

CMS Manual System

Pub 100-03 Medicare National Coverage Determinations

Transmittal 31

Department of
Health &
Human Services
Center for Medicare
and Medicaid Services
Date: APRIL 1, 2005
Change Request
3741

SUBJECT: PET for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers

I. SUMMARY OF CHANGES: Effective for services performed on or after January 28, 2005, Medicare will cover an FDG PET scan as an adjunct test for the detection of pre-treatment metastases (i.e., staging) in newly diagnosed cervical cancer subsequent to conventional imaging that is negative for extra-pelvic metastasis. For all remaining indications that are the subject of this NCD, as well as other indications for cervical cancer not specifically mentioned, effective January 28, 2005, Medicare will cover FDG PET scans only when providers are participating in, and patients are enrolled in, an approved FDG PET clinical study, or an FDG PET clinical trial meeting FDA category B IDE exemption status. All currently covered FDG PET indications remain in effect. All currently non-covered FDG PET indications based on lack of evidence or benefit remain in effect. For all other currently non-covered FDG PET indications (not based on lack of evidence or benefit), Medicare will cover FDG PET scans meeting the clinical study/trial criteria outlined in this NCD. Although effective, Medicare will notify the medical community where these services can be accessed, as they become available, via a quarterly **Federal Register** Notice and the CMS Coverage Web site. These revisions to sections 220.6-220.6.13, & additions of 220.6.14 & 220.6.15 of Pub. 100-03 are national coverage determinations (NCDs) made under section 1862(a)(1) of the Social Security Act. The NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR sections 405.732, 405.860). An NCD that expands coverage is also binding on a Medicare Advantage Organization. In addition, an administrative law judge may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW/REVISED MATERIAL :

EFFECTIVE DATE : **January 28, 2005**

IMPLEMENTATION DATE : **April 18, 2005**

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will

receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R = REVISED, N = NEW, D = DELETED

R/N/D	Chapter / Section / Subsection / Title
R	1/Table of Contents
R	1/220.6/PET Scans (Various Effective Dates)
R	1/220.6.1/PET for Perfusion of the Heart
R	1/220.6.2/FDG PET for Lung Cancer
R	1/220.6.3/FDG PET for Esophageal Cancer
R	1/220.6.4/FDG PET for Colorectal Cancer
R	1/220.6.5/FDG PET for Lymphoma
R	1/220.6.6/FDG PET for Melanoma
R	1/220.6.7/FDG PET for Head and Neck Cancers
R	1/220.6.8/FDG PET for Myocardial Viability
R	1/220.6.9/FDG PET for Refractory Seizures
R	1/220.6.10/FDG PET for Breast Cancer
R	1/220.6.11/FDG PET for Thyroid Cancer
R	1/220.6.12/FDG PET for Soft Tissue Sarcoma
R	1/220.6.13/FDG PET for Dementia and Neurodegenerative Diseases
N	1/220.6.14/FDG PET for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers
N	1/220.6.15/FDG PET for All Other Cancer Indications Not Previously Specified

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1)

Coverage Determinations

Table of Contents

(Rev. 31, 04-01-05)

220.6.14 – FDG PET for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers

220.6.15 – FDG PET for All Other Cancer Indications Not Previously Specified

220.6 - Positron Emission Tomography (PET) Scans

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

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: This manual section 220.6 lists all Medicare-covered uses of PET scans. *Except as set forth below in cancer indications listed as “Coverage with Evidence Development”*, a particular use of PET scans is not covered unless this manual specifically provides that such use is covered. Although this section 220.6 lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all non-covered uses.

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, restaging
Esophageal Cancer	July 1, 2001	Diagnosis, staging, restaging
Colorectal Cancer	July 1, 1999	Determining location of tumors if rising CEA level suggests recurrence
Colorectal Cancer	July 1, 2001	Diagnosis, staging, restaging
Lymphoma	July 1, 1999	Staging and restaging only when used as alternative to Gallium scan
Lymphoma	July 1, 2001	Diagnosis, staging and restaging
Melanoma	July 1, 1999	Evaluating recurrence prior to surgery as alternative to Gallium scan
Melanoma	July 1, 2001	Diagnosis, staging, 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 loco-regional 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, restaging
Thyroid Cancer	October 1, 2003	Restaging of recurrent or residual thyroid cancers of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and negative I-131 whole body scan performed
Myocardial Viability	July 1, 2001 to September 30, 2002	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	Pre-surgical evaluation only
Perfusion of the heart using Rubidium 82* tracer	March 14, 1995	Noninvasive imaging of the perfusion of the heart
Perfusion of the heart using ammonia N-13* tracer	October 1, 2003	Noninvasive imaging of the perfusion of the heart

*Not FDG-PET.

EFFECTIVE JANUARY 28, 2005: This manual section lists Medicare-covered uses of PET scans effective for services performed on or after January 28, 2005. Except as set forth below in cancer indications listed as “coverage with evidence development”, a particular use of PET scans is not covered unless this manual specifically provides that such use is covered. Although this section 220.6 lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all non-covered uses.

For cancer indications listed as “coverage with evidence development” CMS determines that the evidence is sufficient to conclude that an FDG PET scan is reasonable and necessary only when the provider is participating in, and patients are enrolled in, one of the following types of prospective clinical studies that is designed to collect additional information at the time of the scan to assist in patient management:

- A clinical trial of FDG PET that meets the requirements of Food and Drug Administration (FDA) category B investigational device exemption (42 CFR 405.201);
- An FDG PET clinical study that is designed to collect additional information at the time of the scan to assist in patient management. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all enrolled patients not included in other qualifying trials through adequate auditing mechanisms; and, all patient confidentiality, privacy, and other Federal laws must be followed.

Effective January 28, 2005: For PET services identified as “Coverage with Evidence Development. Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- Federal Register Notice
- CMS coverage Web site at: www.cms.gov/coverage

<i>Indication</i>	<i>Covered¹</i>	<i>Nationally Non-covered²</i>	<i>Coverage with Evidence Development³</i>
<i>Brain</i>			<i>X</i>
<i>Breast</i> -Diagnosis -Initial staging of axillary nodes -Staging of distant metastasis -Restaging, monitoring *	<i>X</i> <i>X</i>	<i>X</i> <i>X</i>	
<i>Cervical</i> -Staging as adjunct to conventional imaging -Other staging -Diagnosis, restaging, monitoring *	<i>X</i>		<i>X</i> <i>X</i>
<i>Colorectal</i> -Diagnosis, staging, restaging -Monitoring *	<i>X</i>		<i>X</i>

<i>Esophagus</i> -Diagnosis, staging, restaging -Monitoring *	X		X
<i>Head and Neck (non-CNS/thyroid)</i> -Diagnosis, staging, restaging -Monitoring *	X		X
<i>Lymphoma</i> -Diagnosis, staging, restaging -Monitoring *	X		X
<i>Melanoma</i> -Diagnosis, staging, restaging -Monitoring *	X		X
<i>Non-Small Cell Lung</i> -Diagnosis, staging, restaging -Monitoring *	X		X
<i>Ovarian</i>			X
<i>Pancreatic</i>			X
<i>Small Cell Lung</i>			X
<i>Soft Tissue Sarcoma</i>			X
<i>Solitary Pulmonary Nodule</i> (characterization)	X		
<i>Thyroid</i> -Staging of follicular cell tumors -Restaging of medullary cell tumors -Diagnosis, other staging & restaging -Monitoring *	X		X X X
<i>Testicular</i>			X
<i>All other cancers not listed herein</i> (all indications)			X

¹ Covered nationally based on evidence of benefit. Refer to National Coverage Determination Manual Section 220.6 in its entirety for specific coverage language and limitations for each indication.

² Non-covered nationally based on evidence of harm or no benefit.

³ Covered only in specific settings discussed above if certain patient safeguards are provided. Otherwise, non-covered nationally based on lack of evidence sufficient to establish either benefit or harm or no prior decision addressing this cancer. Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- *Federal Register Notice*
- *CMS coverage Web site at: www.cms.gov/coverage*

** Monitoring = monitoring response to treatment when a change in therapy is anticipated.*

II. General Conditions of Coverage for FDG PET

Allowable FDG PET Systems

A. Definitions: For purposes of this section:

- "Any FDA-approved" means all systems approved or cleared for marketing by the Food and Drug Administration (FDA) to image radionuclides in the body.
- "FDA-approved" means that the system indicated has been approved or cleared for marketing by the FDA to image radionuclides in the body.
- "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” will not be covered by Medicare. In addition, scans performed with systems with crystals greater than or equal to 5/8” in thickness, but that do not meet the other listed design characteristics are not covered by Medicare.

B. 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/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/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/Partial ring, certain coincidence systems
Staging or restaging of lymphoma only when used as alternative to gallium scan	Effective 7/1/1999, any FDA-approved	Any FDA-approved	FDA-approved: Full/Partial ring, certain coincidence systems
Evaluating recurrence of melanoma prior to surgery as alternative to gallium scan	Effective 7/1/1999, any FDA-approved.	Any FDA-approved	FDA-approved: Full/Partial ring, certain coincidence systems
Diagnosis, staging, restaging of colorectal cancer	Not covered by Medicare	Full ring	FDA-approved: Full/Partial ring
Diagnosis, staging, restaging of esophageal cancer	Not covered by Medicare	Full ring	FDA-approved: Full/Partial ring
Diagnosis, staging, restaging of head and neck cancers (excluding CNS and thyroid)	Not covered by Medicare	Full ring	FDA-approved: Full/Partial ring
Diagnosis, staging, restaging of lung cancer (non small cell)	Not covered by Medicare	Full ring	FDA-approved: Full/Partial ring
Diagnosis, staging, restaging of lymphoma	Not covered by Medicare	Full ring	FDA-approved: Full/Partial ring
Diagnosis, staging, restaging of melanoma (non-covered for evaluating regional nodes)	Not covered by Medicare	Full ring	FDA-approved: Full/Partial ring
Determination of myocardial viability only following inconclusive SPECT	Not covered by Medicare	Full ring	FDA-approved: Full/Partial ring
Pre-surgical evaluation of refractory seizures	Not covered by Medicare	Full ring	FDA-approved: Full ring
Breast Cancer	Not covered	Not covered	Effective October 1, 2002, Full/Partial ring
Thyroid Cancer	Not covered	Not covered	Effective October 1, 2003, Full/Partial ring
Myocardial Viability Primary or initial diagnosis prior to revascularization	Not covered	Not covered	Effective October 1, 2002, Full/Partial ring

<i>All other oncology indications not previously specified</i>	<i>Not covered</i>	<i>Not covered</i>	<i>Effective January 28, 2005, Full/Partial ring</i>
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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 prior to June 30, 2001:

- Submission of claims for payment must include any information Medicare requires to ensure 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 FDA.
- 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.

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:

- 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.
- The ordering physician is responsible for documenting the medical necessity of the study and ensuring 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:

A. **Diagnosis:** PET is covered only in clinical situations in which: (1) the PET results may assist in avoiding an invasive diagnostic procedure, or in which (2) 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 *generally performed* for staging *rather than* diagnosis.

PET is not covered *as a screening test (i.e., testing patients without specific signs and symptoms of disease).*

B. **Staging:** PET is covered for staging 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 (CT), magnetic resonance imaging (MRI), or ultrasound), or (1)(b) 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.

- C. Restaging: PET is covered for restaging: (1) after completion of treatment for the purpose of detecting residual disease, (2) for detecting suspected recurrence *or metastasis*, (3) to determine the extent of a known recurrence, or (4) 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. *Restaging applies to testing after a course of treatment is completed, and is covered subject to the conditions above.*
- D. Monitoring: *This refers to use of PET to monitor tumor response to treatment during the planned course of therapy (i.e., when a change in therapy is anticipated).*

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

(This NCD last reviewed December 2004.)

220.6.1 - PET for Perfusion of the Heart (Various Effective Dates Below)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

1. Rubidium 82 (Effective March 14, 1995)

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:

- 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 performed after an inconclusive noninvasive cardiac test. The information submitted with respect to the previous noninvasive cardiac test must specify the type of test

performed 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.

2. Ammonia N-13 (Effective October 1, 2003)

Effective for services performed on or after October 1, 2003, 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 ammonia N-13 are covered, provided the requirements below are met:

- The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a 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 whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)

(This NCD last reviewed April 2003.)

220.6.2 - FDG PET for Lung Cancer (Various Effective Dates Below)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

1. Characterization of Single Pulmonary Nodules (SPNs) (Effective January 1, 1998)

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 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 record file at the referring physician's office to support the medical necessity of the procedure, as is normal business practice. The following documentation is required:

- 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 4 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 PET scan results. When there is 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.

2. Initial Staging of Non-Small-Cell Lung Carcinoma (NSCLC) (Effective January 1, 1998)

Effective for services performed from January 1, 1998, through June 30, 2001, Medicare approved coverage of FDG PET for initial staging of 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 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.

3. Diagnosis, Staging, and Restaging of NSCLC (Effective July 1, 2001)

Effective for services performed on or after July 1, 2001, Medicare covers FDG PET for diagnosis, staging, and restaging of NSCLC.

4. *Monitoring response to treatment of NSCLC (Effective January 28, 2005)*

Effective for services performed on or after January 28, 2005, Medicare only covers FDG PET for monitoring response to treatment for NSCLC as “coverage with evidence development”.

Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- *Federal Register Notice*
- *CMS coverage Web site at: www.cms.gov/coverage*

Requirements: PET is covered in *any/all* of the following circumstances:

A. **Diagnosis:** PET is covered only in clinical situations in which: (1) the PET results may assist in avoiding an invasive diagnostic procedure, or in which (2) 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 *generally* performed for staging *rather than* diagnosis.

B. **Staging and/or Restaging:** PET is covered for staging 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 (CT, magnetic resonance imaging, or ultrasound) or, (1)(b) the use of PET 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 is covered for restaging after the completion of treatment for: (1) the purpose of detecting residual disease, (2) detecting suspected recurrence, (3) determining the extent of a known recurrence, or (4) potentially replacing one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

*C. **Monitoring Response to Treatment:** PET is covered for monitoring response to treatment when a change in therapy is anticipated.*

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.

(This NCD last reviewed March 2005.)

220.6.3 - FDG PET for Esophageal Cancer (*Various Effective Dates Below*)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

Effective for services performed on or after July 1, 2001, Medicare covers FDG PET for the diagnosis, staging, and restaging of esophageal cancer.

Effective for services performed on or after January 28, 2005, Medicare only covers FDG PET for monitoring response to treatment for esophageal cancer as “coverage with evidence development”.

Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- *Federal Register Notice*
- *CMS coverage Web site at: www.cms.gov/coverage*

Requirements: PET is covered in *any/all* of the following circumstances:

- A. Diagnosis: PET is covered only in clinical situations in which: (1) the PET results may assist in avoiding an invasive diagnostic procedure, or (2) 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 *generally* performed for staging *rather than* diagnosis.
- B. Staging and/or Restaging: PET is covered for staging 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 (CT, magnetic resonance imaging, or ultrasound), or (1)(b) the use of PET 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 is covered for restaging after the completion of treatment for: (1) the purpose of detecting residual disease, (2) detecting suspected recurrence, (3) determining the extent of a known recurrence, or (4) potentially replacing one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

- C. Monitoring Response to Treatment: PET is covered for monitoring response to treatment when a change in therapy is anticipated.*

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.

(This NCD last reviewed March 2005.)

220.6.4 - FDG PET for Colorectal Cancer (Various Effective Dates Below)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

1. Recurrent Colorectal Carcinoma With Rising Levels of Biochemical Tumor Marker Carcinoembryonic Antigen (CEA) (Effective July 1, 1999)

Effective for services performed on or after July 1, 1999, Medicare covers FDG PET for patients with recurrent colorectal carcinomas, suggested by rising levels of the biochemical tumor marker CEA.

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.

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.

2. Diagnosis, Staging, and Re-Staging (Effective July 1, 2001)

Effective for services performed on or after July 1, 2001, Medicare covers FDG PET 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/extra-hepatic 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/symptoms of recurrence.

3. *Monitoring Response to Treatment (Effective January 28, 2005)*

Effective for services performed on or after January 28, 2005, Medicare only covers FDG PET for monitoring response to treatment for colorectal cancer as “coverage with evidence development”.

Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- *Federal Register Notice*
- *CMS coverage Web site at: www.cms.gov/coverage*

Requirements: PET is covered in *any/all* of the following circumstances:

- A. Diagnosis: PET is covered only in clinical situations in which: (1) the PET results may assist in avoiding an invasive diagnostic procedure, or in which (2) 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 *generally* performed for of staging *rather than* diagnosis.

- B. Staging and/or Restaging: PET is covered for staging 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 (1)(b) the use of PET 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 is covered for restaging after completion of treatment for the purpose of: (1) detecting residual disease, (2) detecting suspected recurrence, (3) determining the extent of a known recurrence, or (4) potentially replacing one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

C. Monitoring Response to Treatment: PET is covered for monitoring response to treatment when a change in therapy is anticipated.

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

(This NCD last reviewed March 2005.)

220.6.5 - FDG PET for Lymphoma (Various Effective Dates Below)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

1. Staging and Restaging as Alternative to Gallium Scan (Effective July 1, 1999)

Effective for services performed on or after July 1, 1999, FDG PET is covered for the staging and restaging of lymphoma.

Requirements:

- 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 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 performed within 50 days of a Gallium scan performed by the same facility where the patient has remained during the 50-day period. Gallium scans performed 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 ensure that PET scans are covered only as an alternative to a Gallium scan within the same facility. *The CMS is* aware that, in order to ensure 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 restaging at an earlier date is medically necessary. Since PET scans for restaging are generally performed following cycles of chemotherapy, and since such cycles usually take at least 8 weeks, *CMS* believes 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.

Effective for services performed on or after 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.

2. *Diagnosis, Staging, and Restaging (Effective July 1, 2001)*

Effective for services performed on or after July 1, 2001, Medicare covers FDG PET for the diagnosis, staging and restaging of lymphoma.

3. *Monitoring Response to Treatment (Effective January 28, 2005)*

Effective for services performed on or after January 28, 2005, Medicare only covers FDG PET for monitoring response to treatment for lymphoma as "coverage with evidence development".

Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- *Federal Register Notice*
- *CMS coverage Web site at: www.cms.gov/coverage*

Requirements: PET is covered in *any/all* of the following circumstances:

- A. **Diagnosis:** PET is covered only in clinical situations in which: (1) the PET results may assist in avoiding an invasive diagnostic procedure, or (2) 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 *generally* performed for the staging *rather than* diagnosis.
- B. **Staging and/or Restaging:** PET is covered for staging 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 (CT, magnetic resonance

imaging, or ultrasound), or (1)(b) the use of PET 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 is covered for restaging after completion of treatment for the purpose of: (1) detecting residual disease, (2) detecting suspected recurrence, (3) determining the extent of a known recurrence, or (4) potentially replacing one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

C. Monitoring Response to Treatment: PET is covered for monitoring response to treatment when a change in therapy is anticipated.

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

(This NCD last reviewed March 2005.)

220.6.6 - FDG PET for Melanoma (Various Effective Dates Below)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

1. Evaluation of Recurrent Melanoma Prior to Surgery As Alternative to Gallium Scan (Effective July 1, 1999)

Effective for services *performed* on or after July 1, 1999, FDG PET (when used as an alternative to a Gallium scan) is covered for patients with recurrent melanoma prior to surgery for tumor evaluation. FDG PET is not covered for the evaluation of regional nodes.

Frequency Limitations: Whole body PET scans cannot be ordered more frequently than once every 12 months, unless medical necessity documentation, maintained in the beneficiary's 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 they are performed within 50 days of a Gallium scan performed by the same PET facility where the patient has remained under the care of the same facility during the 50-day period. Gallium scans performed 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 ensure that PET scans are covered only as an alternative to a Gallium scan within the same facility. *The CMS is* aware that, in order to ensure 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, *CMS* will apply this 50-day rule only to PET scans performed by the same facility that performed the Gallium scan.

Effective for services performed on or after 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.

2. Diagnosis, Staging, and Restaging (Effective July 1, 2001)

Effective for services performed on or after July 1, 2001, FDG PET is covered for the diagnosis, staging, and restaging of melanoma. FDG PET is not covered for the evaluation of regional nodes.

3. *Monitoring Response to Treatment (Effective January 28, 2005)*

Effective for services performed on or after January 28, 2005, Medicare only covers FDG PET for monitoring response to treatment for melanoma as "coverage with evidence development".

Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- *Federal Register Notice*
- *CMS coverage Web site at: www.cms.gov/coverage*

Requirements: PET is covered in *any/all* of the following circumstances:

A. Diagnosis: PET is covered only in clinical situations in which: (1) the PET results may assist in avoiding an invasive diagnostic procedure, or (2) 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 *generally* performed for staging *rather than* diagnosis.

B. Staging and/or Restaging: PET is covered for staging 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 (1)(b) the use of PET 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 is covered for restaging after the completion of treatment for the purpose of: (1) detecting residual disease, (2) detecting suspected recurrence, (3) determining the extent of a known recurrence, or (4) potentially replacing one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

C. *Monitoring Response to Treatment: PET is covered for monitoring response to treatment when a change in therapy is anticipated.*

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

(This NCD last reviewed March 2005.)

220.6.7 - FDG PET for Head and Neck Cancers (*Various Effective Dates Below*)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

Effective for services performed on or after July 1, 2001, Medicare covers FDG PET for *diagnosis, staging and restaging of* 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 unnecessary radiation.

Limitations: **PET scans for head and neck cancers are not covered for CNS or thyroid cancers** prior to October 1, 2003. Refer to section 220.6.11 for coverage for thyroid cancer effective October 1, 2003.

Effective for services performed on or after January 28, 2005, Medicare only covers FDG PET for monitoring response to treatment for head and neck cancers as “coverage with evidence development”.

Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- *Federal Register Notice*
- *CMS coverage Web site at: www.cms.gov/coverage*

Requirements: PET is covered in *any/all* of the following circumstances:

- A. **Diagnosis:** PET is covered only in clinical situations in which: (1) the PET results may assist in avoiding an invasive diagnostic procedure, or (2) 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 *generally* performed for staging *rather than* diagnosis.
- B. **Staging and/or Restaging:** PET is covered for staging 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 (1)(b) the use of PET 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 is covered for restaging after completion of treatment for the purpose of: (1) detecting residual disease, (2) detecting suspected recurrence, (3) determining the extent of a known recurrence, or (4) potentially replacing one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

C. Monitoring Response to Treatment: PET is covered for monitoring response to treatment when a change in therapy is anticipated.

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

(This NCD last reviewed March 2005.)

220.6.8 - FDG PET for Myocardial Viability (Various Effective Dates Below)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

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.

1. FDG PET is covered for the determination of myocardial viability following an inconclusive single photon emission computed tomography (SPECT) test 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.
2. 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 a patient receives a SPECT test with inconclusive results, a PET scan may be covered. However, if a patient receives a FDG PET study with inconclusive results, a follow up SPECT test 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 §220.12 for SPECT coverage)

(This NCD last reviewed September 2002.)

220.6.9 – FDG PET for Refractory Seizures (Effective July 1, 2001)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

Beginning July 1, 2001, Medicare covers 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.

(This NCD last reviewed June 2001.)

220.6.10 – FDG PET for Breast Cancer (Effective October 1, 2002)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

Effective for services performed on or after October 1, 2002, Medicare covers FDG PET only as an adjunct to other imaging modalities for: (1) staging breast cancer patients with distant metastasis, (2) restaging patients with loco-regional recurrence or metastasis, or (3) monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is contemplated.

Limitations: Medicare continues to nationally non-cover initial diagnosis of breast cancer and staging of axillary lymph nodes.

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

(This NCD last reviewed September 2002.)

220.6.11 – FDG PET for Thyroid Cancer (*Various Effective Dates Below*)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

1. Effective for services *performed* on or after October 1, 2003, Medicare covers the use of FDG PET for thyroid cancer only for restaging of recurrent or residual thyroid cancers of follicular cell origin that have been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and negative I-131 whole body scan performed.
2. *Effective for services performed on or after January 28, 2005, Medicare only covers FDG PET for diagnosis, other staging and restaging, restaging of medullary cell*

tumors, and monitoring response to treatment as “coverage with evidence development”

Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- Federal Register Notice
- CMS coverage Web site at: www.cms.gov/coverage

Requirements: PET is covered in any/all of the following circumstances:

A. Diagnosis: PET is covered only in clinical situations in which: (1) the PET results may assist in avoiding an invasive diagnostic procedure, or (2) 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 generally performed for staging rather than diagnosis.

B. Staging and/or Restaging: PET is covered for staging 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 (1)(b) the use of PET 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 is covered for restaging after completion of treatment for the purpose of: (1) detecting residual disease, (2) detecting suspected recurrence, (3) determining the extent of a known recurrence, or (4) potentially replacing one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

C. Monitoring Response to Treatment: PET is covered for monitoring response to treatment when a change in therapy is anticipated.

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

(This NCD last reviewed March 2005.)

220.6.12 – FDG PET for Soft Tissue Sarcoma (*Various Effective Dates Below*)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

Following a thorough review of the scientific literature, including a technology assessment on the topic, Medicare maintains its national non-coverage determination for all uses of FDG PET for soft tissue sarcoma.

- 1. Effective for services performed on or after October 1, 2003, FDG PET for soft tissue sarcoma is nationally non-covered.*
- 2. Effective for services performed on or after January 28, 2005, Medicare only covers FDG PET for soft tissue sarcoma as “coverage with evidence development”.*

Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- Federal Register Notice*
- CMS coverage Web site at: www.cms.gov/coverage*

(This NCD last reviewed March 2005.)

220.6.13 – *FDG PET for Dementia and Neurodegenerative Diseases (Effective September 15, 2004)*

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

A. General

Medicare covers FDG-PET scans for either the differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer’s disease (AD) under specific requirements; OR, its use in a Centers for Medicare & Medicaid Services (CMS)-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases. Specific requirements for each indication are clarified below:

B. Nationally Covered Indications

1. FDG-PET Requirements for Coverage in the Differential Diagnosis of AD and FTD

An FDG-PET scan is considered reasonable and necessary in patients with a recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD. These patients have been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remains uncertain.

The following additional conditions must be met before an FDG-PET scan will be covered:

- a. The patient’s onset, clinical presentation, or course of cognitive impairment is such that FTD is suspected as an alternative neurodegenerative cause of the cognitive decline. Specifically, symptoms such as social disinhibition, awkwardness, difficulties

with language, or loss of executive function are more prominent early in the course of FTD than the memory loss typical of AD;

- b. The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology (AAN)) encompassing a medical history from the patient and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination (including formal documentation of cognitive decline occurring over at least 6 months) aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT);
- c. The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;
- d. The evaluation of the patient did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information available through FDG-PET is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment;
- e. The FDG-PET scan is performed in a facility that has all the accreditation necessary to operate nuclear medicine equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry, with experience interpreting such scans in the presence of dementia;
- f. A brain single photon emission computed tomography (SPECT) or FDG-PET scan has not been obtained for the same indication. (The indication can be considered to be different in patients who exhibit important changes in scope or severity of cognitive decline, and meet all other qualifying criteria listed above and below (including the judgment that the likely diagnosis remains uncertain). The results of a prior SPECT or FDG-PET scan must have been inconclusive or, in the case of SPECT, difficult to interpret due to immature or inadequate technology. In these instances, an FDG-PET scan may be covered after 1 year has passed from the time the first SPECT or FDG-PET scan was performed.)
- g. The referring and billing provider(s) have documented the appropriate evaluation of the Medicare beneficiary. Providers should establish the medical necessity of an FDG-PET scan by ensuring that the following information has been collected and is maintained in the beneficiary medical record:
 - Date of onset of symptoms;
 - Diagnosis of clinical syndrome (normal aging; mild cognitive impairment or MCI; mild, moderate or severe dementia);
 - Mini mental status exam (MMSE) or similar test score;
 - Presumptive cause (possible, probable, uncertain AD);
 - Any neuropsychological testing performed;
 - Results of any structural imaging (MRI or CT) performed;

- Relevant laboratory tests (B12, thyroid hormone); and,
- Number and name of prescribed medications.

The billing provider must furnish a copy of the FDG-PET scan result for use by CMS and its contractors upon request. These verification requirements are consistent with federal requirements set forth in 42 Code of Federal Regulations section 410.32 generally for diagnostic x-ray tests, diagnostic laboratory tests, and other tests. In summary, section 410.32 requires the billing physician and the referring physician to maintain information in the medical record of each patient to demonstrate medical necessity [410.32(d) (2)] and submit the information demonstrating medical necessity to CMS and/or its agents upon request [410.32(d)(3)(I)] (OMB number 0938-0685).

2. **FDG-PET Requirements for Coverage in the Context of a CMS-approved Practical Clinical Trial Utilizing a Specific Protocol to Demonstrate the Utility of FDG-PET in the Diagnosis, and Treatment of Neurodegenerative Dementing Diseases**

An FDG-PET scan is considered reasonable and necessary in patients with mild cognitive impairment or early dementia (in clinical circumstances other than those specified in subparagraph 1) only in the context of an approved clinical trial that contains patient safeguards and protections to ensure proper administration, use and evaluation of the FDG-PET scan.

The clinical trial must compare patients who do and do not receive an FDG-PET scan and have as its goal to monitor, evaluate, and improve clinical outcomes. In addition, it must meet the following basic criteria:

- a. Written protocol on file;
- b. Institutional Review Board review and approval;
- c. Scientific review and approval by two or more qualified individuals who are not part of the research team; and,
- d. Certification that investigators have not been disqualified.

C. Nationally Non-covered Indications

All other uses of FDG-PET for patients with a presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., possible or probable AD, clinically typical FTD, dementia of Lewy bodies, or Creutzfeld-Jacob disease) for which CMS has not specifically indicated coverage continue to be non-covered.

D. Other

Not applicable.

(This NCD last reviewed September 2004.)

220.6.14 – FDG PET for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers (Effective January 28, 2005)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

A. Staging for Invasive Cervical Cancer as an Adjunct to Conventional Imaging

The CMS has determined that there is sufficient evidence to conclude that an FDG PET scan is reasonable and necessary for the detection of metastases during the pre-treatment management phase (i.e., staging) in patients with newly diagnosed and locally advanced cervical cancer with no extra-pelvic metastasis on conventional imaging tests, such as computed tomography (CT) or magnetic resonance imaging (MRI). Use of FDG PET as an adjunct may more accurately assist in the non-invasive detection of para-aortic, pelvic nodal involvement and other metastases in the pre-treatment phase of disease. The following conditions must be met:

- *A pathologic diagnosis of cervical cancer must have already been made before the FDG PET scan is performed,*
- *The results of other imaging procedures used (e.g., MRI or CT) must be reported, and,*
- *The available conventional imaging tests are negative for extra-pelvic metastasis.*

NOTE: *Other staging utilizing FDG PET (e.g., as a substitute for conventional structural imaging; when a previous MRI or CT is positive or inconclusive for para-aortic metastasis and negative for supra-clavicular nodal metastasis) are only covered as “coverage with evidence development”.*

Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- *Federal Register Notice*
- *CMS coverage Web site at: www.cms.gov/coverage*

B. Brain, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers, and other indications of Cervical Cancer not mentioned in Section A above

“Coverage with evidence development” applies to all FDG PET indications for brain, ovarian, pancreatic, small cell lung, testicular cancers, and other indications of cervical cancer not mentioned in Section A above.

For cancer indications listed as “coverage with evidence development” CMS determines that the evidence is sufficient to conclude that an FDG PET scan is reasonable and necessary only when the provider is participating in, and patients are enrolled in, one of the following types of prospective clinical studies that is designed to collect additional information at the time of the scan to assist in patient management:

- *A clinical trial of FDG PET that meets the requirements of Food and Drug Administration (FDA) category B investigational device exemption (42 CFR 405.201); or*
- *An FDG PET clinical study that is designed to collect additional information at the time of the scan to assist in patient management. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all enrolled patients not included in other qualifying trials through adequate auditing mechanisms; and, all patient confidentiality, privacy, and other Federal laws must be followed.*

Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- *Federal Register Notice*
- *CMS coverage Web site at: www.cms.gov/coverage*

(This NCD last reviewed March 2005.)

220.6.15 – FDG PET for All Other Cancer Indications Not Previously Specified (Effective January 28, 2005)

(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

Effective for services performed on or after January 28, 2005: “coverage with evidence development” applies to all FDG PET indications for all other cancers not previously specified in Section 220.6 above in its entirety.

For cancer indications listed as “coverage with evidence development” CMS has determined that the evidence is sufficient to conclude that an FDG PET scan is reasonable and necessary only when the provider is participating in, and patients are enrolled in, one of the following types of prospective clinical studies that is designed to collect additional information at the time of the scan to assist in patient management:

- *A clinical trial of FDG PET that meets the requirements of Food and Drug Administration (FDA) category B investigational device exemption (42 CFR 405.201); or*
- *An FDG PET clinical study that is designed to collect additional information at the time of the scan to assist in patient management. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all enrolled patients not included in other qualifying trials through adequate auditing*

mechanisms; and, all patient confidentiality, privacy, and other Federal laws must be followed.

Medicare shall notify providers and beneficiaries where these services can be accessed, as they become available, via the following:

- *Federal Register Notice*
- *CMS coverage Web site at: www.cms.gov/coverage*

(This NCD last reviewed March 2005.)