CHCPP NEWS
COMMISSION ON
HEALTH CARE POLICY AND PRACTICE

HCFA's Coverage Instructions for Lung PET

What follows is policy from the Health Care Financing Administration (HCFA) concerning coverage of PET imaging for the diagnosis of solitary pulmonary nodules (SPNs) and initial staging of non-small-cell lung carcinoma (NSCLC). The following information is extracted from the instructions HCFA provided to its carriers (*Medicare Carriers Manual*, Part 3—Claims Process, Chapter 4, Sections 4172.6–4173.5). This information deserves careful review.

The two new HCPCS codes listed, G0125 and G0126, are not only indication-specific but also describe different procedures: HCPCS G0125 is for the evaluation of SPNs and PET imaging of the chest; HCPCS G0126 is for the initial staging of proven NSCLC and PET imaging of the chest and at least the abdomen. Also noteworthy are the requirement that PET facilities retain medical records including CT and biopsy results and the comment that HCFA will not necessarily pay for a tissue biopsy after a negative PET study. Because HCFA will conduct its own study of the effect of PET imaging for these two indications, practitioners should plan for a possible future medical record audit. For additional information on these regulations, contact your local Medicare carrier.

New Procedures—Effective Date: Dates of Service on and After January 1, 1998

Section 4173, *Positron Emission Tomography (PET) Scans*, has been updated to include coverage of PET scans for the characterization of solitary pulmonary nodules and for the initial staging of lung cancer, conditioned upon its ability to effect the management and treatment of patients with either suspected or demonstrated lung cancer.

Section 4173.2, *Conditions of Coverage of PET Scans for Characterization of Solitary Pulmonary Nodules (SPNs) and PET Scans Using FDG to Initially Stage Lung Cancer*, provides that the conditions and limitations of this coverage are contained in CIM [*Carrier Instruction Manual*] §50-36.

Section 4173.3, *Billing Requirements for PET Scans*, provides specific instructions for providers to use when billing for PET scans. Submission of claims data/documentation is necessary.

Section 4173.4, *HCPCS and Modifiers for PET Scans*, lists the new HCPCS codes for providers to use when reporting PET scans for the imaging of the lungs. Previous PET scan modifiers have been revised so that they can also be used for lung PET scans.

Section 4173.5, *Claims Processing Instructions for PET Scan Claims*, has been revised to include processing instructions for lung PET scans.

Note: Claims submitted for dates of service January 1, 1998, and after should be held until your system maintainer has released the necessary software changes. Payment should be made for any applicable interest. Interest is payable for "clean" claims not paid timely in accordance with the claims processing timeliness guidelines in Section 5240 of the *Medicare Carriers Manual*, Part 2. You should also include language in your next scheduled newsletter to your providers alerting them that you will be holding claims pending required systems changes and plan to notify providers again as soon as the system changes have been completed and the claims can begin to be processed.

These instructions should be implemented within your current operating budget.

Disclaimer: The revision date and transmittal number only apply to the redlined material [not identified here]. All other material was previously published in the manual and is only being reprinted.

4173. POSITRON EMISSION TOMOGRAPHY (PET) SCANS.

BACKGROUND:

For dates of service on or after March 14, 1995, Medicare covers one use of PET scans, imaging of the perfusion of the heart using Rubidium-82 (^{82}Rb). For dates of service on or after January 1, 1998, Medicare also covers the use of PET scans for the characterization of solitary pulmonary nodules and for the initial staging of lung cancer, conditioned upon its ability to effect the management and treatment of patients with either suspected or demonstrated lung cancer. All other uses of PET scans remain not covered by Medicare.

Regardless of any other terms or conditions, *all uses* of PET scans, in order to be covered by the Medicare program, must meet the following conditions:

- Scans must be performed using PET scanners that have either been approved or cleared for marketing by the FDA as PET scanners;
- Submission of claims for payment must include any information Medicare requires to assure that the PET scans performed were: (a) reasonable and necessary; (b) did not unnecessarily duplicate other covered diagnostic tests; and (c) did not involve investigational drugs or procedures using investigational drugs, as determined by the Food and Drug Administration (FDA); and
- The PET scan entity submitting claims for payment must keep such patient records as Medicare requires on file for each patient for whom a PET scan claim is made.

4173.2 *Conditions of Coverage of PET Scans for Characterization of Solitary Pulmonary Nodules (SPNs) and PET Scans Using FDG to Initially Stage Lung Cancer*—PET scans using the glucose analog 2-[fluorine-18]-fluoro-2-deoxy-D-glucose (FDG) are covered for services on or after January 1, 1998, subject to the conditions and limitations described in CIM §50-36.

Note: A tissue sampling procedure (TSP) should not be *routinely* covered in the case of a negative PET scan for characterization of SPNs since the patient is presumed not to have a malignant lesion, based upon the PET scan results. Claims submitted for a TSP after a negative PET must be submitted with documentation in order to determine if the TSP is reasonable and necessary in spite of a negative PET. Claims submitted for a TSP after a negative PET without documentation should be denied. Physicians should discuss with their patients the implications of this decision, both with respect to the patient's responsibility for payment for such a biopsy if desired, as well as the confidence the physician has in the results of such PET scans, prior to ordering such scans for this purpose. This physician–patient decision should occur with a clear discussion and understanding of the sensitivity and specificity trade-offs between a computerized tomography (CT) and PET scans. In cases where a TSP is performed, it is the responsibility of the physician ordering the TSP to provide sufficient documentation of the reasonableness and necessity for such procedure or procedures. Such documentation should include, but is not necessarily limited to, a description of the features of the PET scan that call into question whether it is an accurate representation of the patient's condition, the existence of other factors in the patient's condition that call into question the accuracy of the PET scan, and such other information as the contractor deems necessary to determine whether the claim for the TSP should be covered and paid.

In cases of serial evaluation of SPNs using both CT and regional PET chest scanning, such PET scans will not be covered if repeated within 90 days following a negative PET scan.

4173.3 *Billing Requirements for PET Scans*—Effective for services on or after January 1, 1998, claims for characterizing SPNs should include:

- Evidence of the initial detection of a primary lung tumor, usually by CT. This should include an indication of the results of such CT or other detection method, indicating an indeterminate or possibly malignant lesion, not exceeding four centimeters (cm) in diameter. This indication should be included with the claim, along with the result of the PET scan, using the appropriate modifiers. For example, you should not get a claim showing G0125 with modifier N; if you do, deny the claim.
- In order to ensure that the PET scan is properly coordinated with other diagnostic modalities, PET scan claims must include the results of concurrent thoracic CT, which is necessary for anatomic information.
- In view of the limitations on this coverage, you may consider conducting pre- or post-payment reviews to determine that the use of PET scans is consistent with Medicare instructions. Providers must keep patient record information on file for each Medicare patient for whom a PET scan claim is made. These medical records may be used in any review and must include information necessary to substantiate the need for the PET scan.

Note: PET scans are not covered by Medicare for routine screening of asymptomatic patients, regardless of the level of risk factors applicable to such patients.

Effective for services on or after January 1, 1998, claims for staging metastatic non-small-cell lung carcinoma (NSCLC) must include:

- Evidence of primary tumor. Since this service is covered only in those cases in which a primary cancerous lung tumor has been confirmed, claims for PET must show evidence of the detection of such primary lung tumor (for example, a diagnosis code). A surgical pathology report that documents the presence of an NSCLC must be kept on file with the provider. If you deem it necessary, contact the provider for a copy of this documentation.
- Whole body PET scan results and results of concurrent CT and follow-up lymph node biopsy. In order to ensure that the PET scan is properly coordinated with other diagnostic modalities, claims must include both (1) the results of concurrent thoracic CT, which is necessary for anatomic information, and (2) the results of any lymph node biopsy performed to finalize whether the patient will be a surgical candidate.

Note: A lymph node biopsy is not covered in the case of a negative CT and negative PET, where the patient is considered a surgical candidate, given the presumed absence of metastatic NSCLC.

4173.4 *HCPCS and Modifiers for PET Scans*—The following codes should be reported for PET scans used for the imaging of the lungs:

- G0125—PET lung imaging of solitary pulmonary nodules using 2-[fluorine-18]-fluoro-2-deoxy-D-glucose (FDG), following CT (71250/71260 or 71270); or
- G0126—PET lung imaging of solitary pulmonary nodules using 2-[fluorine-18]-fluoro-2-deoxy-D-glucose (FDG), following CT (71250/71260 or 71270); for initial staging of pathologically diagnosed non-small-cell lung cancer.

In addition, providers must indicate the results of the PET scan and the previous test using a two-digit modifier. (The modifier is not required for technical component-only billings, or billings to the intermediary.) The first character should indicate the result of the PET scan; the second character should indicate the results of the prior test. Depending on the procedure codes with which the modifiers are used, the meaning of the modifier will be apparent. The test result modifiers and their descriptions are as follows:

Modifier	*Description*
N	Negative;
E	Equivocal;
P	Positive, but not suggestive of, malignant single pulmonary nodule; and
S	Positive and suggestive of, malignant single pulmonary nodule.

These modifiers may be used in any combination.

4173.5 *Claims Processing Instructions for PET Scan Claims*

A. *FDA Approval*—PET scans are covered only when performed at a PET imaging center with a PET scanner that

has been approved or cleared by the FDA. When submitting the claim, the provider is certifying this and must be able to produce a copy of this approval upon request. An official approval letter need not be submitted with the claim.

You may consider conducting a review on a post-payment basis to verify, based on a sample of PET scan claims, that the PET scan was performed at a center with a PET scanner which was approved or cleared for marketing.

B. *EOMB and Remittance Messages*—Providers must indicate the results of the PET scan and the previous test using a two-digit modifier as specified in §4173.4.

Assigned claims received on or after January 1, 1998 without the proper documentation for claims for staging metastatic NSCLC or for characterizing SPNs must be denied using the following EOMB message:

"Your service was denied because information required to make payment was missing. We have asked your provider to resubmit a claim with the missing information so that it may be reprocessed." (Message 9.33)

Use the following remittance message for assigned claims:

"The procedure code is inconsistent with the modifier used, or a required modifier is missing." (Reason Code 4)

C. *Type of Service*—The type of service for the PET scan codes in the "G" range is 4, Diagnostic Radiology.

—Wendy J.M. Smith, MPH, is the SNM director of health care policy.

Workforce Requirements

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