Federal Regulations and Reimbursement for PET

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Objective: The regulatory and reimbursement environment for PET has changed significantly over the past several years. The Food and Drug Administration's (FDA) findings of the safety and efficacy of key PET drugs have been published, as well as guidelines for the applications to produce PET drugs. In addition, the national Medicare coverage policy for PET has been expanded, most recently with additional indications and coverage restrictions added as of July 2001. The payment rates under the new Hospital Outpatient Prospective Payment System (HOPPS) have been set for PET as well. This communication reviews these recent changes and discusses their impact on the development and operation of a PET center. After reading this article, the nuclear medicine technologist should be able to: (a) state the indications for the use of PET drugs that have been found to be safe and effective by the FDA; (b) detail the general procedures a PET drug production site would have to undertake to be in compliance with FDA regulations; (c) list specific studies that have been approved for payment by Medicare; and (d) describe billing codes used for PET scans. Clarification of regulatory and reimbursement issues is leading to rapid expansion of clinical PET. Keeping abreast of these changes will ensure the successful expansion of any nuclear medicine program to include PET services.

Key Words: G-codes; Medicare; reimbursement; PET drugs; Hospital Outpatient Prospective Payment System; Food and Drug Administration

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Knowledge of regulatory and reimbursement policy has become increasingly important for nuclear medicine technologists. Recent changes in regulatory policy and the implementation of complicated Medicare reimbursement schemas require staff to develop the expertise to ensure that their department is maximizing payments and efficiency.

Regulations for PET are set by the Food and Drug Administration (FDA) for the production and use of PET drugs, the Nuclear Regulatory Commission or state radiation regulatory agency for the handling of PET isotopes, and the Environmental Protection Agency (EPA) for the release of PET radionuclides into the environment. Because the regulations for handling the short-lived PET tracers are substantially the same as those for traditional nuclear medicine isotopes, this article will focus on the role of the FDA in the approval for use and production of PET radiopharmaceuticals. Closely related to regulatory compliance is the issue of reimbursement. Both public (Medicare, Medicaid) and private sector (indemnity insurance, HMOs) insurance providers make payment decisions on new drugs and procedures after approval by the FDA. Incorporated in this article is a summary of the status of reimbursement for PET and payment levels a site may expect to receive.

FDA OVERSIGHT OF PET

The FDA typically approves drugs after a company conducts a rigorous scientific study, performs and reports phased clinical trials, and subsequently submits a manufacturing application. Control of access to the drug is maintained during this testing period. Once the drug is approved, marketing exclusivity is granted for a period of time before generic drugs can be made, so that the company has a period of time to recoup the costs of drug development and testing. Sites that manufacture the drugs must register with the FDA as a "drug establishment." Drugs must be produced exactly according to the specifications and procedures in the application and in compliance with Current Good Manufacturing Practices (CGMPs).

This traditional pathway of drug approval could not be easily applied to PET. By the time FDA approvals were contemplated, the drugs were in widespread use, without proprietary exclusion. They were originally produced, not by industry, but by academic institutions and hospitals. By the time commercial entities began producing the commonly used clinical PET drugs, proprietary distribution to offset the cost of FDA application was not possible. In addition, the academic community had conducted and published a number of studies on the use of these PET drugs; however, many of the publications did not contain the detail or controls of typical FDA trial submissions. At the encouragement of the FDA, members of the community sought to apply for approvals, but the FDA requirements for production and manufacturing did not easily fit either the short-lived tracers produced or the small-scale production environment in which most PET drugs are made.

The FDA Modernization and Accountability Act of 1997 (FDAMA) sought to remedy the regulatory challenges facing PET. FDAMA required the FDA to adopt "appropriate"

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procedures for approval of New Drug Applications (NDAs) and abbreviated NDAs for PET radiopharmaceuticals, as well as "appropriate" CGMPs for the production of PET compounds. In addition, the FDA was to take "due account of any relevant differences" between commercial PET centers and not-for-profit PET facilities, to reduce the burden of coming into compliance for noncommercial PET production facilities. The new requirements were to be determined by the FDA, in consultation with industry, patients, and the user community.

A PET Radiopharmaceutical Committee (PET-RC) was formed under the initiative of the Institute for Clinical PET (now the Academy of Molecular Imaging [AMI]), with representatives of the Society of Nuclear Medicine (SNM). The PET-RC began assisting the FDA with developing the regulations mandated by FDAMA. FDA efforts initially focused on completing safety and efficacy evaluation of PET radiopharmaceuticals in clinical use today, as well as on developing chemistry guidelines for NDAs and CGMPs for PET production sites.

Safety and Efficacy of PET Compounds

An important step toward bringing PET into regulatory compliance is to provide a mechanism by which current and future PET drugs can be approved for use. Because there was no clear sponsor for developing NDAs for PET drugs in common clinical use, the FDA determined that it would conduct the safety and efficacy evaluations of several of these PET radiopharmaceuticals. Before this, two positron-emitting drugs had been approved by the FDA: ^{82}Rb for perfusion imaging of the heart and [^{18}F]-fluoro-deoxyglucose (FDG) for the evaluation of epilepsy (at a single site, The Downstate Clinical PET Center at Methodist Medical Center in Peoria, IL). The PET-RC targeted approval of FDG for additional indications, as well as [^{13}N]-ammonia (NH_3), [^{15}O]-water (H_2O), [^{18}F]-fluoride (^{18}F-ion), and [^{18}F]-fluoro-dopa (F-DOPA).

FDA-conducted safety and efficacy evaluations are based on the publications in the peer-reviewed literature. Their findings are then published in the *Federal Register* and accompanied by invitations for applications to produce the cited drugs. The FDA has done this in the past for other drugs, including the use of birth control pills as emergency "morning after" contraception (*1*).

The evaluation was completed for FDG, NH_3, and H_2O in consultation with the PET community. These analyses were then presented to the FDA Medical Imaging Drug Advisory Committee in June 1999. The FDA uses advisory committees such as this to provide recommendations to the FDA on the approval of new drugs. Based on the review presented to them, the Advisory Committee found the following:

- FDG is safe and effective in PET imaging for assessment of abnormal glucose metabolism to assist in the evaluation of malignancy in patients with known or suspected abnormalities found by other testing modalities, or in patients with existing diagnoses of cancer.
- FDG is safe and effective in PET imaging in patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging, to examine myocardial glucose metabolism and to identify myocardium with reversible loss of systolic function.
- NH_3 is safe and effective in PET imaging of the myocardium under rest or pharmacological stress conditions to evaluate myocardial perfusion in patients with suspected or existing coronary artery disease.

The Advisory Committee needed to review additional published literature on the validation of water as a brain perfusion agent. The FDA has agreed to gather and analyze the literature for this indication as well as for F-DOPA for movement disorders. The PET-RC and the PET community will provide an analysis of the literature in support of the clinical use of FDG in dementia. Once these are completed, the Medical Imaging Drug Advisory Committee will be reconvened to evaluate these other PET drugs. This same process, managed in the future by the PET community, will remain as one mechanism for obtaining FDA approval of new PET radiopharmaceuticals.

The March 10, 2000, *Federal Register* published the FDA findings on the safety and efficacy of FDG and NH_3 (*2*). PET production sites were invited to submit an NDA or an Abbreviated New Drug Application (ANDA) for each of these products, referencing this *Federal Register* announcement as the basis for the clinical efficacy and safety of these compounds.

Chemistry and Manufacturing Regulations

Establishing the safety and efficacy of PET compounds was just one step in making the PET drugs "approvable" by the FDA. The FDA has maintained that its role also includes the assurance that the sites manufacturing these drugs produce high-quality compounds on a continual basis. Ordinarily, this is done through the registration of manufacturing sites, the filing of applications to manufacture the drugs (NDAs and ANDAs), and the enforcement of standard manufacturing practices.

The FDA asserts that all PET production sites will need to follow substantially the same process. Each cyclotron production site will need to register as a drug establishment and list the drugs in "clinical use" (for which there is an exchange of value for their use). Sites would file NDAs or ANDAs for the production of the compounds, follow CGMPs for PET, and be open to FDA inspection. FDAMA required that these processes be facilitated for PET and set up in a manner appropriate to their site and scale of use, as well as half-life properties, so the FDA developed drug application templates and is in the process of devising new manufacturing regulations and guidelines.

The NDA and ANDA templates described above were published as a part of a Draft Guidance for Industry on the Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emis-

sion Tomography Drug Products (*2*). The availability of the draft guidance was published in the March 10, 2000, *Federal Register*. Copies of the draft guidance can be downloaded from the FDA Web site at http:/www.fda.gov/cder/regulatory/pet. These PET production templates were developed by the FDA in consultation with the PET-RC and consist primarily of the chemistry, manufacturing, and controls (CMC) sections of NDA and ANDA applications. Templates are specific to each type of PET drug and contain details about manufacturing that particular PET compound. Because the safety and efficacy of PET drugs were established through the *Federal Register* announcement described above, NDAs and ANDAs will be composed solely of these templates for the CMC, and a few other basic forms. With the availability of safety and efficacy findings and CMC templates, the PET drug application process has been substantially simplified compared with submittal of an NDA or ANDA under the previous regulatory framework.

The remaining issue to be resolved in the regulation of PET is the development of appropriate manufacturing practices that can be used as standards for facilities producing these compounds. The FDA had drafted several outlines of new CGMPs, with the most recent draft being distributed at a public meeting in September 1999. Discussions were held at that meeting to suggest modifications. Subsequently, the FDA participated in tours of several PET production centers to see how production standards could be developed. Draft proposed CGMPs for PET and draft proposed guidance for their implementation are expected to be published by the FDA on its Web site and announced in the *Federal Register* in the spring of 2002. The FDA will invite the community to discuss these drafts at a public meeting. After the meeting, it is expected that these drafts will be further modified, then published as "proposed" regulations and guidance. The public will have a defined period for comment on this rule (generally 60–90 days). Once comments are received, a final rule will be published. Final guidance documents would also be published at the same time to assist the PET community with setting up their centers in accordance with the new guidelines.

PET production sites will have 2 years from that point to come into compliance with this new regulatory framework. They will be required to file the appropriate paperwork with the FDA to "register" as PET manufacturing or production sites, file NDAs or ANDAs for all approved clinical PET drugs, conduct activities and operations within the standards of the new CGMPs for PET, and participate in FDA site inspections. It is anticipated that the FDA will continue to provide education to PET production sites and FDA inspectors to facilitate the transition to this fully regulated environment.

REIMBURSEMENT FOR PET

In addition to progress on the regulatory front, tremendous headway has been made in increasing public sector reimbursement for PET. Working with Jeffrey Kang, MD, Director, Office of Clinical Standards and Quality, as well as members of the Center for Medicare and Medicaid Services (CMS) Coverage and Analysis Group, representatives of the AMI and the SNM secured Medicare coverage for PET scanning.

Medicare Coverage for Specific PET Indications

The CMS is the oversight body in the federal government for Medicare health insurance coverage. CMS can choose to make decisions on a national level that mandate coverage for all beneficiaries or defer decisions to the local insurance providers of Medicare services. CMS first authorized coverage at the national level for PET in 1995 for studies using the cardiac perfusion agent ^{82}Rb. At that time, the national Medicare coverage policy for PET restricted coverage for all Medicare patients to ^{82}Rb applications; other indications for PET were considered experimental. Thus, unlike many new technologies, in which coverage decisions could be made at a local level, all coverage decisions for PET are currently restricted to CMS.

As a result of meetings between Donna Shalala, former Secretary of Health and Human Services, and Ted Stevens (R-AK), along with other congressional leaders, CMS revised its national coverage policy for PET in 1997. Medicare beneficiaries were afforded access to coverage for PET scans for characterization of solitary pulmonary nodules and initial staging of lung cancer in certain patient populations beginning January 1, 1998. This was the first of several steps taken by the CMS toward a careful expansion of PET reimbursement. Billing and coverage would be provided using the HCFA Common Procedure Coding System (HCPCS), which is a nationwide system that categorizes procedures into a standardized list of alphanumeric codes. Specifically, CMS assigned G-codes so that they could collect data on PET efficacy.

CMS held a public town hall meeting on January 20 and 21, 1999, to facilitate reimbursement approval of other indications for PET. CMS determined that this meeting would focus on discussions of the clinical data supporting the use of PET imaging in five potential indications: colorectal cancer, melanoma, head and neck cancer, lymphoma, and brain tumors.

As a result of these efforts, in March of 1999, CMS announced that Medicare's coverage policy would be expanded, effective July 1, 1999, to include three new indications for whole-body PET scans using FDG:

- Evaluation of recurrent colorectal cancer in patients with rising levels of carcinoembryonic antigen (CEA)
- Staging and characterization of lymphoma (both Hodgkin's and non-Hodgkin's lymphoma, when done as an alternative to a gallium scan)
- Detection of recurrent or metastatic melanoma prior to surgery

In keeping with their coding schema, additional G-codes were issued for these new indications as well.

In July 2000, members of the PET community petitioned CMS to expand the covered indications of PET once again. Leaders in the PET community, such as R. Edward Coleman, MD; Sanjiv Gambhir, MD, PhD; Peter Valk, MD; and others from the AMI and SNM compiled a 170-page analysis of the literature. The in-depth analysis referenced published literature and utilized decision analysis techniques to demonstrate the utility of PET. The CMS issued its decision on the petition for expanded coverage on December 15, 2000, which became effective July 1, 2001 (*3*). This expansion included the following:

- Diagnosis, staging, and restaging of non–small cell lung cancer, esophageal cancer, colorectal cancer, lymphoma, melanoma, and head and neck cancer (excluding thyroid and CNS cancers)
- Evaluation of myocardial viability following an inconclusive SPECT scan
- Presurgical evaluation of refractory seizures

Effectively, this policy expanded the coverage that had been limited for lung and colorectal cancer, melanoma, and lymphoma, and developed coverage for esophageal and head and neck cancer, as well as epilepsy and cardiac viability. The coverage of ^{82}Rb for rest/stress perfusion imaging and the coverage of the use of FDG in solitary pulmonary nodules were unchanged with this new policy. As with previous policies, all other indications for PET will remain not covered, with no local carrier discretion for the addition of covered indications (*3*).

One major change in the policy effective July 1, 2001, is that these newly covered indications are eligible for payment only when performed using dedicated PET devices. Specifically, coincidence gamma cameras, often called hybrid PET scanners, are excluded from this coverage. Eligible dedicated PET devices must have bismuth germanate (BGO), sodium iodide (NaI), or new crystal detector technologies of equal or superior performance, and may be of either a full-ring or a partial-ring design system. In a separate coverage decision of July 3, 2001, CMS announced that coverage for camera-based PET would be restricted to the five indications in effect before July 1, 2001 (*4*). The reason for this decision was that most of the literature on which they based their evaluation for expansion were from studies conducted on dedicated PET devices.

CMS has deferred its decision on coverage for the use of PET in breast cancer and Alzheimer's disease, as well as expansion of its policy for myocardial viability, to its Medicare Coverage Advisory Committee (MCAC). The MCAC Diagnostic Imaging Panel met on June 19, 2001, to discuss the use of PET in breast cancer. The Committee recommended the use of PET in suspected recurrent breast cancer. Next year, the Committee will meet to consider Alzheimer's disease and the expanded use of PET in the heart. It is hoped that in 2002, the CMS will publish its decision for expanded coverage in each of these areas.

Medicare Billing Requirements and Codes for PET

Billing Codes for ^{82}Rb. ^{82}Rb rest or stress myocardial perfusion examinations are billed using one of 18 G-codes set up for that purpose (G0030–G0047). The correct G-code for the procedure is based on whether single or multiple studies are performed (rest and/or stress) and on testing that the patient had before the PET scan. Specifically, the codes for billing ^{82}Rb studies are shown in Table 1.

When billing ^{82}Rb procedures, the radiopharmaceutical should be coded and billed separately using a radiopharmaceutical supply code that is yet to be determined. The PET scan, whether at rest alone, or rest with stress, can be performed in place of, but not in addition to, a SPECT scan; or it can be done following a SPECT that was inconclusive.

Billing Codes for FDG: Dedicated PET Scanners. Outlined in Table 2 are the codes that are to be used for billing FDG procedures performed on dedicated PET scanners. For the oncology indications, separate codes were assigned for each type of cancer as well as each potential use (diagnosis, initial staging, and restaging).

The coverage policy details patient eligibility requirements for some of the G-codes that must be followed for patients to be eligible for Medicare payment. CMS also provides definitions to help clarify when the scans should be done and how they should be properly coded. Specifically, for G0125 the solitary pulmonary nodule under evaluation must be less than 4 cm in diameter and the radiographic study used as an initial evaluation must find the nodule either indeterminate or possibly malignant.

For all of the oncology scans listed above, "diagnosis scans" (before tissue confirmation) are covered only when PET may help avoid another procedure or determine optimal location for biopsy. Staging/restaging scans are covered when the stage is in doubt after standard work-up or if PET replaces a test in the standard work-up, and the clinical management of the patient would differ depending on stage by PET. Restaging scans can be performed to detect residual disease or suspected recurrence, or to determine the extent of a known recurrence. PET is *not* covered for "monitoring tumor response," defined as a PET scan during the course of therapy; according to the CMS definition, restaging occurs only after a treatment course is finished. The FDG PET scan will not be covered if it is being done *only* for the evaluation of regional nodes in patients with melanoma. Finally, PET is not covered for screening.

Local Medicare carriers/intermediaries can determine the frequency in which PET scans can be covered, unless the national instructions describe patient eligibility for repeat scanning. The only frequency limitation set in the national policy is for patients with lymphoma; PET scans can be repeated after 50 days.

Billing Codes for FDG: Camera-Based PET. Table 3 describes the codes that are to be used for billing PET scans performed on gamma camera or hybrid PET until January 1, 2002. By the end of October 2001, a detailed coverage policy was to be issued by CMS for camera-based PET that

TABLE 1
^{82}Rb Billing Codes for Medicare

G-code	Coverage description
G0030	PET myocardial perfusion imaging (following previous PET G0030–G0047); single study; rest or stress (exercise or pharmacologic)
G0031	PET myocardial perfusion imaging (following previous PET G0030–G0047); *multiple study;* rest or stress (exercise or pharmacologic)
G0032	PET myocardial perfusion imaging (following rest SPECT, 78464); single study; rest or stress (exercise or pharmacologic)
G0033	PET myocardial perfusion imaging (following rest SPECT, 78464); *multiple study;* rest or stress (exercise or pharmacologic)
G0034	PET myocardial perfusion imaging (following stress SPECT, 78465); single study; rest or stress (exercise or pharmacologic)
G0035	PET myocardial perfusion imaging (following stress SPECT, 78465); *multiple study;* rest or stress (exercise or pharmacologic)
G0036	PET myocardial perfusion imaging (following coronary angiography, 93510–93529); single study; rest or stress (exercise or pharmacologic)
G0037	PET myocardial perfusion imaging (following coronary angiography, 93510–93529); *multiple study;* rest or stress (exercise or pharmacologic)
G0038	PET myocardial perfusion imaging (following stress planar myocardial perfusion, 78460); single study; rest or stress (exercise or pharmacologic)
G0039	PET myocardial perfusion imaging (following stress planar myocardial perfusion, 78460); *multiple study;* rest or stress (exercise or pharmacologic)
G0040	PET myocardial perfusion imaging (following stress cardiogram, 93350); single study; rest or stress (exercise or pharmacologic)
G0041	PET myocardial perfusion imaging (following stress cardiogram, 93350); *multiple study;* rest or stress (exercise or pharmacologic)
G0042	PET myocardial perfusion imaging (following stress nuclear ventriculogram, 78481 or 78483); single study; rest or stress (exercise or pharmacologic)
G0043	PET myocardial perfusion imaging (following stress nuclear ventriculogram, 78481 or 78483); *multiple study;* rest or stress (exercise or pharmacologic)
G0044	PET myocardial perfusion imaging (following rest EKG, 93000); single study; rest or stress (exercise or pharmacologic)
G0045	PET myocardial perfusion imaging (following rest EKG, 93000); *multiple study;* rest or stress (exercise or pharmacologic)
G0046	PET myocardial perfusion imaging (following stress EKG, 93015); single study; rest or stress (exercise or pharmacologic)
G0047	PET myocardial perfusion imaging (following stress EKG, 93015); *multiple study;* rest or stress (exercise or pharmacologic)

would contain new codes, specific to gamma camera PET imaging, that will take effect after December 31, 2001 (CMS Coverage and Analysis Department; personal communication).

As stated earlier, the only indications that are eligible for payment are those that were in effect before the addition of coverage in July 2001. The previous codes for these procedures have been replaced, as shown in Table 3. Although the new codes are to be used, sites should follow the patient eligibility criteria in the July 1999 coverage policy.

The coverage policy details a number of specific patient eligibility requirements for Medicare payment. Specifically, for G0125, as for dedicated PET scan devices, the solitary pulmonary nodule under evaluation must be less than 4 cm in diameter and the radiographic study used as an initial evaluation must find the nodule either indeterminate or possibly malignant. Patients with non–small cell lung cancer (billed with G0211) are eligible for a scan only at initial staging, before definitive treatment (surgery or therapy) has been undertaken. Patients eligible for PET scans on camera-based systems under G0215 must demonstrate a rising CEA value. Scans performed under G0218 for restaging must be performed only when surgery is being contemplated. Finally, scans performed under G0221 or G0222 must be performed in lieu of ^{67}Ga scanning.

This coverage will remain in effect for camera-based PET scanners until December 2002. Efficacy data will need to be presented to the CMS by then or coverage for PET on these devices will be eliminated (*4*). The CMS Web address for updates on technology coverage is http://www.hcfa.gov/coverage/8b3-oo.htm.

Medicare Payment Rates

Implementation of the complex G-codes and national coverage policy decision was difficult for many local Medicare carriers and thus for the PET sites billing them. Many PET centers in operation have had to undertake the task of educating local Medicare providers about PET and about the new national policy. In addition, the requirements of the national policy are quite complex, and setting up billing and operations systems to handle the codes initially delayed payment at many sites.

TABLE 2
Codes to Bill FDG PET Scans Performed on Dedicated PET Scanners

G-code	Coverage description
G0125	PET imaging regional or whole body; single pulmonary nodule
G0210	PET imaging whole body; *diagnosis;* lung cancer, non–small cell
G0211	PET imaging whole body; *initial staging;* lung cancer; non–small cell (replaces G0126)
G0212	PET imaging whole body; *restaging;* lung cancer; non–small cell
G0213	PET imaging whole body; *diagnosis;* colorectal cancer
G0214	PET imaging whole body; *initial staging;* colorectal cancer
G0215	PET imaging whole body; *restaging;* colorectal cancer (replaces G0163)
G0216	PET imaging whole body; *diagnosis;* melanoma
G0217	PET imaging whole body; *initial staging;* melanoma
G0218	PET imaging whole body; *restaging;* melanoma (replaces G0165)
G0219	PET imaging whole body; melanoma for noncovered indications
G0220	PET imaging whole body; *diagnosis;* lymphoma
G0221	PET imaging whole body; *initial staging;* lymphoma (replaces G0164)
G0222	PET imaging whole body; *restaging;* lymphoma (replaces G0164)
G0223	PET imaging whole body or regional; *diagnosis;* head and neck cancer; excluding thyroid and CNS cancers
G0224	PET imaging whole body or regional; *initial staging;* head and neck cancer; excluding thyroid and CNS cancers
G0225	PET imaging whole body or regional; *restaging;* head and neck cancer, excluding thyroid and CNS cancers
G0226	PET imaging whole body; *diagnosis;* esophageal cancer
G0227	PET imaging whole body; *initial staging;* esophageal cancer
G0228	PET imaging whole body; *restaging;* esophageal cancer
G0229	PET imaging; metabolic brain imaging for presurgical evaluation of refractory seizures
G0230	PET imaging; metabolic assessment for myocardial viability following inconclusive SPECT study

Freestanding PET centers are paid for PET scans performed on Medicare outpatients by the resource-based practice expense relative value unit (RVU) system set up for physician billing. Because of the few number of sites performing procedures with ^{82}Rb in 1995, no national RVU values were set. Payments are determined by the local Medicare carrier; payment levels vary around the country by Medicare region. Bracco Diagnostics, the manufacturer of the ^{82}Rb generators, estimates that average reimbursement ranges from $1600 to $2000 for a combined rest/stress study, inclusive of the isotope (Bracco Diagnostics; personal communication). A national RVU value was set for the FDG whole-body oncology studies approved in 1999, which assigns 57.54 RVUs and an average payment of $2201 around the country; this remains the value set for G0125. No RVU values have been assigned to the new codes effective for coverage as of July 1, 2001 (G0210 through G0230), and, like ^{82}Rb, they will be set by local Medicare carriers.

Hospitals are paid for outpatient Medicare patients via the HOPPS rule, which was published in the April 7, 2000, *Federal Register* (*5*). The rule lays out the new payment structure for Medicare outpatient procedures performed in hospitals or hospital-owned imaging centers. Payment rates were developed by CMS based on cost data collected in 1996 for all the then-approved HCPCS codes. Because ^{82}Rb cardiac perfusion imaging was approved by CMS prior to this time, data on its costs were available. A PET scan code was placed in the Ambulatory Payment Category (APC) system (APC 285) specifically for the cardiac perfusion imaging with ^{82}Rb. FDG PET imaging was not approved prior to 1996, so the data collected for APC 285 did not apply to these procedures.

In 2001 the payment rate for APC 285 was approximately $756, on average, around the country. This payment is meant to cover the technical scan fee for the PET scan, *exclusive of the radiopharmaceutical*. Data collected in 1996, like data on all nuclear medicine procedures, omitted the cost of the radiopharmaceuticals. The 1999 Balanced Budget Refinement Act provides a venue for billing for an additional payment for the radiopharmaceutical at a rate equal to 95% of the average wholesale price (AWP) of that

TABLE 3
Camera-Based or Hybrid PET Codes for FDG Imaging

G-code	Coverage description
G0125	PET imaging regional or whole body; single pulmonary nodule
G0211	PET imaging whole body; *initial staging;* lung cancer; non–small cell (replaces G0126)
G0215	PET imaging whole body; *restaging;* colorectal cancer (replaces G0163)
G0218	PET imaging whole body; *restaging;* melanoma (replaces G0165)
G0221	PET imaging whole body; *initial staging;* lymphoma (replaces G0164)
G0222	PET imaging whole body; *restaging;* lymphoma (replaces G0164)

radiopharmaceutical (*6*). Special HCPC codes will be developed for each radiopharmaceutical. Cardiac perfusion PET scans performed with ^{82}Rb (billed under G0030–G0047 and a to-be-determined code for ^{82}Rb) will be reimbursed by Medicare under APC 285 for the G-code and the add-on payment mechanism for the ^{82}Rb. Over time, CMS will collect data on the cost of the radiopharmaceuticals and, in the future, will merge the supplemental radiopharmaceutical payment into the APCs. A proposed rule issued in the August 24, 2001, *Federal Register* proposes an increase in the payment rate of APC 285 to $1020.40 (*7*). A final rule listing APC payment levels for 2002 is expected in November, with a January 2002 effective date.

As stated earlier, Medicare had not approved FDG PET imaging when the data for payment levels were collected. The 1999 Budget Refinement Act also provided a method of paying for emerging procedures that were not covered by Medicare during the data collection period. "New Technology" codes were developed for these procedures, and the FDG PET studies were originally assigned to Level XI (APC 0981) (*5*). The payment rate for APC 0981 is $2249.80 for 2001. Data have started to be collected on the costs of providing these scans. It is anticipated that the FDG PET will be merged into the routine APC groups sometime in the future. The new procedure APC codes are not eligible for supplemental payments for the radiopharmaceutical because the costs of these are presumably built in. The proposed rule for 2002 APC payments published in the August 24, 2001, *Federal Register* recategorized the FDG PET studies to APC 976, which provides a payment of $841 (*7*). Monitor the SNM Web site (www.snm.org) for updates to this information, given that the proposed rule will become final and be implemented in January of 2002.

Private Insurance Billing, Coverage, and Payments

There is no "standard" coverage by private insurance carriers around the country; however, most use at least the CMS-mandated coverage as a baseline for covered indications. Many have expanded coverage beyond CMS indications. Private carrier reimbursement can be expanded in each market through the education of private carriers on the benefits of PET.

Although some private carriers accept the Medicare G-codes for billing, in general, Current Procedural Terminology (CPT) codes will most likely be required. Table 4 summarizes the CPT codes that can be used for private carrier billing. Unlike the G-codes, the CPT codes are not specific to any clinical condition, but instead describe the procedure itself. Thus, these codes can be used for indications not covered by Medicare.

Just as the types of procedures that are covered vary from company to company, so do the rates of private carrier payments. Payment rates by the private sector may be based on the Usual and Customary Rates (UCR) set by region, privately set RVU-type values (set by entities such as the Health Insurance Association of America, St. Anthony's Press, and McGraw-Hill), or by the costs of providing the services. Accepting low payment levels may adjust the rates that insurance carriers pay; therefore, it is important to work with insurance providers in your region to ensure a reasonable payment rate for PET.

TABLE 4
CPT Codes for PET

PET procedure	CPT code
Metabolic evaluation of tumors	78810
Cardiac metabolism	78459
Cardiac perfusion	78491 or 78492
Brain metabolism	78608
Brain perfusion	78609
Radiopharmaceutical	78990, or S8085 for FDG

CONCLUSION

Clarification of regulatory requirements of PET, favorable payment rates, and expanded reimbursement coverage have led to growth in the number of clinical PET operations around the country. New FDA regulations will apply to the production of PET drugs. All sites producing PET drugs, whether for commercial sale or on-site use, will be under these new guidelines. Reimbursement guidelines will continue to change and, as technologists, we must become familiar with the requirements of private and public insurance providers to ensure that we are adequately compensated for our services. As PET reimbursement becomes more routine, collecting reasonable payments for our activities will become less complex. In the interim, however, for programs to succeed, attention must be paid to these important issues.

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