

CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 956

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: MAY 19, 2006

Change Request 5124

SUBJECT: Payment for Positron Emission Tomography Scans in CMS-Approved Clinical Trials and Coverage With Evidence Development - Use of QR and QV Modifiers

I. SUMMARY OF CHANGES: Effective for services performed on or after January 28, 2005, carrier claims, other than inpatient, for PET scans for neurodegenerative diseases submitted in conjunction with a Centers for Medicare & Medicaid Services (CMS)-approved clinical trial (see Pub. 100-03, National Coverage Determinations (NCD) Manual, section 220.6.13), will require the appropriate CPT code and the QR modifier, which replaces the QV modifier previously indicated in Transmittal 527, dated April 15, 2005. Also for services on or after January 28, 2005, PET scan claims for all cancer indications previously specified in the NCD Manual, Pub. 100-03, sections 220.6.2-220.6.7, 220.6.10-220.6.12, and 220.6.14 (lung, esophageal, colorectal, lymphoma, melanoma, head & neck, breast, thyroid, soft tissue sarcoma, brain, cervical, ovarian, pancreatic, small cell lung, and testicular), as well as PET scans for all other cancer indications not previously specified at section 220.6.15, will be covered in conjunction with a CMS-approved clinical trial. These other than inpatient carrier claims must also be submitted using the QR modifier. Claims submitted to FIs shall contain the appropriate principal diagnosis code, the appropriate CPT code, and V70.7 diagnosis code. Section 60.12, has been revised, and section 60.15 has been added with this new information for PET scans performed in conjunction with a CMS-approved clinical trial.

NEW/REVISED MATERIAL

EFFECTIVE DATE: January 28, 2005

IMPLEMENTATION DATE: June 19, 2006

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:

R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	13/Table of Contents
R	13/60.12/Coverage for PET Scans for Dementia and Neurodegenerative Diseases
N	13/60.15/Billing Requirements for CMS-Approved Clinical Trial Claims for PET Scans for Neurodegenerative Diseases, Previously Specified Cancer Indications, and 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 2006 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 956	Date: May 19, 2006	Change Request 5124
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SUBJECT: Payment for Positron Emission Tomography Scans in CMS-Approved Clinical Trials and Coverage With Evidence Development - Use of QR and QV Modifiers

I. GENERAL INFORMATION

A. Background: PET – Generally:

Positron emission tomography (PET) is a noninvasive imaging procedure that assesses perfusion and the level of metabolic activity in various organ systems of the human body. A positron camera (tomograph) is used to produce cross-sectional tomographic images which are obtained by detecting radioactivity from a radioactive tracer substance (radionuclide), 2-[F-18] Fluoro-D-Glucose (FDG). Refer to Pub.100-03, National Coverage Determinations (NCD) Manual, section 220.6, for coverage instructions that indicate conditions under which a PET scan is performed.

For a broad range of cancers listed as “coverage with evidence development” in Pub. 100-03, section 220.6, effective for services performed on or after January 28, 2005, FDG PET scans are reasonable and necessary only when the provider is participating in, and patients are enrolled in, one of the following types of prospective clinical studies:

- A clinical trial of FDG PET that meets the requirements of Food and Drug Administration 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.

PET – Alzheimer’s Disease and Dementia:

Effective for services performed on or after September 15, 2004, Medicare covers a Centers for Medicare & Medicaid Services (CMS)-approved clinical trial focused on the utility of FDG PET in the diagnosis or treatment of dementia and neurodegenerative diseases, Pub. 100-03, section 220.6.13.

Prior Medicare claims processing instructions (Transmittal 527, section 60.12) to carriers indicated **QV** as the correct modifier for beneficiaries participating in a CMS-approved clinical trial for FDG PET scans for dementia and neurodegenerative diseases. This instruction revises TR 527 by requiring the appropriate CPT code and the use of the **QR** modifier (Item or service provided in a Medicare-specified study) for these services in place of **QV** on carrier claims. Transmittal 527 did not identify a claims modifier for FDG PET for a broad range of cancer indications listed as “coverage with evidence development.” The **QR** modifier should now be used for all “coverage with evidence development” claims.

B. Policy: This CR provides revised billing and claims processing information for PET scans performed in conjunction with a CMS-approved clinical trial for neurodegenerative diseases, lung cancer, esophageal cancer, colorectal cancer, lymphoma, melanoma, head & neck cancers, breast cancer, thyroid cancer, soft tissue sarcoma, brain cancer, cervical cancer, ovarian cancer, pancreatic cancer, small cell lung cancer, testicular cancer, and all other cancers not previously specified. (See Pub 100-03, sections 220.6.2-220.6.7, 220.6.10-220.6.15). Effective for services performed on and after January 28, 2005, for the above PET indications, a **QR** modifier shall be used, along with the appropriate CPT code, to identify an item/service provided in a Medicare-specified study on all carrier claims. The **QR** modifier was created for use on Part B claims (and other outpatient claims) to identify items/services that are covered when provided in a Medicare-specified study as defined in the Healthcare Common Procedure Coding System. The **QV** modifier shall no longer be used when a beneficiary undergoes an FDG PET scan in a facility participating in a Medicare-approved study specified by the above-referenced NCDs.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
5124.1	Effective for PET scan claims for dates of service on or after January 28, 2005, contractors shall accept claims with the appropriate CPT code and the QR modifier for neurodegenerative diseases (Pub. 100-03, section 220.6.13), for cancer indications previously specified (lung, esophageal, colorectal, lymphoma, melanoma, head & neck, breast, thyroid, soft tissue sarcoma, brain, cervical, ovarian, pancreatic, small cell lung, and testicular at Pub. 100-03, sections 220.6.2-220.6.7 & 220.6.10-220.6.12 & 220.6.14) and for cancer indications not previously specified (Pub. 100-03, section 220.6.15) when these services are performed in conjunction with a CMS-approved clinical trial.	X		X						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		
5124.2	Effective for PET scan claims for dates of service on or after January 28, 2005, FIs shall instruct providers to continue reporting diagnosis code V70.7 and the appropriate principal diagnosis and CPT codes for PET scan claims for neurodegenerative diseases as well as for cancer indications referred to in 5124.1 above when these services are performed in conjunction with a CMS-approved clinical trial.	X							
5124.3	Contractors shall note that effective for services performed on or after January 28, 2005, the QV modifier is no longer applicable for PET scan claims for neurodegenerative diseases and cancer indications referred to in 5124.1 above when performed in conjunction with a CMS-approved clinical trial.			X					
5124.4	Contractors shall note that PET scan claims for other cancers identified in 5124.1 above at Pub. 100-03, section 220.6.15, remain non-covered unless these claims are for services performed in conjunction with a CMS-approved clinical trial.	X		X					
5124.5	Effective for PET scan claims with dates of service on or after January 28, 2005, until implementation of this CR, contractors need not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.	X		X					

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		

						F I S S	M C S	V M S	C W F	
5124.6	<p>A provider education article related to this instruction will be available at www.cms.hhs.gov/MLNMattersArticles shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>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 shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic.</p> <p>Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.</p>	X		X						

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: NA

X-Ref Requirement #	Instructions

B. Design Considerations: NA

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

V. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date*: January 28, 2005</p> <p>Implementation Date: June 19, 2006</p> <p>Pre-Implementation Contact(s): Coverage: Stuart Caplan, stuart.caplan@cms.hhs.gov, 410-786-8564, Susan Harrison, susan.harrison@cms.hhs.gov, 410-786- 1806, Carrier: Yvette Cousar, yvette.cousar@cms.hhs.gov, 410-786-2160, FI: Bill Ruiz, william.ruizcolon@cms.hhs.gov, 410-786- 9283</p> <p>Post-Implementation Contact(s): Regional office</p>	<p>No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.</p>
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***Unless otherwise specified, the effective date is the date of service.**

60.12 - Coverage for PET Scans for Dementia and Neurodegenerative Diseases

(Rev. 956, Issued: 05-19-06; Effective: 01-28-06; Implementation: 06-19-06)

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, NCD Manual, section [220.6.13](#), for complete coverage conditions and clinical trial requirements and section 60.15 of this manual for claims processing information.

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:

- CPT Code for PET Scans for Dementia and Neurodegenerative Diseases

Contractors shall advise providers to use the appropriate CPT code from section 60.3.1 for dementia and neurodegenerative diseases for services performed on or after January 28, 2005.

- Diagnosis Codes for PET Scans for Dementia and Neurodegenerative Diseases

The contractor shall ensure one of the following appropriate diagnosis codes is present on claims for PET Scans for AD:

- 290.0, 290.10 - 290.13, 290.20 - 290, 21, 290.3, 331.0, 331.11, 331.19, 331.2, 331.9, 780.93

Medicare contractors shall use an appropriate Medicare Summary Notice (MSN) message such as 16.48, "Medicare does not pay for this item or service for this condition" to deny claims when submitted with an appropriate CPT code from section 60.3.1 and with a diagnosis code other than the range of codes listed above. Also, contractors shall use an appropriate Remittance Advice (RA) such as 11, "The diagnosis is inconsistent with the procedure."

Medicare contractors shall instruct providers to issue an Advanced Beneficiary Notice to beneficiaries advising them of potential financial liability prior to delivering the service if one of the appropriate diagnosis codes will not be present on the claim.

- Provider Documentation Required with the PET Scan Claim

Medicare contractors shall inform providers to ensure the conditions mentioned in the NCD Manual, section [220.6.13](#), 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.

60.15 - Billing Requirements for CMS-approved Clinical Trial Claims for PET Scans for Neurodegenerative Diseases, Previously Specified Cancer Indications, and All Other Cancer Indications Not Previously Specified

(Rev. 956, Issued: 05-19-06; Effective: 01-28-06; Implementation: 06-19-06)

- Carrier and FI

Effective for services on or after January 28, 2005, contractors shall accept and pay for claims for PET scans for lung cancer, esophageal cancer, colorectal cancer, lymphoma, melanoma, head & neck cancer, breast cancer, thyroid cancer, soft tissue sarcoma, brain cancer, cervical cancer, ovarian cancer, pancreatic cancer, small cell lung cancer, and testicular cancer, as well as for neurodegenerative diseases and all other cancer indications not previously mentioned in this chapter, if these scans were performed as part of a CMS-approved clinical trial. (See Pub. 100-03, sections 220.6.2-220.6.7 and 220.6.10-220.6.15.)

Contractors shall also be aware that PET scans for all cancers not previously specified at Pub. 100-03, section 220.6.15, remain nationally non-covered unless performed in conjunction with a CMS-approved clinical trial.

- Carriers Only

*Carriers shall pay claims for PET scans for beneficiaries participating in a CMS-approved clinical trial submitted with an appropriate CPT code from 60.3.1 and the **QR** (Item or Service Provided in a Medicare Specified Study) modifier.*

- 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 CMS-1450 (UB-92), or the electronic equivalent, with the appropriate principal diagnosis code and an appropriate CPT code from section 60.3.1. Effective for PET scan claims for dates of service on or after January 28, 2005, FIs shall accept claims with the **QR** modifier on other than inpatient claims.*