

Medicare Coverage Issues Manual

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<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
Table of Contents	2 pp.	2 pp.
50-36	13 pp.	12 pp.
50-56 - 50-58	2 pp.	---

NEW/REVISED MATERIAL--EFFECTIVE DATE: July 1, 2002
IMPLEMENTATION DATE: July 1, 2002

Section 50-56 Home Prothrombin Time International Normalized Ratio (INR) Monitoring for Anticoagulation Management, (Effective for Services Furnished on or after July 1, 2002) is added to provide coverage for Home Prothrombin Time monitoring and management only for patients with mechanical heart valves when certain conditions have been met under the Medicare program.

NEW/REVISED MATERIAL--EFFECTIVE DATE: October 1, 2002
IMPLEMENTATION DATE: October 1, 2002

Section 50-36 Positron Emission Tomography (PET) Scans, implements the National Coverage Determinations (NCDs) for both PET scans for myocardial viability and PET scans for breast cancer under section 1862 (a)(1)(A) of the Social Security Act. Section 50-56 regarding Single Photon Emission Computed Tomography has also been added as part of the determination regarding myocardial viability.

Section 50-57 Current Perception Threshold/Sensory Nerve Conduction Threshold test (sNCT), the Current Perception Threshold/Sensory Nerve Conduction Threshold (sNCT) test is a diagnostic test used to diagnose sensory neuropathies. The device is a noninvasive test that uses transcutaneous electrical stimuli to evoke a sensation. There is insufficient scientific or clinical evidence to consider this device as reasonable and necessary within the meaning of §1862(a)(1)(A) of the Social Security Act and will not be covered by Medicare.

A new code G0255 has been established for this test. The code descriptor is Current Perception Threshold/Sensory Nerve Conduction Threshold test (sNCT), per limb, any nerve - (Not covered by Medicare).

Section 50-58 Single Photo Emission Tomography – Covered, implements the National Coverage Determinations (NCDs) for both PET scans for myocardial viability and PET scans for breast cancer under §1862 (a)(1)(A) of the Social Security Act. Section 50-56 regarding Single Photon Emission Computed Tomography has also been added as part of the determination regarding myocardial viability.

These sections of the Coverage issues Manual are National Coverage Determinations (NCDs) under §1862(a)(1) of the Social security Act (the Act). 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.

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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
Breast Cancer	October 1, 2002	As an adjunct to standard imaging modalities for staging patients with distant metastasis or restaging patients with locoregional recurrence or metastasis; as an adjunct to standard imaging modalities for monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is anticipated.
Head and Neck Cancers (excluding CNS and thyroid)	July 1, 2001	Diagnosis, staging and restaging

Myocardial Viability	July 1, 2001 to September 30, 2002	Covered only following inconclusive SPECT
Myocardial Viability	October 1, 2002	Primary or initial diagnosis, or following an inconclusive SPECT prior to revascularization. SPECT may not be used following an inconclusive PET scan.
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 Systems

1. 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

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
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
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

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
Breast Cancer	Not covered	Not covered	Effective October 1, 2002, Full and partial ring
Myocardial Viability Primary or initial diagnosis prior to revascularization	Not covered	Not covered	Effective October 1, 2002, Full and 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 **except for breast cancer**. 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.

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 to convince 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

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 such as FDG PET distinguish between dysfunctional but viable myocardial tissue and scar tissue in order to affect management decisions in patients with ischemic cardiomyopathy and left ventricular dysfunction.

FDG PET is covered for the determination of myocardial viability following an inconclusive SPECT from July 1, 2001 through September 30, 2002. Only full ring PET scanners are covered from July 1, 2001 through December 31, 2001. However, as of January 1, 2002, full and partial ring scanners are covered.

Beginning October 1, 2002, Medicare covers FDG PET for the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization, or following an inconclusive SPECT. Studies performed by full and partial ring scanners are covered.

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. However, if a patient received a FDG PET study with inconclusive results, a follow up SPECT is not 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.

(See §50-58 of the CIM for SPECT coverage.)

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.

XIII. Breast Cancer

Beginning October 1, 2002, Medicare covers FDG PET as an adjunct to other imaging modalities for staging patients with distant metastasis, or restaging patients with locoregional recurrence or metastasis. Monitoring treatment of a breast cancer tumor when a change in therapy is contemplated is also covered as an adjunct to other imaging modalities.

Limitations: Effective October 1, 2002, Medicare continues to have a national non-coverage determination for initial diagnosis of breast cancer and staging of axillary lymph nodes. Medicare coverage for staging patients with distant metastasis or restaging patients with locoregional recurrence or metastasis; and for monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is anticipated, is only covered as an adjunct to other imaging modalities.

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

50-56 HOME PROTHROMBIN TIME INTERNATIONAL NORMALIZED RATIO (INR) MONITORING FOR ANTICOAGULATION MANAGEMENT

Use of the International Normalized Ratio (INR) allows physicians to determine the level of anticoagulation in a patient independent of the laboratory reagents used. The INR is the ratio of the patient's prothrombin time compared to the mean prothrombin time for a group of normal individuals. Maintaining patients within the therapeutic range minimizes adverse events associated with inadequate or excessive anticoagulation such as serious bleeding or thromboembolic events. Patient self-testing and self-management through the use of a home INR monitor may be used to improve the time in therapeutic rate (TTR) for select groups of patients. Increased TTR leads to improved clinical outcomes and reductions in thromboembolic and hemorrhagic events.

Home prothrombin monitoring with the use of INR devices is covered only for patients with mechanical heart valves. The monitor and the home testing must be prescribed by a treating physician as provided at 42 C.F.R. 410.32 (a) and the following requirements must be met:

1. The patient must have been anticoagulated for at least three months prior to use of the home INR device;
2. The patient must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and
3. Self-testing with the device should not occur more frequently than once a week.

50-57 CURRENT PERCEPTION THRESHOLD/SENSORY NERVE CONDUCTION THRESHOLD TEST (sNCT) NONCOVERED

The Current Perception Threshold/Sensory Nerve Conduction Threshold (sNCT) test is a diagnostic test used to diagnose sensory neuropathies. The device is a noninvasive test that uses transcutaneous electrical stimuli to evoke a sensation. There is insufficient scientific or clinical evidence to consider this device reasonable and necessary within the meaning of Section 1862(a)(1)(A) of the law and will not be covered by Medicare.

50-58 SINGLE PHOTON EMISSION TOMOGRAPHY – COVERED

Single-photon emission computed tomography (SPECT) acquires information on the concentration of radionuclides introduced into the patient's body. It is useful in the diagnosis of several clinical conditions including:

- stress fracture
- spondylosis
- infection (e.g. discitis)
- tumor (e.g. osteoid osteoma)
- analyze blood flow to an organ, as in the case of myocardial viability
- differentiate ischemic heart disease from dilated cardiomyopathy.

Frequency limitations: Contractor discretion.

In the case of myocardial viability, FDG PET may be used following a SPECT that was found to be inconclusive. However, SPECT may not be used following an inconclusive FDG PET performed to evaluate myocardial viability.