
CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 310

Date: OCTOBER 1, 2004

CHANGE REQUEST 3426

NOTE: This transmittal replaces Transmittal 279, dated August 13, 2004

SUBJECT: Billing Requirements for Positron Emission Tomography (PET) Scans for Dementia and Neurodegenerative Diseases

I. SUMMARY OF CHANGES: This instruction updates Pub. 100-04, chapter 13, section 60, to include billing and claims processing requirements for PET Scans for beneficiaries with either a differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease (AD) OR; its use in a CMS-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: September 15, 2004

IMPLEMENTATION DATE: October 4, 2004

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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:

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	13/Table of Contents
R	13/60.1/Billing Instructions
R	13/60.3/PET Scan Qualifying Conditions and HCPCS Code Chart
N	13/60/60.12/ Coverage for PET Scans for Dementia and Neurodegenerative Diseases

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 310	Date: October 1, 2004	Change Request 3426
-------------	------------------	-----------------------	---------------------

NOTE: This transmittal replaces Transmittal 279, dated August 13, 2004

SUBJECT: PET Scans for Dementia and Neurodegenerative Diseases

I. GENERAL INFORMATION

This instruction updates Pub 100-04, chapter 13, section 60, by providing general Medicare coverage and billing requirements for PET Scans for dementia and neurodegenerative diseases. Refer to Publication 100-03, National Coverage Determinations (NCD) Manual section 220.6, for complete coverage policy.

A. Background: Effective for dates of service on or after September 15, 2004, Medicare will cover 2-deoxy-2- [F-18] fluoro-D-glucose Positron Emission Tomography (FDG-PET) scans for a differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease; OR, its use in a CMS-approved practical neurodegenerative disease clinical trial. Clinical trial results are expected to help in determining if PET scans contribute to the effective diagnosis and management of Medicare beneficiaries with early dementia, or add information that will help manage this disease. Refer to Pub. 100-04, chapter 13, section 60.12 for further claims processing, billing and contractor requirements and Pub 100-03, NCD Manual, section 220.6, for complete coverage policy and clinical trial requirements.

B. Policy: Refer to Publication 100-03, NCD Manual section 220.6, for complete coverage policy. Medicare will cover 1 FDG-PET Scan per beneficiary's lifetime for either the differential diagnosis of FTD and AD under specific requirements; OR, its use in a CMS-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases.

C. Provider Education: A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.

Requirement Number	Requirements	Responsibility (place an "X" in the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3426.6.2	Medicare contractors shall pay hospitals not subject to OPPS, with the exception of Critical Access Hospitals, under current payment methodologies.	X								
3426.6.3	Medicare contractors shall pay on a reasonable cost basis for SNF bill types 22x and 23x.	X								
3426.6.4	All claims submitted for services provided by critical access hospitals are paid on a reasonable cost basis. This payment method applies to bill type 85x.	X								
3426.7	<p>Contractors shall advise providers via a Medlearn Matters article that the following conditions of coverage must be met before performing the PET Scan:</p> <ul style="list-style-type: none"> • Patient has a recent diagnosis of dementia and documented cognitive decline of at least 6 months; • Patient meets diagnostic criteria for both Alzheimer’s disease (AD) and fronto-temporal dementia (FTD) and has been evaluated for specific alternate degenerative diseases or causative factors; and, • The cause of the clinical symptoms remains uncertain. 	X		X						

Requirement Number	Requirements	Responsibility (place an "X" in the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3426.8	<p>Contractors shall establish the medical necessity of an FDG-PET scan for dementia and neurodegenerative diseases by advising providers via the Medlearn Matters article to ensure the following documentation is collected and maintained in the beneficiary's medical record:</p> <ul style="list-style-type: none"> • 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) <p>Number and name of prescribed medications</p>	X		X						
3426.9	<p>Medicare contractors shall instruct providers, via a Medlearn Matters article, to bill PET Scans for neurodegenerative diseases in accordance with the specific coverage guidelines outlined in Pub. 100-03, sec. 220.6</p>	X		X						

Requirement Number	Requirements	Responsibility (place an "X" in the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CFW	
3426.10	In addition to the above requirements, Medicare contractors shall pay for PET scans (G0336) for dates of service beginning September 15, 2004, for patients participating in a practical clinical trial at a CMS-approved facility utilizing a specific protocol to demonstrate the utility of FDG-PET in the diagnosis or treatment of neurodegenerative dementing diseases. Contractors should not expect to receive clinical trial claims until approved facilities have been established and posted on the CMS Web site. Contractors shall monitor the Web site regularly in order to pay claims for services rendered in an approved clinical trial facility.	X		X						
3426.11	Medicare carriers shall instruct physicians via a Medlearn Matters article to bill for a CMS approved neurodegenerative disease practical clinical trial with the QV modifier. The approved facilities for these trials will be listed on the CMS Web site in the future.			X						
3426.12	Fiscal Intermediaries (FIs) shall require the presence of ICD-9 code V70.7 in the second diagnosis code position on Form CMS-1450, or its electronic equivalent, to identify and pay CMS-approved facilities for clinical trials for dates of service on or after September 15, 2004.	X								
3426.12.1	FIs shall manually review claims with ICD-9 code V70.7 in order to check the CMS Web site that identifies the approved clinical trial facilities for this service.	X								

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions
3426.4	Payment pricing information for the new HCPCS code, G0336, shall be listed in the October quarterly update of the MPFSDB.

3426.5&6	Refer to Pub. 100-04, chapter 25, Completing and Processing UB-92 (CMS-1450) Data Set, for billing instructions and mapping of the UB-92 (Form CMS-1450) to the HIPAA X12N 837 institutional 837 transaction.
----------	---

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date*: September 15, 2004</p> <p>Implementation Date: October 4, 2004</p> <p>Pre-Implementation Contact(s): Yvette Cousar (410) 786-2160 (carrier claims processing); Kelly Buchanan (410) 786-66132 (institutional claims processing); Samantha Richardson (410) 786-6940 (coverage policy)</p> <p>Post-Implementation Contact(s): Appropriate regional office</p>	<p>Medicare contractors shall implement these instructions within their current operating budgets.</p>
--	---

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

Medicare Claims Processing Manual

Chapter 13 - Radiology Services and Other Diagnostic Procedures

Table of Contents

(Rev.310, 10-01-04)

60 - Positron Emission Tomography (PET) Scans - General Information

60.1 - Billing Instructions

60.3 - PET Scan Qualifying Conditions and HCPCS Code Chart

60.12 Coverage for PET Scans for Dementia and Neurodegenerative Diseases

60.1 - Billing Instructions

(Rev.310, Issued: 10-01-04, Effective: 09-15-04, Implementation: 10-04-04)

A - Billing and Payment Instructions or Responsibilities for Carriers

Claims for PET scan services must be billed on Form-CMS 1500 or the electronic equivalent with the appropriate HCPCS and diagnosis codes to the local carrier. Effective for claims received on or after July 1, 2001, PET modifiers were discontinued and are no longer a claims processing requirement for PET scan claims. Therefore, July 1, 2001, and after the MSN messages regarding the use of PET modifiers can be discontinued. The type of service (TOS) for the new PET scan procedure codes is TOS 4, Diagnostic Radiology. Payment is based on the Medicare Physician Fee Schedule.

B - Billing and Payment Instructions or Responsibilities for FIs

Claims for PET scan procedures must be billed to the FI on Form CMS-1450 (UB-92) or the electronic equivalent with the appropriate diagnosis and HCPCS "G" codes to indicate the conditions under which a PET scan was done. These codes represent the technical component costs associated with these procedures when furnished to hospital and SNF outpatients. They are paid as follows:

- under OPPS for hospitals subject to OPPS
- under current payment methodologies for hospitals not subject to OPPS
- on a reasonable cost basis for critical access hospitals.
- on a reasonable cost basis for skilled nursing facilities.

Institutional providers bill these codes under Revenue Code 0404 (PET Scan).

C - Frequency

In the absence of national frequency limitations, for all indications covered on and after July 1, 2001, contractors can, if necessary, develop frequency limitations on any or all covered PET scan services.

D - Post-Payment Review for PET Scans

As with any claim, but particularly in view of the limitations on this coverage, Medicare may decide to conduct post-payment reviews to determine that the use of PET scans is consistent with coverage instructions. Pet scanning facilities must keep patient record information on file for each Medicare patient for whom a PET scan claim is made. These medical records can be used in any post-payment reviews and must include the information necessary to substantiate the need for the PET scan. These records must include standard information (e.g., age, sex, and height) along with sufficient patient histories to allow determination that the steps required in the coverage instructions were followed. Such information must include, but is not limited to, the date, place and results of previous diagnostic tests (e.g., cytopathology and surgical pathology reports, CT), as well as the results and reports of the PET scan(s) performed at the center. If available, such records should include the prognosis derived from the PET scan, together with information regarding the physician or institution to which the patient proceeded

following the scan for treatment or evaluation. The ordering physician is responsible for forwarding appropriate clinical data to the PET scan facility.

Effective for claims received on or after July 1, 2001, CMS no longer requires paper documentation to be submitted up front with PET scan claims. *Contractors shall be aware and advise providers of the specific documentation requirements for PET scans for dementia and neurodegenerative diseases. This information is outlined in section 60.12.*

Documentation requirements such as physician referral and medical necessity determination are to be maintained by the provider as part of the beneficiary's medical record. This information must be made available to the carrier or FI upon request of additional documentation to determine appropriate payment of an individual claim.

60.3 - PET Scan Qualifying Conditions and HCPCS Code Chart

(Rev.310, Issued: 10-01-04, Effective: 09-15-04, Implementation: 10-04-04)

Below is a summary of all covered PET Scan conditions, with effective dates.

(NOTE: PET Scanners must be FDA-approved.)

Conditions	Coverage Effective Date	HCPCS Code
*Myocardial perfusion imaging (following previous PET G0030-G0047) single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0030
*Myocardial perfusion imaging (following previous PET G0030-G0047) multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0031
*Myocardial perfusion imaging (following rest SPECT, 78464); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0032
*Myocardial perfusion imaging (following rest SPECT 78464); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0033
*Myocardial perfusion (following stress SPECT 78465); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0034
*Myocardial Perfusion Imaging (following stress SPECT 78465); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0035
*Myocardial Perfusion Imaging (following coronary angiography 93510-93529); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0036
*Myocardial Perfusion Imaging, (following coronary angiography), 93510-93529); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0037
*Myocardial Perfusion Imaging (following stress planar myocardial perfusion, 78460); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0038

Conditions	Coverage Effective Date	HCPCS Code
*Myocardial Perfusion Imaging (following stress planar myocardial perfusion, 78460); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0039
*Myocardial Perfusion Imaging (following stress echocardiogram 93350); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0040
*Myocardial Perfusion Imaging (following stress echocardiogram, 93350); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0041
*Myocardial Perfusion Imaging (following stress nuclear ventriculogram 78481 or 78483); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0042
*Myocardial Perfusion Imaging (following stress nuclear ventriculogram 78481 or 78483); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0043
*Myocardial Perfusion Imaging (following stress ECG, 93000); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0044
*Myocardial perfusion (following stress ECG, 93000), multiple studies; rest or stress (exercise and/or pharmacologic)	3/14/95	G0045
*Myocardial perfusion (following stress ECG, 93015), single study; rest or stress (exercise and/or pharmacologic)	3/14/95	G0046
*Myocardial perfusion (following stress ECG, 93015); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0047

PET imaging regional or whole body; single pulmonary nodule	1/1/98	G0125
---	--------	-------

Conditions	Coverage Effective Date	HCPCS Code
Lung cancer, non-small cell (PET imaging whole body) Diagnosis, Initial Staging, Restaging	7/1/01	G0210 G0211 G0212
Colorectal cancer (PET imaging whole body) Diagnosis, Initial Staging, Restaging	7/1/01	G0213 G0214 G0215
Melanoma (PET imaging whole body) Diagnosis, Initial Staging, Restaging	7/1/01	G0216 G0217 G0218
Melanoma for non-covered indications	7/1/01	G0219
Lymphoma (PET imaging whole body) Diagnosis, Initial Staging, Restaging	7/1/01	G0220 G0221 G0222
Head and neck cancer; excluding thyroid and CNS cancers (PET imaging whole body or regional) Diagnosis, Initial Staging, Restaging	7/1/01	G0223 G0224 G0225
Esophageal cancer (PET imaging whole body) Diagnosis, Initial Staging, Restaging	7/1/01	G0226 G0227 G0228
Metabolic brain imaging for pre-surgical evaluation of refractory seizures	7/1/01	G0229

Metabolic assessment for myocardial viability following inconclusive SPECT study	7/1/01	G0230
Recurrence of colorectal or colorectal metastatic cancer (PET whole body, gamma cameras only)	1/1/02	G0231

Conditions	Coverage Effective Date	HCPCS Code
Staging and characterization of lymphoma (PET whole body, gamma cameras only)	1/1/02	G0232
Recurrence of melanoma or melanoma metastatic cancer (PET whole body, gamma cameras only)	1/1/02	G0233
Regional or whole body, for solitary pulmonary nodule following CT, or for initial staging of non-small cell lung cancer (gamma cameras only)	1/1/02	G0234
Non-Covered Service Initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes), not covered (full- and partial-ring PET scanners only)	10/1/02	G0252
Breast cancer, staging/restaging of local regional recurrence or distant metastases, i.e., staging/restaging after or prior to course of treatment (full- and partial-ring PET scanners only)	10/1/02	G0253
Breast cancer, evaluation of responses to treatment, performed during course of treatment (full- and partial-ring PET scanners only)	10/1/02	G0254
Myocardial imaging, positron emission tomography (PET), metabolic evaluation)	10/1/02	78459
Restaging or previously treated thyroid cancer of follicular cell origin following negative I-131 whole body scan (full- and partial-ring PET scanner only)	10/1/03	G0296
Tracer Rubidium**82 (Supply of Radiopharmaceutical Diagnostic Imaging Agent)	10/1/03	Q3000

(This is only billed through Outpatient Perspective Payment System, OPSS.) (Carriers must use HCPCS Code A4641).		
Supply of Radiopharmaceutical Diagnostic Imaging Agent, Ammonia N-13	01/1/04	A9526

Conditions	Coverage Effective Date	HCPCS Code
<i>PET imaging, brain imaging for the differential diagnosis of Alzheimer's disease with aberrant features vs. fronto-temporal dementia</i>	<i>09/15/04</i>	<i>G0336</i>

***NOTE:** Carriers must report A4641 for the tracer Rubidium 82 when used with PET scan codes G0030 through G0047.

****NOTE:** Not FDG PET

*****NOTE:** For dates of service October 1, 2003, through December 31, 2003, use temporary code Q4078 for billing this radiopharmaceutical.

60.12 Coverage for PET Scans for Dementia and Neurodegenerative Diseases

(Rev.310, Issued: 10-01-04, Effective: 09-15-04, Implementation: 10-04-04)

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 OR; its use in a CMS-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases. Refer to Pub. 100-03 (National Coverage Determinations (NCD) Manual), section 220.6, for complete coverage conditions and clinical trial requirements.

A. Carrier and FI Billing Requirements for Pet Scan Claims for FDG-PET for the Differential Diagnosis of Fronto-temporal Dementia and Alzheimer's Disease:

- HCPCS Code for PET Scans for Dementia and Neurodegenerative Diseases

-- G0336: PET imaging, brain imaging for the differential diagnosis of Alzheimer's disease with aberrant features vs. fronto-temporal dementia

Short Descriptor: PET imaging brain Alzheimer's

Type of Service: 4 (Used by Carriers)

G0336 is paid under the Medicare physician fee schedule; it is a carrier-priced service.

- Frequency for G0336

Medicare will cover one PET scan (G0336) for dementia and neurodegenerative diseases per beneficiary's lifetime. The common working file will edit the frequency. The following Remittance Advice (RA) will apply: N117: "This service is paid only once in a patient's lifetime." Contractors shall also use an appropriate Medical Summary Notice such as 20.12: "This service was denied because Medicare only covers this service once in a lifetime."

- Provider Documentation Required with the PET Scan Claim (G0336)

Medicare contractors shall inform providers to ensure the conditions mentioned in the NCD Manual, section 220.6, have been met. The information must also be maintained in the beneficiary's 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, probably, 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 medications.*

B. Carrier and FI Billing Requirements for FDG-PET Scans Claims for CMS-approved Neurodegenerative Disease Practical Clinical Trials

- Carriers and FIs

Contractors should not receive claims for this service until the clinical trial centers have been identified. Once these centers are identified, CMS will list the centers on the CMS Web site.

- Carriers Only

*Carriers shall pay claims PET Scan G0336 for beneficiaries participating in a CMS-approved clinical trial submitted with the **QV**modifier. Refer to Pub. 100-03, NCD Manual, section 220.6, for complete policy and clinical trial requirements.*

- FIs Only

In order to pay claims for PET scans on behalf of beneficiaries participating in a CMS-approved clinical trial, FIs require providers to submit claims with ICD-9 code V70.7 in the second diagnosis position on the Form CMS-1450 (UB-92), or the electronic equivalent, with the appropriate principal diagnosis code and HCPCS code G0336. Refer to Publication 100-03, NCD Manual, section 220.6, for complete coverage policy and clinical trial requirements.