FDG PET Reimbursement

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Today, PET is increasingly accepted as a crucial imaging modality for early detection of disease, precise staging of disease progression, and accurate assessment of the effects of therapy. As the role of PET continues to emerge, so do questions regarding PET reimbursement. Understanding the complexities and complying with reimbursement policies, procedures, and interpretation of payer programs is key to receiving appropriate reimbursement for services performed. Therefore, it is imperative that facilities stay current on reimbursement issues—especially for a fast-evolving modality like PET, where indications and policies for reimbursement are continually being updated by the Centers for Medicare and Medicaid Services (CMS).

EVOLUTION OF CMS FDG PET REIMBURSEMENT

As indicated by the chronological listing below, FDG PET reimbursement by Medicare has evolved substantially over the past few years. Over this time period and through the efforts of many people and professional organizations, clinical data supporting the use of PET imaging and demonstration of the utility of PET, along with analysis of published literature, was submitted to CMS. Based on these submissions, CMS has gradually expanded the coverage of PET imaging.

January 1998

Medicare began coverage of FDG PET for:

- The characterization of single pulmonary nodules (SPNs); and
- The initial staging of non-small-cell lung cancer (NSCLC).

July 1999

Medicare began coverage of FDG PET for:

- Colorectal cancer to determine the location of tumors if a rising CEA level suggests recurrence;
- Lymphoma for staging and restaging only when used as an alternative to a Gallium scan; and
- Melanoma for evaluating recurrence prior to surgery as an alternative to a Gallium scan.

July 2001

Medicare expanded coverage of FDG PET using a *dedicated PET* scanner for the diagnosis, staging and restaging of:

- Non-small-cell lung cancer (NSCLC) including characterization of SPNs;
- Colorectal cancer;
- Lymphoma; and
- Melanoma.

Medicare began providing coverage for FDG PET for:

- Head and neck cancer; and
- Esophageal cancer.

In addition, coverage was announced for:

- The determination of myocardial viability following an inconclusive SPECT; and
- Pre-surgical evaluation of refractory seizures.

The expanded PET coverage *excluded* gamma camera coincidence systems and coverage using these systems was restricted to the original 5 indications established in 1998 and 1999.

January 2002

Medicare instituted unique billing codes for FDG PET when performed with certain gamma camera coincidence systems (Table 1).

April 2002

Medicare began separate, per dose, payment for the radiopharmaceutical FDG, for hospitals paid under the Hospital Outpatient Prospective Payment System (HOPPS), by establishing a new HCPCS code for the FDG (C1775).

October 2002

Medicare began coverage of FDG PET with dedicated PET scanners for breast cancer staging/restaging and the evaluation of response to treatment.

Medicare expanded coverage for the determination of myocardial viability to include primary or initial diagnostic study prior to revascularization.

October 2003

Medicare began coverage of FDG PET with dedicated PET scanners for thyroid cancer restaging (limited coverage).

MEDICARE PAYMENT RATES FOR HOSPITAL OUTPATIENTS

Table 2 summarizes the technical component of 2004 Medicare payment rates to hospitals paid under HOPPS for

TABLE 1
Medicare Covered Clinical Conditions, HCPCS/CPT Codes, and Descriptions for FDG PET—Coincidence Gamma Camera Only

Covered clinical condition	Code	Code description
Colorectal Cancer Determining location of colorectal tumors if rising CEA level suggests recurrence	G0231	PET, whole body, for recurrence of colorectal or colorectal metastatic cancer
Lymphoma Staging or restaging of lymphoma only when used as an alternative to a gallium scan	G0232	PET, whole body, for recurrence of lymphoma
Melanoma Evaluating recurrence of melanoma prior to surgery as an alternative to a gallium scan	G0233	PET, whole body, for recurrence of melanoma or melanoma metastatic cancer
Single Pulmonary Nodule (SPN) Characterization of single pulmonary nodules following CT, lesion not to exceed 4 cm *or* **Lung Cancer—Non Small Cell** Initial Staging	G0234	PET, regional or whole body, for single pulmonary nodule following CT, or for initial staging of pathologically diagnosed non-small cell lung cancer

FDG PET. These claims are processed and paid by the regional Medicare Part A Fiscal Intermediaries and are subject to a slight geographic wage index adjustment. Each HCPCS/CPT code is mapped to an APC and each APC has a payment rate assigned to it.

Revenue Codes: Hospitals should use revenue code 404 for reporting PET imaging procedures and revenue code 636, "drugs requiring detailed coding," for reporting FDG.

MEDICARE PAYMENT RATES IN FREESTANDING FACILITIES

Claims from freestanding facilities are processed and paid by the regional Medicare Part B Carriers. CMS does not establish relative value units for the technical component for PET scans. They are carrier priced, which means each carrier is responsible for establishing the payment rate for the technical component for PET scans in their jurisdiction. The payment rates as listed in the various Medicare Part B 2004 physician fee schedules for the technical component for FDG PET range from $1,779 to $2,951 with high cost-of-living urban areas receiving the higher payments. In general the payment for the supply of the radiopharmaceutical FDG is included in the payment for the procedure. Providers are encouraged to check with their local carrier for verification.

MEDICARE PAYMENT RATES TO PHYSICIANS

Physician claims are processed and paid by the regional Part B Medicare Carriers. CMS establishes relative value units for the professional component for PET scans, which are subject to a slight adjustment based on the geographic practice cost index for each physician fee schedule area. A review of the various Medicare Part B Carrier physician fee schedules shows payments ranging from $73 to $117 for the professional component for FDG PET.

MEDICARE COVERAGE BY ALLOWABLE TYPE OF FDG PET SCANNER

In CMS Program Memorandum, Transmittal AB-01-168, released November 27, 2001, CMS defined its coverage policy for FDG PET when performed with "certain coincidence gamma camera systems." "Certain coincidence systems" must have all of the following features:

TABLE 2
Medicare 2004 HOPPS Payment Rates for FDG PET

	HCPCS/CPT codes	APC code	Medicare APC payment	Total scan payments
FDG, per dose	C1775	1775	$ 324.48	—
Dedicated FDG PET	G0125, G0210–G0218, G0220–G0229, G0253–G0254, G0296	1516	$1,450.00	$1,774.48
Gamma Camera FDG PET	G0231–G0234	1516	$1,450.00	$1,774.48
Myocardial Viability	G0230	1516	$1,450.00	$1,774.48
Myocardial Viability	78459	0285	$ 772.08	$1,096.59

- Crystal at least 5/8-inch thick;
- Techniques to minimize or correct for scatter and/or randoms, and
- Digital detectors and iterative reconstruction.

The program memorandum establishes unique HCPCS codes (G0231-G0234) to be used for PET scans performed with coincidence gamma camera systems (Table 1). All other HCPCS/CPT codes for PET are for full- and partial-ring PET scanners only (Table 3). All PET scans must be performed using systems that are FDA approved in order to be eligible for payment by Medicare. Camera vendors receive FDA approval for their systems by receiving a 510K clearance letter from the FDA. This documentation certifies the system is cleared for marketing by the FDA to image radionuclides in the body. When submitting a PET scan claim to Medicare, the provider is certifying they have an FDA approved system and will be able to produce a copy of this approval upon request. Some Medicare contractors may require providers to submit to them the 510K FDA clearance letter before Medicare will start paying claims. Providers should check with their local Medicare contractor for guidance. Providers should maintain a copy of the FDA 510K clearance letter on file.

MEDICARE CONDITIONS OF COVERAGE

All uses of FDG PET scans, in order to be covered by the Medicare program, must meet the following general conditions as of July 1, 2001:

- The provider of the PET scan should maintain on file the doctor's referral and documentation that the procedure involved only FDA approved drugs and devices, as is normal business practice. The provider's medical records can be used in any post-payment review and must include the information necessary to substantiate the need for the PET scan.
- The ordering physician is responsible for documenting the medical necessity of the study and ensuring that it meets the conditions specified in the instructions. The ordering physician should have documentation in the beneficiary's medical record to support the referral to the PET scan provider.

For all uses of PET relating to malignancies the following conditions apply:

1. **Diagnosis:** PET is covered only in clinical situations in which PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical 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, and colorectal cancers as well as in melanoma should be rare. PET is not covered for other diagnostic uses, and is not covered for screening (testing of patients without specific signs and symptoms of disease).
2. **Staging:** PET is covered only when clinical management of the patient would differ depending on the stage of the cancer identified, and:
   1) 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
   2) 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.
3. **Restaging:** PET is covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. The use of PET would also be considered reasonable and 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 patient.
4. **Monitoring:** Use of PET to monitor tumor response during the planed course of therapy (i.e., when no change in therapy is being contemplated) is not covered. Restaging only occurs after a course of treatment is completed, and this is covered, subject to the conditions above.

The coverage for breast and thyroid cancer is more narrowly focused than for the other covered malignancies.

Breast Cancer Coverage Conditions

- Staging patients with distant metastasis, or restaging patients with locoregional recurrence or metastasis as an adjunct to standard imaging modalities.
- Monitoring response to treatment of locally advanced and metastatic breast cancer when a change in therapy is contemplated as an adjunct to standard imaging modalities.

Thyroid Cancer Coverage Conditions

Medicare covers the use of FDG PET for thyroid cancer only for restaging of recurrent or residual thyroid cancers of follicular cell origin that have been previously treated by thyroidectomy and radioiodine ablation when serum thyroglobulin is greater than 10 ng/ml and a negative I-131 whole body scan has been performed. Four distinct histologic types of follicular cell derived cancers are recognized:

- Follicular;
- Papillary;
- Hürthle cell; and
- Anaplastic.

TABLE 3
Medicare Covered Clinical Conditions, HCPCS/CPT Codes and Descriptions for FDG PET—Dedicated FDG PET Scanners Only

Covered clinical condition	Code	Code description
Single Pulmonary Nodule (SPN)		
Characterization of single pulmonary nodules following CT, lesion not to exceed 4 cm	G0125	PET imaging; regional or whole body; single pulmonary nodule
Lung Cancer–Non Small Cell		
Diagnosis	G0210	PET imaging whole body; diagnosis; lung cancer, non-small cell
Staging	G0211	PET imaging whole body; initial staging; lung cancer, non-small cell
Restaging	G0212	PET imaging whole body; restaging; lung cancer, non-small cell
Colorectal Cancer		
Diagnosis	G0213	PET imaging whole body; diagnosis; colorectal cancer
Staging	G0214	PET imaging whole body; initial staging; colorectal cancer
Restaging	G0215	PET imaging whole body; restaging; colorectal cancer
Melanoma (not covered for evaluating regional nodes)		
Diagnosis	G0216	PET imaging whole body; diagnosis; melanoma
Staging	G0217	PET imaging whole body; initial staging; melanoma
Restaging	G0218	PET imaging whole body; restaging; melanoma
Non-covered indications	G0219	PET imaging whole body; melanoma, for non-covered indications
Lymphoma		
Diagnosis	G0220	PET imaging whole body; diagnosis; lymphoma
Staging	G0221	PET imaging whole body; initial staging; lymphoma
Restaging	G0222	PET imaging whole body; restaging; lymphoma
Head and Neck Cancer (excluding CNS and thyroid cancers)		
Diagnosis	G0223	PET imaging whole body or regional; diagnosis; head and neck cancer
Staging	G0224	PET imaging whole body or regional; initial staging; head and neck cancers
Restaging	G0225	PET imaging whole body or regional; restaging; head and neck cancers
Esophageal Cancer		
Diagnosis	G0226	PET imaging whole body; diagnosis; esophageal cancer
Staging	G0227	PET imaging whole body; initial staging; esophageal cancer
Restaging	G0228	PET imaging whole body; restaging; esophageal cancer
Pre-surgical evaluation of refractory seizures	G0229	PET imaging; metabolic brain imaging for pre-surgical evaluation of refractory seizures
Myocardial Viability	G0230	PET imaging; metabolic assessment for myocardial viability following an inconclusive SPECT study
Myocardial Viability	78459	PET imaging; metabolic evaluation for determination of myocardial viability as a primary or initial diagnostic study prior to revascularization
Breast Cancer		
Diagnosis (not covered)	G0252	PET imaging; for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g. initial staging of axillary lymph nodes), *not covered by Medicare*
Staging/restaging	G0253	PET imaging for breast cancer; staging/restaging, of local regional recurrence or distant metastases, i.e., staging/restaging after or prior to course of treatment
Evaluation of response to treatment	G0254	PET imaging for breast cancer; evaluation of response to treatment, performed during course of treatment
Thyroid Cancer		
Restaging	G0296	PET imaging; for restaging of previously treated thyroid cancer of follicular cell origin following negative I-131 whole body scan

All other uses of FDG PET in the diagnosis and treatment of thyroid cancer remain noncovered.

Note: Medicare does not cover PET for screening, evaluation of central nervous system cancers, regional lymph node evaluation in melanoma, initial diagnosis of breast cancer, or surgical planning for breast cancer. The Medicare Coverage Issues Manual for PET, Transmittal 171, June 20, 2003 stipulates that a particular use of PET scans is not covered unless the manual specifically provides that such use is covered.

CONDITIONS ON FREQUENCY

Medicare has addressed the issue of frequency limitations with the following general statement: In the absence of

national frequency limitations, contractors may, if necessary, develop frequency requirements on any or all of the indications covered on or after July 1, 2001.

There is one national frequency limitation set forth for SPN. PET for SPN is not covered if repeated within *90* days following a negative PET scan. Providers should consult with their local Medicare contractor to determine if other frequency limitations have been established.

MEDICARE LOCAL VARIABILITY

Although PET coverage is determined at the national level there can be some local variability especially with respect to ICD.9.CM coding or utilization guidelines and possible frequency limitations. Some Medicare contractors have published Local Medical Review Policies (LMRP) for PET where this information may be found. Local guidelines for PET coverage may also be found in the newsletters and bulletins published by individual Medicare contractors. Providers should be familiar with PET LMRP (if published) and the information on PET contained in bulletins on their local Medicare contractor's website.

To obtain the website address for your specific Part A Fiscal Intermediary or Part B Carrier, visit the following CMS website which provides a directory by state http://www.cms.hhs.gov/contacts/

PRIVATE PAYER COVERAGE AND BILLING FOR FDG PET

In general the coverage policies of private payers most often reflect Medicare approved indications, however some have expanded coverage. Some private payers accept the Medicare G codes, but, most likely, CPT codes will be required for billing PET scans. The provider should check with their local private payers for guidance on coverage and billing. (Note: if a private payer accepts both CPT and G codes, the payment rate may differ.)

Table 4 lists the CPT codes used to bill for PET scans.

TABLE 4
CPT Codes for PET Scans

CPT code	Description
78810	Tumor imaging, PET, metabolic evaluation
78459	Myocardial imaging, PET, metabolic evaluation
78491	Myocardial imaging, PET, perfusion; single study at rest or stress
78492	Myocardial imaging, PET, perfusion; multiple studies at rest and/or stress
78608	Brain imaging, PET, metabolic evaluation
78609	Brain imaging, PET, perfusion evaluation
78990 or A4641	Provision of a diagnostic radiopharmaceutical

FUTURE EXPANDED COVERAGE OF PET BY MEDICARE

PET coverage by Medicare is determined at the national level. When Medicare formally considers if it will cover, or not cover, specific services, procedures, or technologies on a national basis, a National Coverage Analysis (NCA) is performed. Decisions on coverage result from CMS investigation of formal requests for an NCA. As this article goes to press, two pending NCAs for expanded PET coverage are under consideration:

1. NCA (CAG-00181N). This NCA encompasses six new indications for consideration of coverage:

   - FDG PET for brain tumors;
   - FDG PET for cervical cancer;
   - FDG PET for ovarian cancer;
   - FDG PET for pancreatic cancer;
   - FDG PET for small cell lung cancer; and
   - FDG PET for testicular cancer.

   CMS estimated the completion date for review for this NCA to be late November 2003; however, a decision memo has not been published.

2. NCA (CAG-00088R). This NCA is to reconsider a previous non-coverage decision for FDG PET for Alzheimer's Disease/Dementia. A more restrictive coverage determination is being considered. CMS estimates the completion date for review for this NCA to be June 2004.

Once a final coverage decision is reached on a particular NCA then CMS will publish a decision memorandum announcing either a non-coverage or coverage decision. If coverage is approved, the specifics of the conditions of coverage will be documented in the decision memorandum. The Medicare NCA database can be found at http://www.cms.hhs.gov/ncdr/ncdr_index.asp.

News of CMS determination is covered on the SNM Web site (http://www.snm.org) under Government Relations. Other billing information, including the latest HOPPS information can be found under Practice Management.

SUMMARY

Medicare coverage of PET will continue to be an evolving process as the current NCAs are determined and as new indications are considered. Providers of PET services must stay abreast of these changes to ensure adequate reimbursement for services provided and to maintain compliance with CMS policies. It is therefore important for providers to pay attention to any changes and make the necessary adjustments in their PET imaging program.

REFERENCES

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