
Program Memorandum Intermediaries/Carriers

Department of Health & Human
Services (DHHS)
The Centers for Medicare &
Medicaid Services (CMS)

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This Program Memorandum re-issues AB-01-54, Change Request 1603 dated April 10, 2001. The only change is the discard date; all other material remains the same.

CHANGE REQUEST 1603

SUBJECT: Expanded Coverage of Positron Emission Tomography (PET) Scans and Related Claims Processing Changes

Introduction

This Program Memorandum (PM) advises you of expanded Medicare coverage for PET scans, which is effective for claims with dates of service on or after July 1, 2001. Also effective for claims received on or after July 1, 2001, CMS will no longer require the designation of the four PET Scan modifiers (N,E,P,S) and has made the determination that no paper documentation needs to be submitted up front with PET scan claims. Documentation requirements such as physician referral and medical necessity determination are to be maintained by the provider as part of the beneficiary's medical record. This information must be made available to you upon request of additional documentation to determine appropriate payment of an individual claim. In light of these changes, you are strongly urged to offer provider education on expanded coverage of PET Scans and revised billing instructions prior to the effective date of July 1, 2001.

Background

PET is a noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body. A positron camera (tomograph) is used to produce cross-sectional tomographic images, which are obtained from positron emitting radioactive tracer substances (radiopharmaceutical) such as FDG (2-{fluorine-18}-fluoro-2-deoxy-D-glucose), that are usually administered intravenously to the patient. At this time Medicare only covers FDG PET Scans.

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:

- As of July 1, 2001, PET scans are covered for those indications otherwise listed in this document. For indications covered beginning July 1, 2001, scans performed with dedicated full-ring scanners will be covered. In the decision memorandum of December 15, 2000, CMS had indicated that gamma camera systems with at least a 1 inch thick crystal would be eligible for coverage. However, coverage of PET using camera-based systems is now under further review as a separate national coverage determination. A final decision on what systems other than dedicated PET will be eligible for coverage, if any, will be announced prior to July 1, 2001. For those indications covered prior to July 1, 2001, all PET scanners approved or cleared for marketing by the FDA remain covered.
- The provider must maintain on file the doctor's referral and documentation that the procedure involved: (a) only FDA approved drugs and devices and, (b) did not involve investigational drugs, or procedures using investigational drugs, as determined by the FDA.
- The ordering physician is responsible for certifying the medical necessity of the study according to the conditions. The physician must have documentation in the beneficiary's medical record to support the referral supplied to the PET scan provider.

- All other uses of PET scanners not listed in this instruction are NOT covered. (See Medicare Coverage Issues Manual (CIM) §50-36 for specific coverage criteria for PET Scans.)

Expansion of Coverage, Effective July 1, 2001

The following is a brief summary of the expanded coverage. Detailed information can be found in the CIM §50-36.

- PET is covered for diagnosis, initial staging and restaging of non-small cell lung cancer (NSCLC).
- Usage of PET for colorectal cancer has been expanded to include diagnosis, staging, and restaging.
- Usage of PET for the initial staging, and restaging of both Hodgkin's and non-Hodgkin's disease.
- Usage of PET for the diagnosis, initial staging, and restaging of melanoma. **(PET Scans are NOT covered for the evaluation of regional nodes.)**
- Medicare covers PET for the diagnosis, initial staging, and restaging of esophageal cancer.
- Usage of PET for Head and Neck Cancers. **(PET scans for head and neck cancer is NOT covered for central nervous system or thyroid cancers.)**
- Usage of PET following an inconclusive single photon emission computed tomography (SPECT) only for myocardial viability. In the event that a patient has received a SPECT and the physician finds the results to be inconclusive, only then may a PET scan be ordered utilizing the proper documentation.
- Usage of PET for pre-surgical evaluation for patients with refractory seizures.

Definitions:

For all uses of PET, excluding Rubidium 82 for perfusion of the heart, myocardial viability and refractory seizures the following definitions apply:

1. **Diagnosis:** PET is 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 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 and/or Restaging:** PET is covered in clinical situations in which (1) (a) 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, (b) 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 and, (2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be 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.

- Monitoring: Use of PET to monitor tumor response during the planned 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.

Limitations

For staging and restaging: PET is covered in either/or both of the following circumstances:

- 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).
- The clinical management of the patient would differ depending on the stage of the cancer identified. PET will be 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. 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.

PET is not covered for other diagnostic uses, and is not covered for screening (testing of patients without specific symptoms). Use of PET to monitor tumor response during the planned course of therapy (i.e. when no change in therapy is being contemplated) is not covered.

Frequency

In the absence of national frequency limitations, for all indications covered on and after July 1, 2001, contractors can, if necessary, develop frequency limitations on any or all covered PET scan services.

Medical Documentation and Provider Education

Additional medical documentation (other than the information needed on the claim form) is no longer required for the submission of PET scan claims. As with any claim, but particularly in view of the limitations on this coverage, contractors should conduct periodic analysis of the utilization data for PET scans to identify aberrant providers and conduct post-payment reviews to determine that the use of PET scans is consistent with this instruction.

CMS emphasizes that provider education regarding PET claim submission is essential. Provider education must at a minimum include the following information:

- PET scanning facilities must keep patient record information on file for each Medicare patient for whom such a PET scan claim is made.
- The 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 medical records must include standard information (e.g., age, sex, and height) along with any annotations regarding body size or type which indicate a need for a PET scan to determine the patient's condition.

HCPCS for PET Scans

For dates of service on or after July 1, 2001, Medicare has established the following new PET Scan codes:

G0210 PET Imaging *whole body*; diagnosis; lung cancer, non-small cell

Short Description: PET img wholebody dxlung ca

- G0211** PET Imaging *whole body; initial* staging; lung cancer; non-small cell(**replaces G0126**)
Short Description: PET img wholbody init lung
- G0212** PET Imaging *whole body; restaging; lung cancer; non-small cell*
Short Description: PET img wholebod restag lung
- G0213** PET Imaging *whole body; diagnosis; colorectal cancer*
Short Description: PET img wholbody dx colorec
- G0214** PET Imaging *whole body; initial* staging; colorectal cancer
Short Description: PET img wholebod init colore
- G0215** PET Imaging *whole body; restaging; colorectal cancer* (**replaces G0163**)
Short Description: PETimg wholebod restag colre
- G0216** PET Imaging *whole body; diagnosis; melanoma*
Short Description: PET img wholebod dx melanoma
- G0217** PET Imaging *whole body; initial* staging; melanoma
Short Description: PET img wholebod init melano
- G0218** PET Imaging *whole body; restaging; melanoma* (**replaces G0165**)
Short Description: PET img wholebod restag mela
- G0219** ***PET Imaging whole body; melanoma for non-covered indications***
Short Description: PET img wholbod melano nonco
- G0220** PET Imaging *whole body; diagnosis; lymphoma*
Short Description: PET img wholebod dx lymphoma
- G0221** PET Imaging *whole body; initial* staging; lymphoma (**replaces G0164**)
Short Description: PET imag wholbod init lympho
- G0222** PET Imaging *whole body; restaging; lymphoma* (**replaces G0164**)
Short Description: PET imag wholbod resta lymph
- G0223** PET Imaging *whole body or regional; diagnosis; head and neck cancer; excluding thyroid and CNS cancers*
Short Description: PET imag wholbod reg dx head
- G0224** PET Imaging *whole body or regional; initial* staging; head and neck cancer; excluding thyroid and CNS cancers
Short Description: PET imag wholbod reg ini hea
- G0225** PET Imaging *whole body or regional; restaging; head and neck cancer, excluding thyroid and CNS cancers*
Short Description: PET whol restag headneckonly

- G0226** PET Imaging *whole body*; diagnosis; esophageal cancer
Short Description: PET img wholbody dx esophagl
- G0227** PET Imaging *whole body*; *initial* staging; esophageal cancer
Short Description: PET img wholbod ini esophage
- G0228** PET Imaging *whole body*; *restaging*; esophageal cancer
Short Description: PET img wholbod restg esopha
- G0229** PET Imaging; Metabolic brain imaging for pre-surgical evaluation of refractory seizures
Short Description: PET img metaboloc brain pres
- G0230** PET Imaging; Metabolic assessment for myocardial viability following inconclusive SPECT study
Short Description: PET myocard viability post s
- NOTE:** G0125 has a definition change: “PET imaging regional or whole body; single pulmonary nodule”
(Short Description: PET image pulmonary nodule
G0126, G0163, G0164 and G0165 will be discontinued June 30, 2001.

Carrier Billing Requirements

Claims for PET scan services must be billed on the Form-CMS 1500 or the electronic equivalent with the appropriate HCPCS and diagnosis codes. **Effective for claims received on or after July 1, 2001, PET modifiers will be discontinued and are no longer a claims processing requirement for PET scan claims.** Therefore, July 1, 2001, and after the MSN/EOMB messages in MCM §4173 regarding the use of PET modifiers can be discontinued. The type of service (TOS) for the new PET scan procedure codes is TOS 4, Diagnostic Radiology.

Fiscal Intermediary Billing Requirements

Claims for PET scan procedures must be billed on Form CMS-1450 (UB-92) or the electronic equivalent with the appropriate diagnosis HCPCS “G” codes to indicate the conditions under which a PET scan was done. These codes represent the technical component costs associated with these procedures when furnished to hospital outpatients and are paid under the Outpatient Prospective Payment System. Bill these codes under Revenue Code 404 (PET scan).

These instructions should be implemented within your current operating budget.

The effective date for this PM is July 1, 2001.

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| This PM may be discarded after July 31, 2003.

If you have any questions, contact your local CMS regional office.