CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 109	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. This revision is an NCD. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i)

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=DELETE

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
R	1/220.6.17/Positron Emission Tomography (PET) (FDG) for Oncologic Conditions (Various Effective Dates)

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. 100-03	Transmittal: 109	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 Pub. 100-03, NCD Manual, section 220.6, 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. The 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, and Pub. 100-04, sections 60.13 and 60.15-60.17.	X		X	X						

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	
6753.2	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	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	
	provider community in billing and administering the Medicare program correctly.										

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 National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1)

Coverage Determinations

Table of Contents

(Rev. 109, 12-04-09)

220.6.17 - Positron Emission Tomography *(PET)* (FDG) for Oncologic Conditions - *(Various Effective Dates)*

220.6.17 - Positron Emission Tomography *(PET)* (FDG) for Oncologic Conditions - *(Various Effective Dates)*

(Rev. 109; Issued: 12-04-09; Effective Date: 11-10-09; Implementation Date: 01-04-10)

General

The Centers for Medicare and Medicaid Services (CMS) was asked to reconsider section 220.6, of the National Coverage Determinations (NCD) Manual, to end the prospective data collection requirements across all oncologic indications of FDG PET except for monitoring response to treatment. Section 220.6 of the NCD Manual, establishes the requirement for prospective data collection for FDG PET used in the diagnosis, staging, restaging, and monitoring response to treatment for brain, cervical, ovarian, pancreatic, small cell lung and testicular cancers, as well as for cancer indications not previously specified in section 220.6 in its entirety.

The CMS received public input indicating that the current coverage framework, which required cancer-by-cancer consideration of diagnosis, staging, restaging, and monitoring response to treatment should be replaced by a more omnibus consideration. Thus, CMS broadened the scope of this review through an announcement on the Web site and solicited additional public comment on the use of FDG PET imaging for solid tumors so that it could transparently consider this possibility.

1. Framework

Effective for claims with dates of service on and after April 3, 2009, CMS is adopting a coverage framework that replaces the four-part diagnosis, staging, restaging and monitoring response to treatment categories with a two-part framework that differentiates FDG PET imaging used to inform the initial antitumor treatment strategy from other uses related to guiding subsequent antitumor treatment strategies after the completion of initial treatment. CMS is making this change for all NCDs that address coverage of FDG PET for the specific oncologic conditions addressed in this decision.

2. Initial Anti-tumor Treatment Strategy

Effective for claims with dates of service on and after April 3, 2009, CMS has determined that the evidence is adequate to determine that the results of FDG PET imaging are useful in determining the appropriate initial treatment strategy for beneficiaries with suspected solid tumors and myeloma and improve health outcomes and thus are reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act).

Therefore, CMS will cover only one FDG PET study for beneficiaries who have solid tumors that are biopsy proven or strongly suspected based on other diagnostic testing 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 the 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.

As exceptions to the *April 3, 2009,* initial treatment strategy section above:

a. The CMS has reviewed evidence on the use of FDG PET imaging to determine initial anti-tumor treatment in patients with adenocarcinoma of the prostate. CMS has determined that the available evidence does not demonstrate that FDG PET imaging improves physician decision making in the determination of initial anti-tumor treatment strategy in Medicare beneficiaries who have adenocarcinoma of the prostate, does not improve health outcomes and is thus not reasonable and necessary under §1862(a)(1)(A) of the Act. Therefore, FDG PET is nationally non-covered for this indication of this tumor type.

b. The CMS received no new evidence demonstrating a change was warranted with respect to the use of FDG PET imaging to determine initial anti-tumor treatment in breast cancer; thus CMS is not making any change to the current coverage policy for FDG PET in breast cancer. CMS is continuing to cover FDG PET imaging for the initial treatment strategy for male and female breast cancer only when used in staging distant metastasis. FDG PET imaging for diagnosis and initial staging of axillary nodes will remain non-covered.

c. The CMS received no new evidence demonstrating a change was warranted with respect to use of FDG PET imaging of regional lymph nodes in melanoma; thus CMS is not changing the current NCD for FDG PET in melanoma. CMS will continue non-coverage of FDG PET for the evaluation of regional lymph nodes in melanoma. Other uses to determine initial treatment strategy remain covered.

d. The CMS received no new evidence demonstrating a change was warranted with respect to use of FDG PET imaging in the initial treatment strategy for cervical cancer. CMS is continuing to cover FDG PET imaging as an adjunct test for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers following conventional imaging that is negative for extra-pelvic metastasis. All other uses of FDG PET for the initial treatment strategy for beneficiaries diagnosed with cervical cancer will continue to only be covered as research under §1862(a)(1)(E) of the Act through Coverage with Evidence Development (CED). Therefore, CMS will cover one initial FDG PET study for newly diagnosed cervical cancer when not used as an adjunct test for the detection of pre-treatment metastases following conventional imaging that is negative for extra-pelvic metastasis only when the beneficiary's treating physician determines that the FDG PET study is needed to inform the initial anti-tumor treatment strategy and the beneficiary is enrolled in, and the FDG PET provider is participating in, the *specific* type of prospective clinical study *outlined under subsequent treatment strategy below.*

e. Effective November 10, 2009, as a result of a reconsideration request, CMS ended the prospective data collection requirements, or coverage with evidence development, for the use of FDG PET imaging in the initial staging of cervical cancer related to initial treatment strategy.

CMS is continuing to cover FDG PET imaging as an adjunct test for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers following conventional imaging that is negative for extra-pelvic metastasis.

Therefore, CMS will cover one initial FDG PET study 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 the tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.*

Additionally, effective November 10, 2009, following a reconsideration request, CMS determines that there is no credible evidence that the results of FDG PET imaging are useful to make the initial diagnoses of cervical cancer, does not improve health outcomes, and is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Therefore, CMS will non-cover FDG PET imaging for initial diagnosis of cervical cancer related to initial treatment strategy.

3. Subsequent Anti-tumor Treatment Strategy

As part of its April 3, 2009, NCD, the CMS reviewed evidence on the use of FDG PET in the subsequent treatment strategy for patients with tumor types other than *those seven indications currently covered without exception (*breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, and non-small cell lung).

As a result, CMS determined that the available evidence is adequate to determine that FDG PET imaging also improves physician decision making in the determination of subsequent treatment strategy in Medicare beneficiaries who have ovarian cancer, cervical cancer, and myeloma, improves health outcomes, and is thus reasonable and necessary under §1862(a)(1)(A) of the Act.

Therefore, effective for claims with dates of service on and after April 3, 2009, for tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, *ovarian, cervical, and myeloma,* CMS has determined that the available evidence is not adequate to determine that FDG PET imaging improves physician decision making in the determination of subsequent anti-tumor treatment strategy or improves health outcomes in Medicare beneficiaries and thus is not reasonable and necessary under §1862(a)(1)(A) of the Act.

However, CMS has determined that the available evidence is sufficient to determine that FDG PET imaging for subsequent anti-tumor treatment strategy for *all other tumor types other than the 10 indications noted above* may be covered as research under §1862(a)(1)(E) of the Act

through CED. Therefore, CMS will cover a subsequent FDG PET study for *all other tumor types other than the 10 indications noted above,* when the beneficiary's treating physician determines that the FDG PET study is needed to inform the subsequent anti-tumor treatment strategy and the beneficiary is enrolled in, and the FDG PET provider is participating in, the following type of prospective clinical study:

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 FDG 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.

The clinical studies for which CMS will provide coverage must answer one or more of the following three questions:

Prospectively, in Medicare beneficiaries whose treating physician determines that the FDG PET study is needed to inform the subsequent anti-tumor treatment strategy, does the addition of FDG PET imaging lead to:

- A change in the likelihood of appropriate referrals for palliative care;
- Improved quality of life; or,
- Improved survival?

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.

b. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

c. The research study does not unjustifiably duplicate existing studies.

d. The research study design is appropriate to answer the research question being asked in the study.

e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46.

If a study is regulated by the Food and Drug Administration (FDA), it also must be in compliance with 21 CFR Parts 50 and 56.

g. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.

h. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.

i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options.

j. The clinical research study is registered on the www.ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject.

k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.

l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

4. Synopsis of New Framework

Effective for claims with dates of service on and after April 3, 2009, the CMS transitioned the prior framework—diagnosis, staging, restaging, and monitoring response to treatment—into the

initial treatment strategy and subsequent treatment strategy framework. *The chart below summarizes FDG PET coverage as of November 10, 2009:*

FDG PET Coverage for Solid Tumors and Myeloma

Tumor Type	**Initial Treatment Strategy** (formerly "diagnosis" & "staging")	**Subsequent Treatment Strategy** (formerly "restaging" & "monitoring response to treatment")
Colorectal	Cover	Cover
Esophagus	Cover	Cover
Head & Neck (not Thyroid, CNS)	Cover	Cover
Lymphoma	Cover	Cover
Non-Small Cell Lung	Cover	Cover
Ovary	Cover	Cover
Brain	Cover	CED
Cervix	*Cover w/exception**	Cover
Small Cell Lung	Cover	CED
Soft Tissue Sarcoma	Cover	CED
Pancreas	Cover	CED
Testes	Cover	CED
Breast (female and male)	*Cover w/exception**	Cover
Melanoma	*Cover w/exception**	Cover
Prostate	Non-Cover	CED
Thyroid	Cover	*Cover w/exception or CED**
All Other Solid Tumors	Cover	CED
Myeloma	Cover	Cover
All other cancers not listed	CED	CED

**Cervix: Non-covered for the initial diagnosis of cervical cancer related to initial treatment strategy. All other indications for initial treatment strategy are covered.*

*Breast: Non-covered for initial diagnosis and/or staging of axillary lymph nodes. Covered for initial staging of metastatic disease. *All other indications for initial treatment strategy are covered.*

*Melanoma: Non-covered for initial staging of regional lymph nodes. All other *indications* for initial treatment strategy are covered.

*Thyroid: Covered for subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and have a negative I-131 whole body scan. All other *indications* for subsequent treatment strategy are CED.

(This NCD last reviewed November 2009.)