Medicare Coverage Issues Manual

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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CHANGE REQUEST 1603

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
50-36 - 50-36 (Cont.)	10 pp.	11 pp.

NEW/REVISED MATERIAL--*EFFECTIVE DATE: July 1, 2001*
IMPLEMENTATION DATE: July1, 2001

Section 50-36, Positron Emission Tomography (PET) Scans, is revised to expand coverage of PET scans to include diagnosis and staging/restaging of non-small cell lung cancer, esophageal cancer, colorectal cancer, lymphoma, melanoma, head and neck cancers; myocardial viability, and refractory seizures. Previously covered uses of PET remain covered. Both diagnosis and staging/restaging are defined for purposes of this revision.

This revision to the Coverage Issues Manual is a national coverage decision (NCD) made under §1862(a)(1) of the Social Security Act. NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, and other contractors. 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 disregard, set aside, or otherwise review an NCD issued under §1862(a)(1). (See 42 CFR 405.732 and 405.860.)

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

Clinical Condition	Effective Date	Coverage
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

A. 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. Such scans must be performed using a camera that has either been approved or cleared for marketing by the FDA to image radionuclides in the body.

2. 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).

3. 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.

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 as of July 1, 2001:

1. 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, HCFA 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.

2. 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.

3. 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.

4. Medicare coverage is predicated upon the use of PET scans with FDG for the purpose of development of appropriate treatment plans for patients. HCFA will evaluate both the data produced by claims for these services, and data obtained from other sources, to determine whether, and to what extent, this coverage policy may need additional modification in order to assure that the services covered are medically effective for the treatment of Medicare beneficiaries.

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 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.

B. Effective for services performed from January 1, 1998 through June 30, 2001, Medicare approved coverage of FDG PET for initial staging of non-small-cell lung carcinoma (NSCLC).

Limitations: This service is covered only when the primary cancerous lung tumor has been pathologically confirmed; claims for PET must include a statement or other evidence of the detection of such primary lung tumor. The evidence should include, but is not restricted to, a surgical pathology report, which documents the presence of an NSCLC. Whole body PET scan results and results of concurrent computed tomography (CT) and follow-up lymph node biopsy must be properly coordinated with other diagnostic modalities. Claims must include both:

- The results of concurrent thoracic CT, necessary for anatomic information, and
- The results of any lymph node biopsy performed to finalize whether the patient will be a surgical candidate. The ordering physician is responsible for providing this biopsy result to the PET facility.

NOTE: Where the patient is considered a surgical candidate, (given the presumed absence of metastatic NSCLC unless medical review supports a determination of medical necessity of a biopsy) a lymph node biopsy will not be covered in the case of a negative CT and negative PET. A lymph node biopsy will be covered in all other cases, i.e., positive CT + positive PET; negative CT + positive PET; positive CT + negative PET.

C. Beginning July 1, 2001, Medicare covers FDG PET for diagnosis, staging, and restaging of NSCLC. Documentation should be maintained in the beneficiary's medical file to support the medical necessity of the procedure, as is normal business practice.

Requirements: PET is covered in either/or both of the following circumstances:

- 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.

- 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.

Documentation should be maintained in the beneficiary's medical record at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

VI. Coverage of FDG PET for Esophageal Cancer

A. Beginning July 1, 2001, Medicare covers FDG PET for the diagnosis, staging, and restaging of esophageal cancer. Medical evidence is present to support the use of FDG PET in pre-surgical staging of esophageal cancer.

Requirements: PET is covered in either/or both of the following circumstances:

- 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.

- 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.

Documentation should be maintained in the beneficiary's medical record at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

VII. Coverage of FDG PET for Colorectal Cancer

Medicare coverage of FDG PET for colorectal cancer where there is a rising level of carcinoembryonic antigen (CEA) was effective July 1, 1999 through June 30, 2001. Beginning July 1, 2001 usage of FDG PET for colorectal cancer has been expanded to include diagnosis, staging, and restaging of the disease(see part III).

A. Effective July 1, 1999, Medicare covers FDG PET for patients with recurrent colorectal carcinomas, which are suggested by rising levels of the biochemical tumor marker CEA.

1. Frequency Limitations: Whole body PET scans for assessment of recurrence of colorectal cancer cannot be ordered more frequently than once every 12 months unless medical necessity documentation supports a separate re-elevation of CEA within this period.

2. Limitations: Because this service is covered only in those cases in which there has been a recurrence of colorectal tumor, claims for PET should include a statement or other evidence of previous colorectal tumor, through June 30, 2001.

B. Beginning July 1, 2001, Medicare coverage has been expanded for colorectal carcinomas for diagnosis, staging and re-staging. New medical evidence supports the use of FDG PET as a useful tool in determining the presence of hepatic/extrahepatic metastases in the primary staging of colorectal carcinoma, prior to selecting a treatment regimen. Use of FDG PET is also supported in evaluating recurrent colorectal cancer beyond the limited presentation of a rising CEA level where the patient presents clinical signs or symptoms of recurrence.

Requirements: PET is covered in either/both of the following circumstances:

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.

- 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.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

VIII. Coverage of FDG PET for Lymphoma

Medicare coverage of FDG PET to stage and re-stage lymphoma as alternative to a Gallium scan, was effective July 1, 1999. Beginning July 1, 2001 usage of FDG PET for lymphoma has been expanded to include diagnosis, staging and restaging (see section III) of the disease.

A. Effective July 1, 1999, FDG PET is covered for the staging and restaging of lymphoma.

Requirements:

- FDG PET is covered only for staging or follow-up restaging of lymphoma. Claims must include a statement or other evidence of previous diagnosis of lymphoma when used as an alternative to a Gallium scan.

- To ensure that the PET scan is properly coordinated with other diagnostic modalities, claims must include the results of concurrent computed tomography (CT) and/or other diagnostic modalities when they are necessary for additional anatomic information.

- In order to ensure that the PET scan is covered only as an alternative to a Gallium scan, no PET scan may be covered in cases where it is done within 50 days of a Gallium scan done by the same facility where the patient has remained during the 50-day period. Gallium scans done by another facility less than 50 days prior to the PET scan will not be counted against this screen. The purpose of this screen is to assure that PET scans are covered only when done as an alternative to a Gallium scan within the same facility. We are aware that, in order to assure proper patient care, the treating physician may conclude that previously performed Gallium scans are either inconclusive or not sufficiently reliable.

Frequency Limitation for Restaging: PET scans will be allowed for restaging no sooner than 50 days following the last staging PET scan or Gallium scan, unless sufficient evidence is presented toconvince the Medicare contractor that the restaging at an earlier date is medically necessary. Since PET scans for restaging are generally done following cycles of chemotherapy, and since such cycles

usually take at least 8 weeks, we believe this screen will adequately prevent medically unnecessary scans while allowing some adjustments for unusual cases. In all cases, the determination of the medical necessity for a PET scan for re-staging lymphoma is the responsibility of the local Medicare contractor.

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

B. Effective for services performed on or after July 1, 2001, the Medicare program has broadened coverage of FDG PET for the diagnosis, staging and restaging of lymphoma.

Requirements: PET is covered in either/both of the following circumstances:

- 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.

- 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.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

IX. Coverage of FDG PET for Melanoma

Medicare covered the evaluation of recurrent melanoma prior to surgery when used as an alternative to a Gallium scan, effective July 1, 1999. For services furnished on or after July 1, 2001 FDG PET is covered for the diagnosis, staging, and restaging of malignant melanoma (see part III). FDG PET is not covered for the use of evaluating regional nodes in melanoma patients.

A. Effective for services furnished July 1, 1999 through June 30, 2001, in the case of patients with recurrent melanoma prior to surgery, FDG PET (when used as an alternative to a Gallium scan) is covered for tumor evaluation.

Frequency Limitations: Whole body PET scans cannot be ordered more frequently than once every 12 months, unless medical necessity documentation, maintained in the beneficiaries medical record, supports the specific need for anatomic localization of possible recurrent tumor within this period.

Limitations: The FDG PET scan is covered only as an alternative to a Gallium scan. PET scans can not be covered in cases where it is done within 50 days of a Gallium scan done by the same PET facility where the patient has remained under the care of the same facility during the 50-day period. Gallium scans done by another facility less than 50 days prior to the PET scan will not be counted against this screen. The purpose of this screen is to assure that PET scans are covered only when done as an alternative to a Gallium scan within the same facility. We are aware that, in order to assure proper patient care, the treating physician may conclude that previously performed Gallium scans are either inconclusive or not sufficiently reliable to make the determination covered by this provision. Therefore, we will apply this 50-day rule only to PET scans done by the same facility that performed the Gallium scan.

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.

B. Effective for services performed on or after July 1, 2001 FDG PET scan coverage for the diagnosis, staging and restaging of melanoma (not the evaluation regional nodes) has been broadened.

Limitations: **PET scans are not covered for the evaluation of regional nodes**.

Requirements: PET is covered in either/both of the following circumstances:

- 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.

- 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.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical file, as is normal business practice.

X. Coverage of FDG PET for Head and Neck Cancers **(Cancers of the Central Nervous System (CNS) and thyroid are non covered)**

Effective for services performed on or after July 1, 2001, Medicare will provide coverage for cancer of the head and neck, excluding the central nervous system (CNS) and thyroid. The head and neck cancers encompass a diverse set of malignancies of which the majority is squamous cell carcinomas. Patients may present with metastases to cervical lymph nodes but conventional forms of diagnostic imaging fail to identify the primary tumor. Patients that present with cancer of the head and neck are left with two options either to have a neck dissection or to have radiation of both sides of the

neck with random biopsies. PET scanning attempts to reveal the site of primary tumor to prevent the adverse effects of random biopsies or unneeded radiation.

Limitations: **PET scans for head and neck cancers are not covered for CNS or thyroid cancers.**

Requirements: PET is covered in either/or both of the following circumstances:

- 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.

- 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.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

XI. Coverage of FDG PET for Myocardial Viability

Beginning July 1, 2001, Medicare covers FDG PET for the determination of myocardial viability, following an inconclusive SPECT. The identification of patients with partial loss of heart muscle movement or hibernating myocardium is important in selecting candidates with compromised ventricular function to determine appropriateness for revascularization. Diagnostic tests must distinguish between dysfunctional, but viable myocardial tissue and scar tissue, in order to affect management decisions.

Limitations: In the event that a patient has received a single photon computed tomography test (SPECT) with inconclusive results, a PET scan may be covered.
Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

XII. Coverage of FDG-PET for Refractory Seizures

Beginning July 1, 2001, Medicare will cover FDG-PET for pre-surgical evaluation for the purpose of localization of a focus of refractory seizure activity.

Limitations: Covered only for pre-surgical evaluation.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.