CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 168	**Date: May 28, 2014**
	Change Request 8739

Transmittal 166, dated April 18, 2014, is being rescinded and replaced by Transmittal 168, dated May 28, 2014 to make a technical correction to delete information in the Pub. 100-03 NCD manual that should not have been included. All other information remains the same.

SUBJECT: Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors (This CR rescinds and fully replaces CR8468/TR2873 dated February 6, 2014)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is effective for claims with dates of service on and after June 11, 2013, CMS shall cover three FDG PET scans when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for the same cancer diagnosis. Coverage of any additional FDG PET scans (that is, beyond three) used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for the same diagnosis will be determined by the local Medicare Administrative Contractors.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, 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) of the Social Security Act.)

EFFECTIVE DATE: June 11, 2013
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 19, 2014 - MAC Non-Shared System Edits; July 7, 2014 - CWF development/testing, FISS requirement development; October 6, 2014 - CWF, FISS, MCS Shared System Edits

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	220/6.17/Positron Emission Tomography (FDG PET) for Oncologic Conditions

III. FUNDING:
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 obliged 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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 168	Date: May 28, 2014	Change Request: 8739

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I. GENERAL INFORMATION

A. Background: The Centers for Medicare & 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 in the context of this document. The term FDG PET includes PET/computed tomography (CT) and PET/magnetic resonance (MRI).

The CMS is revising Pub. 100-03, NCD Manual, section 220.6, to reflect that CMS has ended the coverage with evidence development (CED) requirement for 18 fluorodeoxyglucose positron emission tomography (FDG PET) and PET/CT and PET/MRI for all oncologic indications contained in Section 220.6.17 of the NCD Manual. This removes the current requirement for prospective data collection by the National Oncologic PET Registry (NOPR) for oncologic indications for FDG (HCPCS A9552) only.

B. Policy: Effective for claims with dates of service on and after June 11, 2013, CMS shall cover three FDG PET scans when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for the same cancer diagnosis. Coverage of any additional FDG PET scans (that is, beyond three (3)) used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for the same diagnosis will be determined by the local Medicare Administrative Contractors.

Refer to CR6632, Transmittal (TR)1833 issued on October 16, 2009, and CR7148, TR124 issued September 24, 2010, for previous information on this coverage.

NOTE: For clarification purposes, as an example, each, different, cancer dx is allowed 1 initial treatment strategy (-PI modifier) FDG PET Scan and 3 subsequent treatment strategy (-PS modifier) FDG PET Scans without the -KX modifier. The 4th FDG PET Scan and beyond for subsequent treatment strategy for the same cancer dx will always require the -KX modifier. If a different cancer dx is reported, whether reported with a -PI modifier or a -PS modifier, that cancer dx will begin a new count for subsequent treatment strategy for that beneficiary.

NOTE: A beneficiary's file may or may not contain a claim for initial treatment strategy with a -PI modifer. The existence or non-existence of an initial treatment strategy claim has no bearing on the frequency count of the subsequent treatment strategy (-PS) claims.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8739 - 03.1	Effective for claims with dates of service on or after June 11, 2013, contractors shall continue to accept and pay for FDG PET oncologic claims billed to inform initial treatment strategy (-PI modifier) or subsequent treatment strategy (-PS modifier) for suspected or biopsy proven solid tumors, as specified in Pub. 100-03 NCD Manual, section 220.6.17. Please see companion Pub 100-04 for specific business requirements and claims processing instructions.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8739 - 03.2	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 sites 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 the contractor's 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			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): William Ruiz, 410-786-9283 or william.ruiz@cms.hhs.gov (Institutional Claims Processing) , Pat Brocato-SImons, 410-786-0261 or patricia.brocatosimons@cms.hhs.gov (Coverage Policy) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage Policy) , Stuart Caplan, 410-786-8564 or stuart.caplan@cms.hhs.gov (Coverage Policy) , Yvette Cousar, 410-786-2160 or yvette.cousar@cms.hhs.gov (Practitioner Claims Processing) , Chanelle Jones, 410-786-9668 or chanelle.jones@cms.hhs.gov (Practitioner Claims Processing)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

220.6.17 - Positron Emission Tomography (FDG PET) for Oncologic Conditions

(Effective June 11, 2013)

***(Rev. 168, Issued: 05-28-14, Effective: 06-11-13, Implementation: 05-19-14-* MAC Non-Shared System Edits; July 7, 2014 - CWF development/testing, FISS requirement development; October 6, 2014 - CWF, FISS, MCS Shared System Edits)**

A. General

FDG (2-[F18] fluoro-2-deoxy-D-glucose) Positron Emission Tomography (PET) is a minimally-invasive diagnostic imaging procedure used to evaluate glucose metabolism in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. FDG is an injected radionuclide (or radiopharmaceutical) that emits sub-atomic particles, known as positrons, as it decays. FDG PET uses a positron camera (tomograph) to measure the decay of FDG. The rate of FDG decay provides biochemical information on glucose metabolism in the tissue being studied. As malignancies can cause abnormalities of metabolism and blood flow, FDG PET evaluation may indicate the probable presence or absence of a malignancy based upon observed differences in biologic activity compared to adjacent tissues.

The Centers for Medicare and Medicaid Services (CMS) was asked by the National Oncologic PET Registry (NOPR) to reconsider section 220.6 of the National Coverage Determinations (NCD) Manual to end the prospective data collection requirements under Coverage with Evidence Development (CED) across all oncologic indications of FDG PET imaging. The CMS received public input indicating that the current coverage framework of prospective data collection under CED be ended for all oncologic uses of FDG PET imaging.

1. Framework

Effective for claims with dates of service on and after *June 11, 2013,* CMS is adopting a coverage framework that *ends the prospective data collection requirements by NOPR under CED for all oncologic uses of FDG PET imaging.* CMS is making this change for all NCDs that address coverage of FDG PET for oncologic uses addressed in this decision. This decision does not change coverage *for any use of PET imaging using radiopharmaceuticals NaF-18 (fluorine-18 labeled sodium fluoride), ammonia N-13, or rubidium-82 (Rb-82).*

2. Initial Anti-*T*umor Treatment Strategy

CMS continues to believe that the evidence is adequate to determine that the results of FDG PET imaging are useful in determining the appropriate initial anti-tumor treatment strategy for beneficiaries with suspected *cancer* and improve health outcomes and thus are reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act).

Therefore, CMS *continues* to nationally cover one FDG PET study for beneficiaries who have *cancers* 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 *anti-tumor* 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.

See the table at the end of this section for a synopsis of all nationally covered and non-covered oncologic uses of FDG PET imaging.

B.1. Initial Anti-Tumor Treatment Strategy Nationally Covered Indications

a. CMS continues to nationally cover FDG PET imaging for the initial anti-tumor treatment strategy for male and female breast cancer only when used in staging distant metastasis.

b. CMS continues to nationally cover FDG PET to determine initial anti-tumor treatment strategy for melanoma other than for the evaluation of regional lymph nodes.

c. *CMS continues to nationally cover FDG PET imaging for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers.*

d. C.1 Initial Anti-Tumor Treatment Strategy Nationally Non-Covered Indications

a. CMS continues to nationally non-cover initial anti-tumor treatment strategy in Medicare beneficiaries who have adenocarcinoma of the prostate.

b. *CMS continues to nationally non-cover FDG PET imaging for diagnosis of breast cancer and initial staging of axillary nodes.*

c. CMS continues to nationally non-cover FDG PET imaging for initial anti-tumor treatment strategy for the evaluation of regional lymph nodes in melanoma.

d. CMS continues to nationally non-cover FDG PET imaging for the diagnosis of cervical cancer related to initial anti-tumor treatment strategy.

3. Subsequent Anti-*T*umor Treatment Strategy

B.2. Subsequent Anti-Tumor Treatment Strategy Nationally Covered Indications

Three FDG PET scans are nationally covered when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy. Coverage of more than three FDG PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy shall be determined by the local Medicare Administrative Contractors.

4. Synopsis of Coverage of FDG PET for Oncologic Conditions

Effective for claims with dates of service on and after *June 11, 2013, the* chart below summarizes national FDG PET coverage *for oncologic conditions:*

FDG PET for *Cancers* Tumor Type	**Initial Treatment Strategy** (formerly "diagnosis" & "staging"	**Subsequent Treatment Strategy** (formerly "restaging" & "monitoring response to treatment"
Colorectal	Cover	Cover
Esophagus	Cover	Cover
Head and Neck (not thyroid, CNS)	Cover	Cover
Lymphoma	Cover	Cover
Non-small cell lung	Cover	Cover
Ovary	Cover	Cover
Brain	Cover	Cover
Cervix	Cover with exceptions *	Cover

Small cell lung	Cover	*Cover*
Soft tissue sarcoma	Cover	*Cover*
Pancreas	Cover	*Cover*
Testes	Cover	*Cover*
Prostate	**Non-cover**	*Cover*
Thyroid	Cover	*Cover*
Breast (male and female)	Cover with exceptions *	Cover
Melanoma	Cover with exceptions *	Cover
All other solid tumors	Cover	*Cover*
Myeloma	Cover	Cover
All other cancers not listed	*Cover*	*Cover*

*Cervix: Nationally non-covered for the initial diagnosis of cervical cancer related to initial *anti-tumor* treatment strategy. All other indications for initial *anti-tumor* treatment strategy for cervical cancer are nationally covered.

*Breast: Nationally non-covered for initial diagnosis and/or staging of axillary lymph nodes. Nationally covered for initial staging of metastatic disease. All other indications for initial *anti-tumor* treatment strategy for breast cancer are nationally covered.

*Melanoma: Nationally non-covered for initial staging of regional lymph nodes. All other indications for initial *anti-tumor* treatment strategy for melanoma are nationally covered.

D. Other

N/A