Medicare Part B Medical Policy (12-3-04)

Contractor's Determination Number:	AC-99-521
Contractor Name:	Medicare Services
Contractor Number:	00520, 00521, 00522, 00523, 00528
Contractor Type:	Carrier
LCD Title:	POSITRON EMISSION TOMOGRAPHY (PET SCANS)
AMA CPT Copyright Statement:	"CPT codes, descriptions, and other data only are copyright 1999 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply."
CMS National Coverage Policy:	• Title XVIII of the Social Security Act, section 1862(a)(1)(A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary. • Title XVIII of the Social Security Act, section 1833(e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim. • Title XVIII of the Social Security Act, section 1862(a)(7). This section excludes routine physical examinations and screening tests performed in the absence of signs or symptoms from coverage.
Primary Geographic Jurisdiction:	00520 - Arkansas 00521 - New Mexico 00522 - Oklahoma 00523 - Missouri (Eastern) 00528 - Louisiana
Secondary Geographic Jurisdiction:	Not applicable
Oversight Region:	Region VI Dallas
CMS Consortium:	Southern

DMERC Region LCD Covers: Not applicable

Original LCD Effective Date: 07/01/2001

Indications and Limitations of Coverage and/or Medical Necessity: The following indications outline the circumstances for coverage of a PET Scan. Unless otherwise indicated, the clinical conditions listed below as covered are for PET scans using FDG as a tracer.

Other uses of PET scans not listed in this manual are NOT covered.

General Conditions of Coverage:

A. Regardless of any other terms or conditions, all uses of FDG PET scans, in order to be covered by the Medicare program, must meet the following general conditions prior to June 30, 2001:
   1. Such scans must be performed using a camera that has either been approved or cleared for marketing by the FDA to image radionuclides in the body.
   2. Submission of claims for payment must include any information Medicare requires to assure that the PET scans performed were:
      a. medically necessary;
      b. did not unnecessarily duplicate other covered diagnostic tests; or
      c. did not involve investigational drugs or procedures using investigational drugs, as determined by the Food and Drug Administration (FDA).
   3. When submitting a claim for payment, the PET Scan entity must keep the patient record relative to that service on file as Medicare requires.

B. Regardless of any other terms or conditions, all uses of FDG PET scans, in order to be covered by the Medicare program, must meet the following general conditions as of July 1, 2001:
   1. Coverage for PET scans is for those indications otherwise listed in this document. For indications covered beginning July 1, 2001, scans performed with dedicated full-ring scanners will be covered. In the decision memorandum of December 15, 2000, CMS had indicated that gamma camera systems with at least a one-inch thick crystal would be eligible for coverage. However, coverage of PET scans using camera-based systems is now under further review as a separate national coverage determination. An announcement as to the final decision on what systems other than dedicated PET will be eligible for coverage, if any, will be before July 1, 2001. For those indications covered before July 1, 2001, all PET scanners approved or cleared for marketing by the FDA remain covered.
   2. The provider of the PET scan should maintain on file the doctor's referral and documentation that the procedure involved only FDA approved drugs and devices, as is

normal business practice.

3. The ordering physician is responsible for documenting the medical necessity of the study and that it meets the conditions specified in the instructions. The physician should have documentation in the beneficiary's medical record to support the referral to the PET scan provider.
4. Medicare coverage is predicated upon the use of PET scans with FDG for the purpose of development of appropriate treatment plans for patients. CMS will evaluate the claims data for these services and other source data, to determine whether and to what extent, this LCD may need additional modification to assure that covered services are medically effective for the treatment of Medicare beneficiaries.

Covered Indications for PET Scans & Limitations/Requirements of Usage:

For all uses of PET relating to malignancies, the following conditions:

1. Diagnosis: A PET Scan is covered only in clinical situations in which the results may assist in either avoiding an invasive diagnostic procedure or in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, most solid tumors require a tissue diagnosis before the performance of PET scanning. PET scans following a tissue diagnosis are for staging purposes and 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 Scans are not covered for other diagnostic uses, nor are they covered for screening purposes (testing of patients without specific signs and symptoms of disease).
2. Staging and/or Restaging: PET is covered in clinical situations in which:
   a. the stage of the cancer remains in doubt after completion of a standard diagnostic work-up, including conventional imaging (computed tomography, magnetic
   b. the use of PET would also be considered reasonable and necessary if:

      clinical management of the patient would differ depending on the stage of the cancer identified;

      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
   c. After the completion of treatment, PET Scan coverage is for restaging to detect residual disease, suspected recurrence or to determine the extent of a known recurrence. The use of a PET Scan would be reasonable and necessary if it could potentially replace one or more conventional imaging studies when 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 (on or after October 1, 2002). Restaging only occurs after a course of treatment is completed, and coverage is subject to the conditions above.

I. A. Coverage of PET for Perfusion of the Heart:

Rubidium 82:

Effective for services performed on or after March 14, 1995, PET Scans performed either at rest or with pharmacological stress for noninvasive imaging of the perfusion of the heart to diagnose and manage 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 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 the patient's other clinical data and documented in the beneficiary's file.)

Any PET Scan billed to Medicare for dates of services before July 1, 2001, the claimant must submit additional specified information on the claim form (including proper codes and/or modifiers), to indicate the PET Scan results. The claimant must also include information on whether performance of the PET Scan was after an inconclusive noninvasive cardiac test. The information submitted regarding the previous noninvasive cardiac test performed before the PET scan must specify the type of test 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, submit claims with the appropriate codes.

B. Ammonia N-13

Effective for services performed on or after October 1, 2003, PET Scans performed at rest or with pharmacological stress for the noninvasive imaging of the perfusion of the heart to diagnose and manage patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical ammonia N-13

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 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 documented in the beneficiary's file.)

II. 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. January 01, 1998 - Effective for services performed on or after: 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.

July 01, 2001 - Maintain documentation 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. January 1, 1998 through June 30, 2001 - Services performed during:

Medicare approved coverage of FDG PET for initial staging of non-small-cell lung carcinoma (NSCLC).

Limitations:

Coverage of this service is 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. 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.

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 as noted in "Covered Indications for PET Scans & Limitations/ Requirements of Usage" section above:

Diagnosis

Staging and/or Restaging

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.

III. Coverage of FDG PET for Esophageal Cancer

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 as noted in "Covered Indications for PET Scans & Limitations/ Requirements of Usage" section above:

Diagnosis

Staging and/or Restaging

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.

IV. 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. 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. 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/or both of the following circumstances as noted "Covered Indications for PET Scans & Limitations/ Requirements of Usage" section above:

Diagnosis

Staging and/or Restaging

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

V. 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. 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.
- - To ensure that the PET Scan is covered only as an alternative to a Gallium scan, no PET Scan is covered when done within 50-days of a Gallium scan performed 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 Limitations 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 eight 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. July 1, 2001- Effective for services performed on or after:

Medicare program has broadened coverage of FDG PET for the diagnosis, staging and restaging of lymphoma.

Requirements:

PET is covered in either/or both of the following circumstances as noted in "Covered Indications for PET Scans & Limitations/ Requirements of Usage" section above:

Diagnosis

Staging and/or Restaging

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

VI. 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. July 1, 1999, through June 30, 2001 - services performed through: 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:

You cannot order whole body PET Scans 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 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. July 1, 2001 - services performed on or after:

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/or both of the following circumstances as noted in "Covered Indications for PET Scans & Limitations/ Requirements of Usage" section above:

Diagnosis

Staging and/or Restaging

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

VII. Coverage of FDG PET for Head and Neck Cancers

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 (prior to October 1, 2003). Refer to section XI for coverage for thyroid cancer effective October 1, 2003.

Requirements:

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

Diagnosis

Staging and/or Restaging

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 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 single photon computed tomography test (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 will cover FDG PET for the determination of myocardial viability as a primary 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 receives a SPECT with inconclusive results, a PET scan may be performed and 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.

IX. 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.

X. Coverage of FDG PET for Breast Cancer

Effective for dates of service on or after October 1, 2002, Medicare covers FDG PET as an adjunct to other imaging modalities to stage patients with distant metastasis of breast cancer, restage patients with locoregional recurrence, or restage metastasis of breast cancer. Monitoring treatment of a breast cancer tumor when contemplating a change in therapy is covered as an adjunct to other imaging modalities.

Limitations:

Effective for dates of service on or after October 1, 2002, Medicare continues to have a national non-coverage determination for initial diagnosis of breast cancer and initial 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.

XI. Coverage of FDG PET for Thyroid Cancer

1. Effective for services furnished on or after October 1, 2003, Medicare only covers the use of FDG PET for thyroid cancer for restaging of recurrent or residual thyroid cancers of follicular cell origin, previously treated by thyroidectomy and radioiodine ablation, have a serum thyroglobulin >10ng/ml, and negative I-131 whole body scan performed.
2. All other uses of FDG PET in the diagnosis and treatment of thyroid cancer remain non-covered.

XII. Soft Tissue Sarcoma – NOT COVERED

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.

XIII. Dementia and Neurogenerative Diseases –

A. Following a thorough review of the scientific literature, including a technology assessment on the topic, and consideration by the Medicare Coverage Advisory Committee, Medicare maintains a national non-coverage determination for all uses of FDG-PET for the diagnosis and management of patients with dementia or other neurogenerative diseases. This is effective for services provided prior to September 15, 2004.

B. Effective for dates of service on or after September 15, 2004, Medicare will cover FDG PET scans for a differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease.

The following conditions of coverage must be met before performing the PET Scan:

Patient has a recent diagnosis of dementia and documented cognitive decline of at least six 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 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;

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 six months) aided by cognitive scales or

neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT);

The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;

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;

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; and

A brain single photon emission computed tomography (SPECT) or FDGPET 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 one year has passed from the time the first SPECT or FDG-PET scan was performed.)

If the above indications are not met, coverage is allowed only when used in a CMS-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases. Claims for beneficiaries participating in a CMS-approved clinical trial must be submitted with the **QV** modifier.

Limitations:

Medicare will cover one PET scan (G0336) for dementia and neurodegenerative diseases per beneficiary's lifetime.

Noncovered:

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.

Type of Bill Code: Not applicable

Revenue Codes: Not applicable

CPT/HCPCS Codes: The following short descriptors are in accordance with the AMA

copyright agreement. Please refer to the current CPT book for full descriptions.

G0030* PET imaging prev PET single
G0031* PET imaging prev PET multple
G0032* PET follow SPECT 78464 singl
G0033* PET follow SPECT 78464 mult
G0034* PET follow SPECT 76865 singl
G0035* PET follow SPECT 78465 mult
G0036* PET follow cornry angio sing
G0037* PET follow cornry angio mult
G0038* PET follow myocard perf sing
G0039* PET follow myocard perf mult
G0040* PET follow stress echo singl
G0041* PET follow stress echo mult
G0042* PET follow ventriculogm sing
G0043* PET follow ventriculogm mult
G0044* PET following rest ECG singl
G0045* PET following rest ECG mult
G0046* PET follow stress ECG sing
G0047* PET follow stress ECG mult
G0125 Lung image (PET)
G0210 PET img wholebody dxlung ca
G0211 PET img wholebody init lung
G0212 PET img wholebod restag lung
G0213 PET img wholebody dx colore
G0214 PET img wholebod init colore
G0215 PETimg wholebod restag colre
G0216 PET img wholebod dx melanoma
G0217 PET img wholebod init melano
G0218 PET img wholebod restag mela
G0219 *PET img wholbod melano nonco* (NON-COVERED)
G0220 PET img wholebod dx lymphoma
G0221 PET imag wholbod init lympho
G0222 PET imag wholbod resta lymph
G0223 PET imag wholbod reg dx head
G0224 PET imag wholbod reg ini hea
G0225 PET whol restag headneck only
G0226 PET img wholbody dx esophagl
G0227 PET img wholbod ini esophage
G0228 PET img wholbod restg esopha
G0229 PET img metabolic brain pres
G0230 PET myocard viability ring
G0231 PET WhBD colorec; gamma cam
G0232 PET whbd lymphoma; gamma cam

G0233	PET whbd melanoma; gamma cam
G0234	PET WhBD pulm nod; gamma cam
G0252	PET imaging initial dx (NON-COVERED)
G0253	PET Image Brst Detection Recur
G0254	PET Image Brst Eval to Tx
G0296	PET imge Restag Thyroid cancer (10/01/2003)
G0336	PET imaging brain Alzheimer's (09/15/2004)
Q3000**	Rubidium RB-82 (10/01/2003)
Q4078***	Ammonia N-13, per dose(10/01/2003-12/31/2003)
78459	Heart muscle imaging (PET)
A4641*	Diagnostic imaging agent
A9526***	Ammonia N-13, per dose (01/01/2004)

*Use HCPCS A4641 with PET scan codes G0030 through G0047 for the tracer Rubidium 82.

**Only bill HCPCS Q3000 through Outpatient Perspective Payment System (OPPS). Providers billing the Carrier must use HCPCS Code A4641.

***Use HCPCS Q4078 for the N-13 radiopharmaceutical for DOS 10/1/2003-12/31/2003. Effective with DOS 01/01/2004, A9526 is appropriate.

Not Otherwise Classified Codes: Not applicable

ICD-9 Codes that Support Medical Necessity:

G0030-G0047, Q3000, Q4078:

410.10-410.92	Acute MI
411.0-411.89	Other acute & subacute forms of ischemic heart disease
413.0-413.9	Angina pectoris; Angina decubitus
414.00-414.9	Other forms of chronic ischemic heart disease

G0125, G0210, G0211, G0212, G0234:

162.2-162.9	Malignant neoplasm of trachea, bronchus, and lung
518.89	Other pulmonary insufficiency, not elsewhere classified*
793.1	Nonspecific abnormal findings on radiological and other examination of lung field

* Allowed only for the characterization of single pulmonary nodules (SPNs) in accordance with Indications and Limitations II above.

G0213, G0214, G0215, G0231:

153.0-153.9	Malignant neoplasm of colon
154.0-154.1	Malignant neoplasm of rectosigmoid junction & rectum

G0220, G0221, G0222, G0232:

200.00-200.08	Reticulosarcoma

200.10-200.18	Lymphosarcoma
200.20-200.28	Burkitt's tumor or lymphoma
201.00-201.98	Hodgkin's disease
202.00-202.98	Other malignant neoplasms of lymphoid & histiocytic tissue

G0226, G0227, G0228:

150.0-150.9	Malignant neoplasm of esophagus
151.0	Malignant neoplasm of gastroesophageal junction

G0216, G0217, G0218, G0233:

172.0-172.9	Malignant melanoma of skin

G0223, G0224, G0225:

140.0-140.9	Malignant neoplasm of lip
141.0-141.9	Malignant neoplasm of tongue
142.0-142.9	Malignant neoplasm of major salivary glands
143.0-143.9	Malignant neoplasm of gum
144.0-144.9	Malignant neoplasm of floor of mouth
145.0-145.9	Malignant neoplasm of other & unspecified parts of mouth
146.0-146.9	Malignant neoplasm of oropharynx
147.0-147.9	Malignant neoplasm of nasopharynx
148.0-148.9	Malignant neoplasm of hypopharynx
149.0-149.9	Malignant neoplasm of other and ill-defined sites within the lip, oral cavity, and pharynx
160.0-160.9	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
161.0-161.9	Malignant neoplasm of larynx
195.0	Malignant neoplasm of head, face, and neck
196.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck

G0229:

345.01	Generalized nonconvulsive epilepsy w/o mention of intractable epilepsy
345.11	Generalized convulsive epilepsy w/o mention of intractable epilepsy

G0230, 78459:

410.00-410.92	Acute myocardial infarction
411.0-411.89	Other acute and subacute forms of ischemic heart disease
413.0-413.9	Angina pectoris
414.00-414.05	Coronary atherosclerosis
414.10-414.19	Aneurysm of heart

G0253, G0254

174.0-174.9	Malignant neoplasm of female breast

175.0-175.9	Malignant neoplasm of male breast
233.0	Carcinoma in situ, breast

G0296

193	Malignant neoplasm of thyroid gland
237.4	Neoplasm of other and unspecified endocrine gland
V10.87	Personal history of malignant neoplasm of the thyroid gland

G0336 (09/15/2004):

331.0	Alzheimer's disease
331.11	Pick's disease
331.19	Other frontotemporal dementia

Diagnosis that Support Medical Necessity: Not applicable

ICD-9 Codes that DO NOT Support Medical Necessity: Not applicable

Diagnosis Codes that DO NOT Support Medical Necessity: Not applicable

Documentation Requirements:

1. The provider must maintain on file the doctor's referral and documentation that the procedure involved (a) only FDA approved drugs and devices; and (b) did not involve investigational drugs, or procedures using investigational drugs, as determined by the FDA.
2. The ordering physician is responsible for certifying the medical necessity of the study according to the conditions. The physician must have documentation in the beneficiary's medical record to support the referral supplied to the PET scan provider.
3. PET scan facilities must keep patient record information on file for each Medicare patient for whom such a PET scan claim is made.
4. The medical records must include standard information (e.g., age, sex, and height) along with any annotations regarding body size or type that indicate a need for a PET scan to determine the patient's condition.
5. The medical records can be used in any post-payment review and must include the information necessary to substantiate the need for the PET scan.
6. To ensure the medical necessity of an FDG-PET scan for dementia and neurodegenerative diseases, the following documentation is maintained in the beneficiary's medical record

and available upon request:

Date of onset of symptoms;

Diagnosis of clinical syndrome;

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, CT) performed;

Relevant laboratory tests (B12, thyroid hormone); and

Number and name of prescribed medication.

Utilization Guidelines:

Sources of Information and Basis for Decision:

1. CMS Manual System, Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 220.6.
2. Transmittal AB-01-54, CR#1603.
3. Transmittal AB-02-065, CR#2138.
4. Transmittal AB-01-168, CR#1886.
5. Transmittal # 171 and Program Memorandum AB-03-092, CR#2687.
6. CMS Manual System, Pub. 100-04-Medicare Claims Processing, Transmittal 223, CR# 3304, July 2, 2004.
7. CMS Manual System, Pub. 100-04-Medicare Claims Processing, Transmittal 310, CR# 3426; Chapter 13, section 60. October 1, 2004.

Advisory Committee Notes:

The Arkansas consortium combined LCD was presented in August 2001 and accepted.

"This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from all recognized specialties within the state."

Start Date of Comment Period: 07/17/2001

End Date of Comment Period: 09/15/2001

Start Date of Notice Period: 10/31/2003 03/15/2002 11/01/2001

Revision History:

12/03/2004	Policy revised to include restricted coverage for FTD and AD in accordance with CR3426. Sections revised include I&L XIII, CPT/HCPCS (G0336), ICD-9-CM (331.0 and 331.19), and Doc. Req. These changes are effective with DOS 09/15/2004. ICD-9 code 518.89 added to allow for G0125, G0210, G0211, G0212, and G0234 only for SPN in accordance with the guidelines in the I&L section II. This is effective with DOS 12/01/2004.
07/14/2004	Clarified I&L #X. to specify metastasis "of breast cancer" per CR#3304. Revised HCPCS section to delete G0125, G0163, G0164 and G0165 as these were deleted 07/01/2001. Per CR#3304: Added HCPCS code A4641 and A9526; Added end date of 12/31/2003 to Q4078; and Added "*" to G0030-G0047, Q3000, Q4078, and A9526 and clarifying information. Revised Sources to include Pub 100-04, Transmittal 223 and replaced CIM 50-36 with MNCDM Chapter 1, section 220.6. Reformatted to LCD by deleting General Description and moving General Conditions of Coverage and Covered Indications for PET to beginning of the I&L section. Replaced HCFA with CMS. Reworded document to remove passive tense.
07/14/2003	Reformatted "I&L" adding roman numerals to the indications. Updated indications to included added indications of perfusion of the heart using Ammonia N-13 (I&L #1.B.), thyroid cancer ("I&L" #XI), and noncoverage for soft tissue, dementia, and neurogenerative diseases ("I&L"# XII and XIII). Added "Reasons for Denial" #4 as noted above. Revised Sources to include #171 and AB-03-092.
06/16/2003	Added CPT/HCPCS codes G0231-G0234 as per Transmittal AB-01-168 to "CPT/HCPCS" and "ICD-9" sections. These codes were effective with date of service 01/01/2002. Added AB-01-168 to "Sources."
02/13/2003	Added CPT/HCPCS codes: G0253, G0254, 78459, applicable ICD-9-CM list, and descriptive text as required by Transmittal AB-02-065. Effective date of coverage is 10/01/2002.
05/22/2002	Changed the diagnosis codes to 411.89 instead of 411.9 for G0230. (AC-2002-02)

12/11/2001	Added diagnosis codes: 196.0, 160.0-160.9, and 161.0-161.9 to G0223, G0224, and G0225; 151.0 to G0226, G0227, and G0228.