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Insights into PET Reimbursement

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LEARNING OBJECTIVES

Upon completion of this activity, participants should be able to:

- Summarize the mechanism by which reimbursement coverage is determined for PET scans by Medicare and private payers.
- List the current reimbursable indications for PET scans provided to Medicare beneficiaries.
- Explain the limitations to Medicare reimbursement within these generally covered diagnoses.
- Describe the clinical indications that are currently under consideration for payment under the Medicare system.

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PET scanning with FDG has become an important tool in the clinical management of patients. A number of peer-reviewed publications have supported the value of FDG-PET in the management of patients with cancer. Summaries of the literature show that, on average, the sensitivity and specificity of FDG-PET are 84% and 88%, respectively. Management is changed with the introduction of PET into clinical decision-making in approximately 30% of patients.¹ Despite these reports, the reimbursable indications for PET continue to lag.

A critical roadblock to payers' acceptance of FDG-PET was resolved in 2000 when the FDA published its findings on the safety and efficacy of FDG. The FDA concluded that in oncology, FDG "can be found to be safe and effective in PET imaging for assessing abnormal glucose metabolism to assist in evaluating malignancy in patients with known or suspected abnormalities found by other testing modalities or in patients with an existing diagnosis of cancer."² This ruling provided a pathway by which the FDA acknowledged the efficacy of FDG in cancer imaging.

FDA approval does not guarantee that insurance companies will pay for a drug or procedure, however, in either the public or private sector. The Centers for Medicare and Medicaid Services defines coverage

benefits for Medicare beneficiaries through contracts with private insurance carriers, also known as Medicare carriers and/or fiscal intermediaries (Medicare contractors). The CMS determines what services will be eligible for coverage (i.e., what it deems to be "reasonable and necessary") by defining a national coverage decision or by delegating coverage decisions to its Medicare contractors. National coverage decisions are policies that provide for or restrict Medicare coverage for a particular medical service and generate obligatory benefits for all Medicare beneficiaries.³

Each independent private insurance company determines the benefits offered to its subscribers. Payments by insurance companies for a service or procedure may be influenced by a number of factors, including published technology assessments, FDA approval, peer-reviewed literature, and standard medical practice in a region.

How reimbursement decisions for PET scans are made by Medicare and private insurance providers, current guidelines and restrictions for patient eligibility for PET scans within the Medicare system, and clinical indications under consideration for reimbursement by Medicare are related, often confusing, topics. FDG-PET imaging has demonstrated significant value in the clinical

management of patients with cancer, and reimbursement is an important component of its availability.

MEDICARE COVERAGE FOR PET

A national coverage decision has been issued for PET scanning, meaning there is a national definition of the types of PET scans that Medicare beneficiaries are eligible to receive.⁴ Compared with most other radiology services, PET is unique in this regard, but national coverage determinations exist for many medical services, including MR angiography⁵ and use of cardiac rehabilitation therapy.⁶

Most of the published coverage instructions for other tests and treatments are more straightforward than those published for PET, which contributes to the difficulty that some Medicare contractors have had in the implementation of the PET guidelines. Nonetheless, the nationwide coverage assures that a Medicare patient is eligible for PET scans in certain diagnoses and clinical situations. The Medicare contractor does not have the authority to expand this coverage, even if the national guidelines fall behind the utility demonstrated in the peer-reviewed literature or local medical practice.

The CMS has been very cautious with its expansion of coverage for PET. Its coverage decisions have restricted not only the scope of eligible diagnoses, but have also limited clinical eligibility within a covered diagnosis based on the CMS's strict interpretation of the indication demonstrated by portions of the published literature. Professional societies have taken the lead in petitioning the CMS to expand coverage so that appropriate clinical situations are included in the coverage guidelines,⁷ but it has denied many petitions. Several formal requests are pending.

- *Current coverage guidelines.*

Guidelines for reimbursement of PET are prescribed in the *Medicare Coverage Issues Manual*, section 50-36. The CMS places the responsibility for ensuring that the patient qualifies on the referring physician.⁴ PET providers, however, also have a responsibility to ascertain whether the patient meets the prescriptive criteria prior to billing for services (Table 1).

Medicare patients are eligible for PET scans for the diagnosis, staging, and restaging of six common cancers,

sive diagnostic procedure.²⁴

The CMS defines a PET scan for staging to be for initial staging of the patient's disease; that is, if there is a known diagnosis of cancer but no treatment (surgery, radiation, or chemotherapy) has been initiated. PET scans done later in the course of the patient's disease management are considered restaging and should be done after the completion of treatment for the purpose of detecting residual disease or suspected recurrence or to determine the extent of

a known recurrence. PET scans for staging and restaging are covered when the stage of the cancer is in doubt after a standard diagnostic workup, or if PET could potentially replace another imaging study and clinical management of the patient would differ

Table 1. Medicare Covered Indications

Clinical condition	Coverage (within the guidelines of CIM 50-36)
Non-small cell lung cancer	Diagnosis, staging & restaging
Esophageal cancer	Diagnosis, staging & restaging
Colorectal cancer	Diagnosis, staging & restaging
Lymphoma	Diagnosis, staging & restaging
Melanoma	Diagnosis, staging & restaging
Head and neck cancer (excludes CNS thyroid)	Diagnosis, staging & restaging
Breast cancer	Restaging, monitoring response to therapy
Thyroid cancer (follicular cell origin; not medullary)	Restaging
Single pulmonary nodule (<4 cm diameter)	Characterization of inconclusive nodule
Coronary artery disease	Assess rest & stress myocardial perfusion; assess myocardial viability
Refractory seizures	Presurgical evaluation

subject to the requirements of the guidelines:

- non-small cell lung cancer;
- colorectal cancer;
- lymphoma;
- melanoma;
- esophageal cancer; and
- head and neck cancers (excluding central nervous system or thyroid cancers).

For these indications, Medicare has defined the terms diagnosis, staging, and restaging and has outlined the scenarios in which they consider a scan to be "reasonable and necessary," or more specifically, payable. PET scan providers will likely seek information regarding the management of the patient to help determine if a patient qualifies for the procedure under the CMS guidelines. The CMS defines a PET scan for diagnosis as one performed before definitive tissue confirmation of cancer. These scans are covered "only in clinical situations in which the 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 inva-

depending on the stage identified.⁴

Patients with a solitary pulmonary nodule may also be eligible for a PET scan under the Medicare system. If other diagnostic studies, such as CT or chest x-ray, are inconclusive about the malignancy status of a lesion, a PET scan may be done to help characterize it as long as the lesion is <4 cm in diameter. It is important to note that if the PET scan is negative, a biopsy procedure would not also be routinely covered in that patient since all other diagnostic studies have also been inconclusive.⁴

Medicare patients with breast cancer may be eligible for PET scans, but under specified clinical scenarios different from those listed above. The CMS will not cover a PET scan for the diagnosis or "initial (pre-surgical) staging" of the axillary lymph nodes in patients with breast cancer. PET scans may be performed, however, for staging or restaging of patients with distant metastasis or locoregional recurrence. FDG-PET scans may be used in women with locally advanced or metastatic breast cancer to monitor the tumor's response to treat-

ment, as long as a change in therapy is being considered. Breast cancer is currently the only type of cancer in which Medicare recognizes the role of PET in monitoring response to treatment.⁴

Patients with a history of thyroid cancer who are Medicare beneficiaries and have been previously treated by thyroidectomy and radio-iodine ablation have had a negative iodine-131 whole-body scan, and have a serum thyroglobulin >10 ng/mL may also be eligible for PET scans for restaging. This coverage is limited to the types of thyroid cancer with a follicular cell origin, so patients with medullary thyroid cancers are excluded.⁴

In addition to its use in cancer, several PET cardiology and neurology indications are covered for Medicare beneficiaries. These include rest/stress myocardial perfusion imaging and myocardial viability studies, as well as use in the presurgical evaluation of patients with medically retractable seizures. For each of these indications, Medicare imposes certain conditions and restrictions for coverage.⁴

Like most diagnostic tests, FDG-PET scans are not covered for screening defined as testing patients without specific signs and symptoms of disease. The coverage guideline also affirms that PET is not covered for other diagnostic uses, thereby preventing Medicare contractors from expanding coverage beyond the national coverage policy.⁴

F-18 fluoride PET has been touted by Dr. Johannes Czernin, director of nuclear medicine at the University of California, Los Angeles and others as the heir apparent to technetium-99m MDP SPECT for bone scanning. Four studies involving about 200 subjects with various types of cancers have been published since 1998, according to Czernin at the 2004 Academy of Molecular Imaging meeting. In all cases, F-18 fluoride was more accurate than conventional SPECT bone imaging for depicting bone metastases.

More clinical experience is needed to persuade the Centers for Medicare and Medicaid Services to pay for F-18 fluoride, however. The CMS rejected a

reimbursement application in 2003 for the procedure.

Facilities seeking an alternative way to bill for F-18 fluoride should use CPT code 78399 (unlisted musculoskeletal procedure, diagnostic nuclear imaging). The insurance carrier should be contacted to approve coverage and payment.

• *Implications of coverage guidelines on patient referrals.*

It is important for a patient that complete information regarding his or her clinical background be provided to the PET center at the time of scheduling (Table 2). Experts within the center can review the documentation to make an accurate assessment of whether the patient is eligible under Medicare and what billing code should be used to assure payment. Then the center can communicate with the referring physician's office, as well as with the patient, regarding whether Medicare should cover the PET scan.

The clinical information that the PET provider will need prior to scheduling the exam will be in the patient's medical chart. Staff at the PET center may be able to help determine if a preauthorization for the PET scan is needed. With respect to ascertaining Medicare eligibility or obtaining a preauthorization, the PET center will need the latest history and physical exam notes, as well as current progress notes and reports of recent radiographs and blood tests that may have been ordered for the patient. From this, the center can evaluate patient eligibility for a PET scan. Indicating in the progress notes or written prescription for the PET scan how the results are to be used in the management of the patient (such as to differentiate between alternative courses of treatment) will further document patient eligibility under Medicare and may help justify any required preauthorization.

Having a National Coverage Policy does serve to clarify which Medicare

patients are eligible for a PET scan. Unfortunately, patients who might benefit from PET may not be included within the current guidelines. In these cases, the patient can still be referred for a PET scan but would be required

Table 2. Information that the PET center will need

- Patient name, height, and weight
- Age (if pediatric)
- Insurance card/information
- Diagnosis, history, and physical (*Include history of diabetes, if any*)
- Dates of recent surgery and treatments
- Reports of recent radiographs and blood work, if any
- How you plan to use the PET results in the care of the patient (*to help justify medical necessity*)

to sign an advanced beneficiary notification before the scan. This notifies the patient of his or her financial responsibility for the scan.⁸

PRIVATE INSURANCE COVERAGE

Private reimbursement policies for PET vary by company. Each private insurance payer makes an independent decision on which procedures to cover. Some may choose to use the Medicare guidelines, whereas others may choose to set coverage that is more or less restrictive. Most companies have published policies, which may be available from the local PET center.

If a patient's insurance does not cover PET for a particular clinical indication and the patient would benefit from the information provided by PET, it is possible to request consideration of coverage. Each private insurance carrier has a process by which coverage decisions are made, both on a case-by-case basis and for setting general coverage policies. For an individual patient who needs a PET scan that is not routinely covered by insurance, the medical director of the insurance company should be contacted. Insurance regulations dictate that the medical director has the responsibility to make the final coverage decision for an individual patient.

Another approach in expanding reimbursement for PET is to petition the insurance company to include PET routinely as a covered service for a specific indication. Working with local PET centers on this will assure that a common message is delivered. The first step is to determine how a partic-

ular insurance company makes its coverage policy decisions. Some companies may refer to published technology evaluations or Medicare as a starting point, but they often engage clinical advisors to help set medical policy decisions. In some cases, the medical director may set coverage policy independently of these other mechanisms. Contacting the private insurance payer to determine its process will provide the mechanism to elicit a change in its policies. Working with the local PET center to target key insurance companies, identifying key clinical areas, and using peer-reviewed literature for support can bring about expansion of reimbursement in the private insurance sector. Persistence in educating payers at the local level is a major component of obtaining appropriate coverage of PET services.

Recent literature supports the value of appealing denied services.⁹ Although the study cited focused on emergency services rather than diagnostic testing, a significant number (90%) of claims were paid when patients provided justification for the service. Assisting patients with a medical justification for insurance coverage of a PET scan, such that compelling clinical evidence on the use of PET is presented to the insurance company, will benefit patients and ultimately will lead to changes in local coverage practices for PET.

MEDICARE COVERAGE DECISIONS

The CMS reviews petitions for coverage of additional clinical indications on an ongoing basis. It will initiate a review for a national coverage decision when issues are identified internally or when a formal request to review an issue is received. These formal requests can be made by individuals (patients, physicians, or others) or by groups such as professional societies. A formal request must be in writing and should contain the following components:³

- a statement that the document is a "formal request for a national coverage decision";

- supporting documentation that includes at a minimum:

- a complete description of the service and the benefit category or categories of the Medicare program to which it applies;

- a compilation of the medical and scientific information supporting the service, including any clinical trials under way that may impact the decision;

- in the case of a drug or device (or a service using a drug or device subject to regulation by the FDA), the status of FDA approval.

To support its decision, the CMS may request a formal technology evaluation, refer the decision to a Medicare Coverage Advisory Committee, or internally make the decision based on the evidence provided and in the pub-

lic domain.³ The CMS provides the public with updated information on the internet regarding the status of current and past coverage decisions at http://cms.hhs.gov/ncdr/ncdr_index.asp.

The CMS is considering requests for expanded coverage to include PET for specific indications for brain, cervical, ovarian, pancreatic, small cell lung, and testicular cancers in one petition and is reconsidering a petition for coverage of PET and other neuroimaging devices for suspected dementia. Decisions on these indications are expected in 2004. Once a decision memorandum is published, the CMS provides instructions to the Medicare contractors to begin payment for the services at some future date. In the past, once a decision was made by the CMS, at least six months elapsed before coverage was in place for patients.

CONCLUSION

PET scanning with FDG has become an important tool in the clinical management of patients, with a number of peer-reviewed publications supporting its value. Translating the published value of PET into insurance coverage requires concerted effort at the local and national levels. The literature has demonstrated that, on average, the introduction of PET to patient care will change the way a clinician manages that patient in approximately 30% of cases.¹

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REFERENCES

1. Gambhir SS, Czernin J, Schwimmer J, et al. A tabulated summary of the FDG PET literature. *J of Nucl Med* 2001;42:1S-93S.
2. Positron emission tomography drug products; safety and effectiveness of certain PET drugs for specific indications. *Federal Register* 2000; 65(48):12999-13010.
3. Medicare program; procedures for making national coverage decisions. *Federal Register* 1999;64(80): 22619-22625.
4. Positron emission tomography (PET) scans. In:

Medicare coverage issues manual, sec 50-36, rev 171, 06/03. Washington, DC: Health and Human Services Department, Center for Medicare and Medicaid Services, 2004. Available at http://www.cms.hhs.gov/manuals/06_cim/ci50.a.sp#_50_36. Accessed Feb. 25, 2004.

5. Magnetic resonance angiography. In: Medicare coverage issues manual, sec 50-14, rev 170, 05/03. Washington, DC: Health and Human Services Department, Center for Medicare and Medicaid Services 2004. http://www.cms.hhs.gov/manuals/06_cim/ci50.asp#_50_14.

Accessed Feb. 25, 2004.

6. Cardiac rehabilitation programs. In: Medicare coverage issues manual, sec 35-25, rev 41, 08/89. Washington, DC: Health and Human Services Department, Center for Medicare and Medicaid Services, 2004. http://www.cms.hhs.gov/manuals/06_cim/ci50.a.sp. Accessed Feb. 25, 2004.
7. Decision memo for positron emission tomography (FDG) for thyroid cancer (CAG-00095N). Washington, DC: Health and Human Services Department, Center for

Medicare and Medicaid Services, 2003. <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=70>. Accessed Feb. 25, 2004.

8. Determining liability for claims for physician and supplier services. In: Medicare carriers manual part, chap 30:sec 50, rev 1; 2003. <http://www.cms.hhs.gov/medicare/bni/> Accessed Feb. 25, 2004
9. Gresenz CR, Studdert DM. Disputes over coverage of emergency department services: A study of two health maintenance organizations. *Ann Emerg Med* 2004;43(2):155-162.



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