
Medicare Coverage Issues Manual

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<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
50-36 - 50-36 (Cont.)	6 pp.	4 pp.

NEW/REVISED MATERIAL--*EFFECTIVE DATE: January 1, 2002*
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Section 50-36. Positron Emission Tomography (PET) Scans, is revised to clarify the types of allowable PET scanners.

This revision to the Coverage Issues Manual is a national coverage decision (NCD). NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on a Medicare+Choice Organization. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

These instructions should be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

50-36 POSITRON EMISSION TOMOGRAPHY (PET) SCANS

I. General Description

Positron emission tomography (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 (radiopharmaceuticals) such as 2-[F-18] Fluoro-D-Glucose (FDG), that are administered intravenously to the patient.

The following indications may be covered for PET under certain circumstances. Details of Medicare PET coverage are discussed later in this section. Unless otherwise indicated, the clinical conditions below are covered when PET utilizes FDG as a tracer.

NOTE: All other uses of PET scans not listed in this manual are NOT covered.

Clinical Condition	Effective Date	Coverage
Solitary Pulmonary Nodules (SPNs)	January 1, 1998	Characterization
Lung Cancer (Non Small Cell)	January 1, 1998	Initial staging
Lung Cancer (Non Small Cell)	July 1, 2001	Diagnosis, staging and restaging
Esophageal Cancer	July 1, 2001	Diagnosis, staging and restaging
Colorectal Cancer	July 1, 1999	Determining location of tumors if rising CEA level suggests recurrence
Colorectal Cancer	July 1, 2001	Diagnosis, staging and restaging
Lymphoma	July 1, 1999	Staging and restaging only when used as an alternative to Gallium scan
Lymphoma	July 1, 2001	Diagnosis, staging and restaging
Melanoma	July 1, 1999	Evaluating recurrence prior to surgery as an alternative to a Gallium scan
Melanoma	July 1, 2001	Diagnosis, staging and restaging; Non-covered for evaluating regional nodes
Head and Neck Cancers (excluding CNS and thyroid)	July 1, 2001	Diagnosis, staging and restaging
Myocardial Viability	July 1, 2001	Covered only following inconclusive SPECT
Refractory Seizures	July 1, 2001	Covered for pre-surgical evaluation only
Perfusion of the heart using Rubidium 82* tracer	March 14, 1995	Covered for noninvasive imaging of the perfusion of the heart

*Not FDG-PET.

II. General Conditions of Coverage for FDG PET.A. Allowable FDG PET Systems1. Definitions: For purposes of this section,

- a. "Any FDA approved" means all systems approved or cleared for marketing by the FDA to image radionuclides in the body.

- b. "FDA approved" means that the system indicated has been approved or cleared for marketing by the FDA to image radionuclides in the body.
- c. Certain coincidence systems" refers to the systems that have all the following features:
- crystal at least 5/8-inch thick
 - techniques to minimize or correct for scatter and/or randoms, and
 - digital detectors and iterative reconstruction.

Scans performed with gamma camera PET systems with crystals thinner than 5/8-inch will not be covered by Medicare. In addition, scans performed with systems with crystals greater than or equal to 5/8-inch in thickness, but that do not meet the other listed design characteristics are not covered by Medicare.

2. Allowable PET systems by covered clinical indication:

Covered Clinical Condition	Allowable Type of FDG PET System		
	Prior to July 1, 2001	July 1, 2001 through December 31, 2001	On or after January 1, 2002
Characterization of single pulmonary nodules	Effective 1/1/1998, any FDA approved	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems
Initial staging of lung cancer (non small cell)	Effective 1/1/1998, any FDA approved	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems
Determining location of colorectal tumors if rising CEA level suggests recurrence	Effective 7/1/1999, any FDA approved	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems
Staging or restaging of lymphoma only when used as an alternative to a gallium scan	Effective 7/1/1999, any FDA approved	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems

Covered Clinical Condition	Allowable Type of FDG PET System		
	Prior to July 1, 2001	July 1, 2001 through December 31, 2001	On or after January 1, 2002
Evaluating recurrence of melanoma prior to surgery as an alternative to a gallium scan	Effective 7/1/1999, any FDA approved.	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems
Diagnosis, staging, and restaging of colorectal cancer	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of esophageal cancer	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of head and neck cancers (excluding CNS and thyroid)	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of lung cancer (non small cell)	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of lymphoma	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of melanoma (noncovered for evaluating regional nodes)	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Determination of myocardial viability only following an inconclusive SPECT	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Presurgical evaluation of refractory seizures	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring

B. Regardless of any other terms or conditions, all uses of FDG PET scans, in order to be covered by the Medicare program, must meet the following general conditions prior to June 30, 2001:

1. Submission of claims for payment must include any information Medicare requires to assure that the PET scans performed were: (a) medically 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).

2. 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.

C. Regardless of any other terms or conditions, 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:

1. 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.

2. The ordering physician is responsible for documenting the medical necessity of the study and that it meets the conditions specified in the instructions. The physician should have documentation in the beneficiary's medical record to support the referral to the PET scan provider.

III. Covered Indications for PET Scans and Limitations/Requirements for Usage

For all uses of PET relating to malignancies the following **conditions** 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. 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.

3. 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.

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

IV. Coverage of PET for Perfusion of the Heart Using Rubidium 82

Effective for services performed on or after March 14, 1995, PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Rubidium 82 (Rb 82) are covered, provided the requirements below are met.

Requirements:

- The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or
- The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)
- For any PET scan for which Medicare payment is claimed for dates of services prior to July 1, 2001, the claimant must submit additional specified information on the claim form (including proper codes and/or modifiers), to indicate the results of the PET scan. The claimant must also include information on whether the PET scan was done after an inconclusive noninvasive cardiac test. The information submitted with respect to the previous noninvasive cardiac test must specify the type of test done prior to the PET scan and whether it was inconclusive or unsatisfactory. These explanations are in the form of special G codes used for billing PET scans using Rb 82. Beginning July 1, 2001 claims should be submitted with the appropriate codes.

V. Coverage of FDG PET for Lung Cancer

The coverage for FDG PET for lung cancer, effective January 1, 1998, has been expanded. Beginning July 1, 2001 usage of FDG PET for lung cancer has been expanded to include diagnosis, staging, and restaging (see section III) of the disease.

A. Effective for services performed on or after January 1, 1998, Medicare covers regional FDG PET chest scans, on any FDA approved scanner, for the characterization of single pulmonary nodules (SPNs). The primary purpose of such characterization should be to determine the likelihood of malignancy in order to plan future management and treatment for the patient.

Beginning July 1, 2001, documentation should be maintained in the beneficiary's medical file at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

Requirements:

- There must be evidence of primary tumor. Claims for regional PET chest scans for characterizing SPNs should include evidence of the initial detection of a primary lung tumor, usually by computed tomography (CT). This should include, but is not restricted to, a report on the results of such CT or other detection method, indicating an indeterminate or possibly malignant lesion, not exceeding four centimeters (cm) in diameter.
- PET scan claims must include the results of concurrent thoracic CT (as noted above), which is necessary for anatomic information, in order to ensure that the PET scan is properly coordinated with other diagnostic modalities.
- 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.

NOTE: A tissue sampling procedure (TSP) is not 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. When there has been a negative PET, the provider must submit additional information with the claim to support the necessity of a TSP, for review by the Medicare contractor.