CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1866	Date: December 4, 2009
	Change Request 6753

SUBJECT: Positron Emission Tomography (PET) (FDG) for Cervical Cancer

I. SUMMARY OF CHANGES: Effective for claims with dates of service on and after November 13, 2009, CMS will end the coverage with evidence development requirements for FDG PET for cervical cancer and will cover only one FDG PET for cervical cancer for staging in beneficiaries with biopsy-proven tumors when the treating physician determines that the study is needed to determine the location and/or extent of the tumor for specific therapeutic purposes related to initial treatment strategy as outlined in Pub. 100-03, NCD Manual, section 220.6.17.

NEW / REVISED MATERIAL
EFFECTIVE DATE: NOVEMBER 10, 2009
IMPLEMENTATION DATE: JANUARY 4, 2010

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	13/Table of Contents
R	13/60/60.13/Billing Requirements for PET Scans for Specific indications of Cervical Cancer Performed on or After January 28, 2005
R	13/60/60.15/Billing Requirements for CMS - Approved Clinical Trials and Coverage With Evidence Development Claims for PET Scans for Neurodegenerative Diseases, Previously Specified Cancer Indications, and All Other Cancer Indications Not Previously Specified
R	13/60/60.16/Billing and Coverage Changes for PET Scans Effective for Services on and After April 3, 2009
N	13/60/60.17/Billing and Coverage for PET Scans for Cervical Cancer Effective for Services on or After November 13, 2009

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

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

Attachment – Business Requirements

Pub. 100-04	Transmittal: 1866	Date: December 4, 2009	Change Request: 6753

SUBJECT: Positron Emission Tomography (PET) (FDG) for Cervical Cancer

EFFECTIVE DATE: NOVEMBER 10, 2009
IMPLEMENTATION DATE: JANUARY 4, 2010

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) generated a request to reconsider section 220.6 of the National Coverage Determinations (NCD) Manual to end the prospective data collection requirements (coverage with evidence development (CED)) for F-18 flouro-D-glucose (FDG) PET imaging for the initial anti-tumor treatment strategy for cervical cancer under certain circumstances. In the context of this document, the term FDG PET includes FDG PET/CT. CMS is revising Pub.100-03, NCD Manual, section 220.6, and Pub. 100-04, Claims Processing Manual, chapter 13, section 60, to reflect this change. See Pub. 100-03, NCD Manual, section 220.6.17 for specific coverage language, and Pub. 100-04 chapter 13, sections 60.13 and 60.15-60.17.

The CMS previously reviewed scientific literature and established coverage for FDG PET for cervical cancer indications. A summary of past oncologic FDG PET cervical cancer indications is in the following table:

Effective Date	Clinical Condition/Indication	Coverage
January 28, 2005	Brain, cervical, ovarian, pancreatic, small cell lung and testicular cancers	Coverage with evidence development (CED) for all FDG PET indications except limited cervical staging conditions
January 28, 2005	All other cancers and indications not previously specified	Coverage with evidence development
April 3, 2009	Solid Tumors and Myeloma	Coverage for most uses related to initial management, coverage with evidence development for most uses related to subsequent management. Non-coverage for uses related to initial management of prostate cancer.

B. Policy: Effective for claims with dates of service on and after November 10, 2009, CMS will end the CED requirements and will cover only one (1) FDG PET for cervical cancer under the following circumstances:

For staging in beneficiaries who have biopsy proven cervical cancer when the beneficiary's treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to initial treatment strategy:

- To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or
- To determine the optimal anatomic location for an invasive procedure; or
- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

NOTE: Exception: CMS continues to non-cover FDG PET for initial diagnosis of cervical cancer related to initial treatment strategy.

NOTE: The -QO modifier is no longer necessary on claims meeting the above criteria.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6753.1	Effective for claims with dates of service on or after November 10, 2009, contractors shall accept FDG PET oncologic claims billed to inform initial treatment strategy for staging in beneficiaries who have biopsy-proven cervical cancer when the beneficiary's treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor as specified in Pub. 100-03, section 220.6.17.	X		X	X						
6753.1.1	Effective for claims with dates of service on or after November 10, 2009, contractors shall return as unprocessable/return to provider claims for FDG PET for cervical cancer for initial treatment strategy billed without: • PET or PET/CT CPT code (78608, 78811, 78812, 78813, 78814, 78815, OR 78816), AND • -PI modifier, AND • ICD-9 cervical cancer diagnosis code. Use the following messages: Wrong/Lack of modifier: Claim Adjustment Reason Code (CARC) 4 – The procedure code is inconsistent with the modifier used or a required modifier is missing. Remittance Advice Remark Code (RARC) MA130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Submit a new claim with the complete/correct information. RARC M16 - Alert: See our Web site, mailings, or bulletins for more details concerning this policy/procedure/decision.	X		X	X						
6753.2	For FDG PET oncologic cervical cancer claims for initial treatment strategy for dates of service	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	November 10, 2009, through January 3, 2010, contractors shall not search their files. However, contractors shall adjust claims brought to their attention.										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6753.3	A provider education article related to this instruction will be available at http://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. 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 one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. 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.	X		X	X						

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Stuart Caplan, coverage, 410-786-8564, stuart.caplan@cms.hhs.gov, Pat Brocato-Simons, coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov, Yvette Cousar, practitioner claims processing, 410-786-2160, yvette.cousar@cms.hhs.gov, Bill Ruiz, institutional claims processing, 410-786-9283, William.ruiz@cms.hhs.gov, Antoinette Johnson, institutional claims processing, 410-786-9326, Antoinette.johnson@cms.hhs.gov.

Post-Implementation Contact(s): ROs

VI. FUNDING

A. For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. *For Medicare Administrative Contractors (MACs)*:
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Claims Processing Manual
Chapter 13 - Radiology Services and Other Diagnostic Procedures

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Table of Contents
(Rev. 1866, 12-04-09)

60.13 - Billing Requirements for PET Scans for Specific Indications of Cervical Cancer for Services Performed on or After January 28, 2005

(Rev. 1866; Issued: 12-04-09; Effective Date: 11-10-09; Implementation Date: 01-04-10)

Contractors shall accept claims for these services with the appropriate CPT code listed in section 60.3.1. Refer to Pub. 100-03, section *220.6.17,* for complete coverage guidelines for this new PET oncology *indication. The implementation* date for these CPT codes will be April 18, 2005. *Also see section 60.17, of this chapter for further claims processing instructions for cervical cancer indications.*

60.15 - Billing Requirements for CMS - Approved Clinical Trials and Coverage With Evidence Development Claims for PET Scans for Neurodegenerative Diseases, Previously Specified Cancer Indications, and All Other Cancer Indications Not Previously Specified

(Rev. 1866; Issued: 12-04-09; Effective Date: 11-10-09; Implementation Date: 01-04-10)

- **Carriers and FIs**

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, 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, NCD Manual, sections *220.6.13 and 220.6.17*.)

Contractors shall also be aware that PET scans for all cancers not previously specified at Pub. 100-03, NCD Manual, section *220.6.17*, 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 section 60.3.1, of this chapter 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-04), 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.

NOTE: Effective for services on or after January 1, 2008, -Q0 (investigational clinical service provided in a clinical research study that is in an approved clinical research study) replaces the -QR modifier.

60.16 - Billing and Coverage Changes for PET Scans Effective for Services on or After April *3,* 2009

(Rev. 1866; Issued: 12-04-09; Effective Date: 11-10-09; Implementation Date: 01-04-10)

A. Summary of Changes

Effective for services on or after April 3, 2009, Medicare will **not cover** the use of FDG PET imaging to determine **initial treatment strategy** in patients with adenocarcinoma of the prostate.

Medicare will also not cover FDG PET imaging for **subsequent treatment strategy** for tumor types other than breast, cervical, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, myeloma, non-small cell lung, *and* ovarian, unless the FDG PET is provided under the coverage with evidence development (CED) paradigm (billed with modifier -Q0, see section 60.15 of this chapter).

Last, Medicare will cover FDG PET imaging **for initial treatment strategy** for myeloma.

For further information regarding the changes in coverage, refer to Pub.100-03, NCD Manual, section 220.6.17.

B. New Modifiers for PET Scans

Effective for claims with dates of service on or after April 3, 2009, the following modifiers have been created for use to inform for **the initial treatment strategy** of biopsy-proven or strongly suspected tumors or **subsequent treatment strategy** of cancerous tumors:

PI -Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing.

Short descriptor: PET tumor init tx strat

PS - Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the subsequent treatment strategy of cancerous tumors when the beneficiary's treatment physician determines that the PET study is needed to inform subsequent anti-tumor strategy.

Short descriptor: PS - PET tumor subsq tx strategy

C. Billing Changes for A/B MACs, FIs and Carriers

Effective for claims with dates of service on or after April 3, 2009, contractors shall accept FDG PET claims billed to inform **initial treatment strategy** with the following CPT codes **AND** modifier –PI: 78608, 78811, 78812, 78813, 78814, 78815, 78816.

Effective for claims with dates of service on or after April 3, 2009, contractors shall accept FDG PET claims with modifier –PS for the **subsequent treatment strategy** for solid tumors using a CPT code above **AND** an ICD-9 cancer diagnosis code.

Contractors shall also accept FDG PET claims billed to **inform initial treatment strategy or subsequent treatment strategy** when performed under CED with one of the PET or PET/CT CPT codes above **AND** modifier -PI **OR** modifier -PS **AND** an ICD-9 cancer diagnosis code **AND** modifier *-Q0* (Investigational clinical service provided in a clinical research study that is in an approved clinical research study).

NOTE: For institutional claims continue to use diagnosis code V70.7 and condition code 30 on the claim.

D. Medicare Summary Notices, Remittance Advice Remark Codes, and Claim Adjustment Reason Codes

Effective for dates of service on or after April 3, 2009, contractors shall **return as unprocessable/return to provider** claims that do not include the -PI modifier with one of the PET/PET/CT CPT codes listed in subsection C. above when billing for **the initial treatment strategy** for solid tumors in accordance with Pub.100-03, NCD Manual, section 220.6.17.

In addition, contractors shall **return as unprocessable/return to provider** claims that do not include the -PS modifier with one of the CPT codes listed in subsection C. above when billing for the **subsequent treatment strategy** for solid tumors in accordance with Pub.100-03, NCD Manual, section 220.6.17.

The following messages apply:

-Claim Adjustment Reason Code 4 – the procedure code is inconsistent with the modifier used or a required modifier is missing.

-Remittance Advice Remark Code MA-130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Submit a new claim with the complete/correct information.

-Remittance Advice Remark Code M16 - Alert: See our Web site, mailings, or bulletins for more details concerning this policy/procedure/decision.

Also, effective for claims with dates of service on or after April 3, 2009, contractors shall **return as unprocessable/return to provider** FDG PET claims billed to **inform initial treatment strategy or subsequent treatment strategy** when performed under CED without one of the

PET/PET/CT CPT codes listed in subsection C. above **AND** modifier –PI **OR** modifier –PS **AND** an ICD-9 cancer diagnosis code **AND** modifier –Q0.

The following messages apply to **return as unprocessable** claims:

-Claim Adjustment Reason Code 4 – the procedure code is inconsistent with the modifier used or a required modifier is missing.

-Remittance Advice Remark Code MA-130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Submit a new claim with the complete/correct information.

-Remittance Advice Remark Code M16 - Alert: See our Web site, mailings, or bulletins for more details concerning this policy/procedure/decision.

Effective April 3, 2009, contractors shall **deny** claims with ICD-9 diagnosis code 185 for FDG PET imaging for the **initial treatment strategy** of patients with adenocarcinoma of the prostate.

Contractors shall also **deny** claims for FDG PET imaging for **subsequent treatment strategy** for tumor types other than breast, cervical, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, myeloma, non-small cell lung, *and* ovarian, unless the FDG PET is provided under CED (submitted with the -Q0 modifier) and use the following messages:

-Medicare Summary Notice 15.4 - Medicare does not support the need for this service or item

-Claim Adjustment Reason Code 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer.

- Contractors shall use Group Code CO (Contractual Obligation)

If an ABN is provided with a GA modifier indicating there is a signed ABN on file, contractors shall use Group Code PR (Patient Responsibility) and the liability falls to the beneficiary.

If an ABN is provided with a GZ modifier indicating no ABN was provided, contractors shall use Group Code CO (Contractual Obligation) and the liability falls to the provider.

60.17 - Billing and Coverage Changes for PET Scans for Cervical Cancer Effective for Services on or After November 10, 2009

(Rev. 1866; Issued: 12-04-09; Effective Date: 11-10-09; Implementation Date: 01-04-10)

A. Billing Changes for A/B MACs, FIs, and Carriers

Effective for claims with dates of service on or after November 10, 2009, contractors shall accept FDG PET oncologic claims billed to inform initial treatment strategy; specifically for

staging in beneficiaries who have biopsy-proven cervical cancer when the beneficiary's treating physician determines the FDG PET study is needed to determine the location and/or extent of the tumor as specified in Pub 100-03, section 220.6.17.

EXCEPTION: *CMS continues to non-cover FDG PET for initial diagnosis of cervical cancer related to initial treatment strategy.*

NOTE: *Effective for claims with dates of service on and after November 10, 2009, the –Q0 modifier is no longer necessary for FDG PET for cervical cancer.*

B. Medicare Summary Notices, Remittance Advice Remark Codes, and Claim Adjustment Reason Codes

Additionally, contractors shall return as unprocessable /return to provider for FDG PET for cervical cancer for initial treatment strategy billed without the following: one of the PET/PET/CT CPT codes listed in 60.16 C above ***AND*** *modifier –PI* ***AND*** *an ICD-9 cervical cancer diagnosis code.*

Use the following messages:

- *Claim Adjustment Reason Code 4 – the procedure code is inconsistent with the modifier used or a required modifier is missing.*

- *Remittance Advice Remark Code MA-130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Submit a new claim with the complete/correct information.*

- *Remittance Advice Remark Code M16 - Alert: See our Web site, mailings, or bulletins for more details concerning this policy/procedure/decision.*