-collimated SPECT, and equivalent to conventional PET if adequate attenuation correction is used.

**Conclusion**

The data suggest that all 4 methods—conventional thallium SPECT, FDG-collimated-SPECT, FDG-DHC-SPECT, and PET scanning may be clinically useful and considered equivalent in most cases. However, it is difficult to determine in which subsets of patients one technique may be superior to another, or if the diagnostic performance is improved with the combination of techniques. There are no data to suggest that the combination of FDG-SPECT with PET scans improves diagnostic performance of either technique alone. There are no data regarding the use of FDG-SPECT in the evaluation of coronary perfusion defects.

**Neurologic Disorders**

PET scans have been widely used in the evaluation of neurological disorders, ranging from epilepsy to dementias. There are inadequate data to compare FDG-SPECT to PET for neurological disorders.

**Medicare Policy**

The initial 1998 Medicare policy on oncologic aspects of PET scanning states that PET scans must be performed using a camera that has either been approved or cleared for marketing by the U.S. Food and Drug Administration (FDA) to image radionuclides in the body. Since SPECT scans would meet this definition, some local Medicare carriers may have applied the 1998 Medicare policy on PET scanning to FDG-SPECT scans. In December 2000, Medicare announced a new coverage policy for PET scanning, expanding coverage from the original 1998 indications for coverage (evaluation of pulmonary nodules, staging of non-small cell lung cancer, evaluation of recurrent colorectal tumors, staging restaging lymphoma, and evaluating
recurrence of melanoma) to a broadening range of tumor types. At that time, the proposed policy limited coverage to only full ring PET systems. However, based on industry input, Medicare further investigated the relative performance of various camera-based PET systems, including the use of SPECT cameras (i.e., camera-based or gamma cameras). Their review of the scientific data is included in the decision memorandum posted on the Web site. (14) This document offers the following conclusions:

"There are no clear, comparative, broad indication studies, and only very small, indication-specific studies to compare camera-based PET to full-ring PET. Further, these studies are designed to focus mainly on the intrinsic performance of the scanners, not the evaluation of reconstruction and processing algorithms on the sensitivity and specificity of different systems under conditions of actual clinical use. In other words, after an exhaustive search for empirical data, there is no body of evidence that attests to the medical benefit associated with use of camera-based PET that is comparable to the literature used to arrive at the December 15, 2000, decision memorandum for full-ring PET. The extension of that decision memorandum to camera-based systems, while anecdotally supported by nuclear medicine experts, cannot be clearly justified based on existing clinical and scientific data.

In fact, review of the existing literature on camera-based PET leads to the conclusion, present in several articles, that these systems miss a significant number of small- and medium-sized malignant lesions. Because of the limited size of the studies and other methodologic weaknesses, it is not possible to make confident estimates of the frequency with which these different systems produce false positive or false negative results. Furthermore, it is not possible to determine the clinical significance of diagnostic errors that might result from use of these PET technologies. However, given the intended diagnostic role for oncologic uses of PET, it is likely that inaccurate results provided by these imaging systems could lead to errors in treatment, such as early termination of chemotherapy or unnecessary surgical intervention. Without better studies that provide more confident estimates of the sensitivity and specificity from camera-based PET systems, it may not be possible for clinicians to properly interpret the finding from these imaging studies… Given this body of scientific information, gamma camera PET… will not be covered for the clinical indications which are newly-covered, based upon the December 15, 2000, decision memorandum." (14)

In part as a result of this decision memorandum, Medicare introduced new HCPCS codes that distinguish between full- and partial-ring PET scanners and gamma cameras. However, as noted here, the conclusions of the Medicare review were only applied to the new 2000 indications for oncologic applications for PET scanning. Apparently the Medicare policy addressing the 4 original indications approved in 1998 did not specify which types of scanners could be used. While the same limitations in the data would apply to these indications (evaluation of pulmonary nodules, staging of non-small cell lung cancer, evaluation of recurrent colorectal tumors, staging restaging lymphoma, and evaluating recurrence of melanoma), the Medicare policy does not limit the type of scanner used for these situations. Therefore, 4 additional HCPCS codes were created that explicitly describe the use of gamma cameras for PET scanning as follows:

G0231: PET, whole body, for recurrence of colorectal or colorectal metastatic cancer; gamma cameras only

G0232: PET, whole body, for staging and characterization of lymphoma; gamma cameras only
G0233: PET, whole body, for recurrence of melanoma or melanoma metastatic cancer; gamma cameras only

G0234: PET, whole body, for solitary pulmonary nodule following CT or for initial staging of pathologically diagnosed non-small cell lung cancer; gamma cameras only.

CMS discontinued these G codes in 2005.

In summary, the proposed BCBSA policy differs from the Medicare policy in the following ways:

- The BCBSA policy considers all oncologic applications for FDG-PET (i.e., PET with a gamma camera) investigational, while the Medicare policy would consider FDG-PET medically necessary for the 4 oncologic indications originally covered in 1998.

- The BCBSA policy considers FDG-PET to be medically necessary to evaluate myocardial viability; Medicare has no specific policy on cardiac applications of FDG-PET.

Please refer to policy Nos. 6.01.20 and 6.01.26 for more information on specific criteria for cardiac and oncologic applications of PET, respectively.

2005 Update

A search of the literature based on the MEDLINE database did not identify any articles that would prompt reconsideration of this policy; therefore, the policy statement remains unchanged. The expanding indications for PET scanning and positive national Medicare coverage policies regarding various applications of PET scanning have prompted a wider dissemination of dedicated PET scanners. It appears that FDG-SPECT represented a transitional technology that is no longer widely used. Therefore, this policy is assigned to no further review.

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