

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 108	Date: October 16, 2009
	Change Request 6632

This change request rescinds and replaces Transmittal 106, dated September 18, 2009. The effective date has been changed to April 3, 2009 and the implementation date has been changed to October 30, 2009. Business Requirements (BR) 6632.6.1 and 6632.6.2 have been revised to clarify that they are subsets of BR 6632.6 and are specific to CED. All other information remains the same.

SUBJECT: FDG PET for Solid Tumors and Myeloma

I. SUMMARY OF CHANGES: 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 all oncologic conditions. This is a national coverage determination (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) of the Social Security Act.)

NEW / REVISED MATERIAL

EFFECTIVE DATE: APRIL 3, 2009

IMPLEMENTATION DATE: October 30, 2009

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	1/Table of Contents
R	1/220.6/Positron Emission Tomography (PET) Scans
R	1/220.6.1/PET for Perfusion of the Heart (Various Effective Dates Below)
D	1/220.6.2/ FDG PET for Lung Cancer
D	1/220.6.3/ FDG PET for Esophageal Cancer
D	1/220.6.4/FDG PET for Colorectal Cancer

D	1/220.6.5/ FDG PET for Lymphoma
D	1/220.6.6/ FDG PET for Melanoma
D	1/220.6.7/ FDG PET for Head and Neck Cancers
R	1/220.6.9/FDG PET for Refractory Seizures (Effective July 1, 2001)
D	1/220.6.10/ FDG PET for Breast Cancer (Effective October 1, 2002)
D	1/220.6.11/ FDG PET for Thyroid Cancer (Various Effective Dates Below)
D	1/220.6.12/ FDG PET for Soft Tissue Sarcoma (Various Effective Dates Below)
R	1/220.6.13/ FDG PET for Dementia and Neurodegenerative Diseases (Effective September 15, 2004)
D	1/220.6.14/FDG PET for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers (Effective January 28, 2005)
D	1/220.6.15/FDG PET for All Other Cancer Indications Not Previously Specified (Effective January 28, 2005)
N	1/220.6.17/Positron Emission Tomography (FDG) for Oncologic Conditions

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: 108	Date: October 16, 2009	Change Request: 6632
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This change request rescinds and replaces Transmittal 106, dated September 18, 2009. The effective date has been changed to April 3, 2009 and the implementation date has been changed to October 30, 2009. Business Requirements (BR) 6632.6.1 and 6632.6.2 have been revised to clarify that they are subsets of BR 6632.6 and are specific to CED. All other information remains the same.

SUBJECT: FDG PET for Solid Tumors and Myeloma

Effective Date: April 3, 2009

Implementation Date: October 30, 2009

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 F-18 flouro-D-glucose (FDG) PET except for monitoring response to treatment. 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, to reflect a new framework for most solid tumor oncologic indications and for myeloma. The following 11 sections of the NCD Manual are deleted: 220.6.2 (FDG PET for Lung Cancer); 220.6.3 (FDG PET for Esophageal Cancer); 220.6.4 (FDG PET for Colorectal Cancer); 220.6.5 (FDG PET for Lymphoma); 220.6.6 (FDG PET for Melanoma); 220.6.7 (FDG PET for Head and Neck Cancers Non-CNS/Thyroid); 220.6.10 (FDG PET for Breast Cancer); 220.6.11 (FDG PET for Thyroid Cancer); 220.6.12 (FDG PET for Soft Tissue Sarcoma); 220.6.14 (FDG PET for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung And Testicular Cancers), and 220.6.15 (FDG PET for All Other Cancer Indications) and replaced with section 220.6.17, Positron Emission Tomography (FDG) for Oncologic Conditions. See Pub. 100-03, NCD Manual, section 220.6.17, for specific coverage language.

B. Policy:

1. Framework

The CMS is adopting a coverage framework that replaces the 4-part diagnosis, staging, restaging, and monitoring response to treatment categories with a 2-part framework that differentiates FDG PET imaging used to inform the initial treatment strategy from other uses related to guiding subsequent treatment strategies after the completion of initial treatment. CMS is making this change for all NCDs that address coverage of FDG PET for oncologic conditions as noted below, inclusive of those indications that are coverable under CMS' coverage with evidence development (CED) paradigm.

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** or CED	Cover*
Small Cell Lung	Cover*	CED
Soft Tissue Sarcoma	Cover*	CED
Pancreas	Cover*	CED
Testes	Cover*	CED
Breast (female and male)	Cover**	Cover
Melanoma	Cover**	Cover
Prostate	Non-Cover*	CED
Thyroid	Cover	Cover** or CED
All Other Solid Tumors	Cover*	CED
Myeloma	Cover*	Cover*
All other cancers not listed herein	CED*	CED*

*Coverage Change

**Coverage w/Exceptions

2. Initial Treatment Strategy

The CMS will cover 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.

New Coverage for Initial Treatment Strategy

Myeloma: CMS will nationally cover the use of FDG PET imaging to determine initial treatment strategy in patients with myeloma.

Prostate: CMS will nationally non-cover the use of FDG PET imaging to determine initial treatment strategy in patients with adenocarcinoma of the prostate.

All other cancers not listed herein: CMS will nationally cover the use of FDG PET imaging to determine initial treatment strategy in patients with all other cancers not listed herein provided under CED.

3. Subsequent Treatment Strategy

The CMS will non-cover FDG PET imaging for subsequent anti-tumor treatment strategy for tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, and thyroid, unless the FDG PET is provided under CED.

New Coverage for Subsequent Treatment Strategy

Ovarian: CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with ovarian cancer.

Cervical: CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with cervical cancer.

Myeloma: CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with myeloma.

All other cancers not listed herein: CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with all other cancers not listed herein provided under CED.

New Modifiers for PET

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 treating physician determines that the PET study is needed to inform subsequent anti-tumor strategy. Short descriptor: PET tumor subseq tx strategy

NOTE: The two new FDG PET oncologic modifiers –PI and –PS were included in the July quarterly update of the IOCE, with an effective date of April 1, 2009. Upon implementation of this CR, all FDG PET oncologic-related claims for dates of service on or after April 3, 2009, MUST include one of these two new modifiers in order for the claim to be processed correctly.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers			
						F I S S	M C S	V M S	C W F	
6632.1	Effective for claims with dates of service on or after April 3, 2009, contractors shall accept and pay for FDG PET oncologic claims as specified in section Pub. 100-03, NCD Manual, section 220.6.17, to inform initial treatment strategy or subsequent treatment strategy for suspected or biopsy proven solid tumors. Also, see companion manual, Pub. 100-04, Claims Processing Manual, chapter 13, section 60, along with the Business Requirements for detailed information.	X		X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B M A C	D M A C	F I	C A R R I E R	R H I	Shared-System Maintainers			
		F I S S	M C S	V M S	C W F					
	NOTE: FDG PET also applies to FDG PET/CT.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B M A C	D M A C	F I	C A R R I E R	R H I	Shared-System Maintainers			
		F I S S	M C S	V M S	C W F					
6632.2	<p>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.</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	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:

V. CONTACTS

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Post-Implementation Contact(s): Appropriate RO or A/B MAC project officer

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

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(Rev. 108, 10-16-09)

- 220.6 – Positron Emission Tomography (PET) Scans *(Effective April 3, 2009)*
- 220.6.1 – PET for Perfusion of the Heart *(Various Effective Dates)*

220.6 - Positron Emission Tomography (PET) Scans *(Effective April 3, 2009)*

(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

Positron Emission Tomography (PET) *is a minimally invasive* diagnostic imaging procedure *used to evaluate metabolism in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. A radiopharmaceutical is injected into the patient that gives off sub-atomic particles, known as positrons, as it decays. PET uses a positron camera (tomograph) to measure the decay of the radiopharmaceutical. The rate of decay provides biochemical information on the metabolism of the tissue being studied.*

(This NCD last reviewed March 2009.)

220.6.1 - PET for Perfusion of the Heart *(Various Effective Dates)*

(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

1. Rubidium 82 (Effective March 14, 1995)

Effective for services performed on or after March 14, 1995, PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Rubidium 82 (Rb 82) are covered, provided the requirements below are met:

- The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or
- The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)
- For any PET scan for which Medicare payment is claimed for dates of services prior to July 1, 2001, the claimant must submit additional specified information on the claim form (including proper codes and/or modifiers), to indicate the results of the PET scan. The claimant must also include information on whether the PET scan was performed after an inconclusive non-invasive cardiac test. The information submitted with respect to the previous noninvasive cardiac test must specify the type of test performed prior to the PET scan and whether it was inconclusive or unsatisfactory. These explanations are in the form of special G codes used for billing PET scans using Rb 82. Beginning July 1, 2001, claims should be submitted with the appropriate codes.

2. Ammonia N-13 (Effective October 1, 2003)

Effective for services performed on or after October 1, 2003, PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical ammonia N-13 are covered, provided the requirements below are met:

- The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a SPECT; or
- The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)

(This NCD last reviewed *March 2005*.)

220.6.2 - FDG PET for Lung Cancer (Replaced with Section 220.6.17)
(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.3 - FDG PET for Esophageal Cancer (Replaced with Section 220.6.17)
(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.4 - FDG PET for Colorectal Cancer (Replaced with Section 220.6.17)
(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.5 - FDG PET for Lymphoma (Replaced with Section 220.6.17)
(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.6 - FDG PET for Melanoma (Replaced with Section 220.6.17)
(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.7 - FDG PET for Head and Neck Cancers (Replaced with Section 220.6.17)

(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.9 - FDG PET for Refractory Seizures (Effective July 1, 2001)

(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

Beginning July 1, 2001, Medicare covers FDG PET for pre-surgical evaluation for the purpose of localization of a focus of refractory seizure activity.

Limitations: Covered only for pre-surgical evaluation.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

(This NCD last reviewed June 2001.)

220.6.10 – FDG PET for Breast Cancer (Effective October 1, 2002)

(Replaced with Section 220.6.17)

(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.11 – FDG PET for Thyroid Cancer (Various Effective Dates Below) *(Replaced with Section 220.6.17)*

(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.12 – FDG PET for Soft Tissue Sarcoma (Various Effective Dates Below) *(Replaced with Section 220.6.17)*

(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.13 - FDG PET for Dementia and Neurodegenerative Diseases (Effective September 15, 2004)

(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

A. General

Medicare covers *FDG PET* scans for either the differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease (AD) under specific requirements; OR, its use in a Centers for Medicare & Medicaid Services (CMS)-approved practical clinical trial focused on the utility of *FDG PET* in the diagnosis or treatment of dementing neurodegenerative diseases. Specific requirements for each indication are clarified below:

B. Nationally Covered Indications

1. FDG PET Requirements for Coverage in the Differential Diagnosis of AD and FTD

An *FDG PET* scan is considered reasonable and necessary in patients with a recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD. These patients have been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remains uncertain.

The following additional conditions must be met before an *FDG PET* scan will be covered:

- a. The patient's onset, clinical presentation, or course of cognitive impairment is such that FTD is suspected as an alternative neurodegenerative cause of the cognitive decline. Specifically, symptoms such as social disinhibition, awkwardness, difficulties with language, or loss of executive function are more prominent early in the course of FTD than the memory loss typical of AD;
- b. The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology (AAN)) encompassing a medical history from the patient and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination (including formal documentation of cognitive decline occurring over at least 6 months) aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT);
- c. The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;
- d. The evaluation of the patient did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information available through *FDG PET* is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment;
- e. The *FDG PET* scan is performed in a facility that has all the accreditation necessary to operate nuclear medicine equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry, with experience interpreting such scans in the presence of dementia;
- f. A brain single photon emission computed tomography (SPECT) or *FDG PET* scan has not been obtained for the same indication. (The indication can be considered to be different in patients who exhibit important changes in scope or severity of cognitive decline, and meet all other qualifying criteria listed above and below (including the judgment that the likely diagnosis remains uncertain). The results of a prior SPECT or

FDG PET scan must have been inconclusive or, in the case of SPECT, difficult to interpret due to immature or inadequate technology. In these instances, an *FDG PET* scan may be covered after 1 year has passed from the time the first SPECT or *FDG PET* scan was performed.)

g. The referring and billing provider(s) have documented the appropriate evaluation of the Medicare beneficiary. Providers should establish the medical necessity of an *FDG PET* scan by ensuring that the following information has been collected and is maintained in the beneficiary medical record:

- Date of onset of symptoms;
- Diagnosis of clinical syndrome (normal aging; mild cognitive impairment (*MCI*); mild, moderate or severe dementia);
- 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 or CT) performed;
- Relevant laboratory tests (B12, thyroid hormone); and,
- Number and name of prescribed medications.

The billing provider must furnish a copy of the *FDG PET* scan result for use by CMS and its contractors upon request. These verification requirements are consistent with federal requirements set forth in 42 Code of Federal Regulations section 410.32 generally for diagnostic x-ray tests, diagnostic laboratory tests, and other tests. In summary, section 410.32 requires the billing physician and the referring physician to maintain information in the medical record of each patient to demonstrate medical necessity [410.32(d) (2)] and submit the information demonstrating medical necessity to CMS and/or its agents upon request [410.32(d)(3)(I)] (OMB number 0938-0685).

2. *FDG PET* Requirements for Coverage in the Context of a CMS-approved Practical Clinical Trial Utilizing a Specific Protocol to Demonstrate the Utility of *FDG PET* in the Diagnosis, and Treatment of Neurodegenerative Dementing Diseases

An *FDG PET* scan is considered reasonable and necessary in patients with *MCI* or early dementia (in clinical circumstances other than those specified in subparagraph 1) only in the context of an approved clinical trial that contains patient safeguards and protections to ensure proper administration, use and evaluation of the *FDG PET* scan.

The clinical trial must compare patients who do and do not receive an *FDG PET* scan and have as its goal to monitor, evaluate, and improve clinical outcomes. In addition, it must meet the following basic criteria:

- a. Written protocol on file;
- b. Institutional Review Board review and approval;

- c. Scientific review and approval by two or more qualified individuals who are not part of the research team; and,
- d. Certification that investigators have not been disqualified.

C. Nationally Non-Covered Indications

All other uses of *FDG PET* for patients with a presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., possible or probable AD, clinically typical FTD, dementia of Lewy bodies, or Creutzfeld-Jacob disease) for which CMS has not specifically indicated coverage continue to be non-covered.

D. Other

Not applicable.

(This NCD last reviewed September 2004.)

220.6.14 – FDG PET for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers (Effective January 28, 2005)

(Replaced with Section 220.6.17)

(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.15 – FDG PET for All Other Cancer Indications Not Previously Specified (Effective January 28, 2005)

(Replaced with Section 220.6.17)

(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.17 - Positron Emission Tomography (FDG) for Oncologic Conditions

(Rev. 108; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

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

The 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

The 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 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) as outlined immediately below and in section 3.

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 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 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 with newly diagnosed cervical cancer who have not been found following conventional imaging to be negative for extra-pelvic metastases and whose treating physician determines that the FDG PET study is needed to inform the initial 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 standards of scientific integrity and relevance to the Medicare population as described in section 3, items a through m, below.

3. Subsequent Anti-tumor Treatment Strategy

The CMS reviewed evidence on the use of FDG PET in the subsequent treatment strategy for patients with tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, and thyroid.

For tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, and thyroid, 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 tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, and thyroid 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 tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, and thyroid 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.

As exceptions to the subsequent treatment strategy section above:

a. The CMS has reviewed evidence on the use of FDG PET imaging to determine subsequent treatment strategy in patients with ovarian cancer. CMS has determined that the available evidence is adequate to determine that FDG PET imaging improves physician decision making in the determination of subsequent treatment strategy in Medicare beneficiaries who have ovarian cancer, improves health outcomes, and is thus reasonable and necessary under §1862(a)(1)(A) of the Act. Therefore, CMS has determined that FDG PET imaging is nationally covered for this indication for this tumor type.

b. The CMS has reviewed evidence on the use of FDG PET imaging to determine subsequent treatment strategy in patients with cervical cancer. CMS has determined that the available evidence is adequate to determine that FDG PET imaging improves physician decision making in the determination of subsequent treatment strategy in Medicare beneficiaries who have cervical cancer, improves health outcomes, and is thus

reasonable and necessary under §1862(a)(1)(A) of the Act. Therefore, CMS has determined that FDG PET imaging is nationally covered for this indication for this tumor type.

4. Myeloma

The CMS reviewed evidence on the use of FDG PET in the initial and subsequent treatment strategy for myeloma. CMS has determined that the available evidence is sufficient to determine that FDG PET imaging improves physician decision making for these uses in Medicare beneficiaries who have myeloma, improves health outcomes, and is thus reasonable and necessary under §1862(a)(1)(A) of the Act. Therefore, CMS has determined that FDG PET imaging is nationally covered for this indication for this tumor type.

5. Further Exceptions

The CMS specifically requested public comments with respect to treatment strategy of nine cancers that were covered in prior NCDs under 1862(a)(1)(A). For the nine tumor types listed below, CMS will continue to cover FDG PET for those specific indications currently covered under §1862(a)(1)(A) of the Act. CMS has not received public input suggesting coverage for these uses should be restricted. These include specific indications pertinent to:

- *Breast*
- *Cervix*
- *Colorectal*
- *Esophagus*
- *Head and Neck (non-CNS/thyroid)*
- *Lymphoma*
- *Melanoma*
- *Non-small cell lung*
- *Thyroid*

The CMS has transitioned the prior framework—diagnosis, staging, restaging, and monitoring response to treatment—into the initial treatment strategy and subsequent treatment strategy framework while maintaining current coverage.

The chart below summarizes section 220.6.1:

<i>Tumor Type</i>	<i>Initial Treatment Strategy *</i>	<i>Subsequent Treatment Strategy **</i>
<i>Colorectal</i>	<i>Cover</i>	<i>Cover</i>
<i>Esophagus</i>	<i>Cover</i>	<i>Cover</i>
<i>Head & Neck (not thyroid or CNS)</i>	<i>Cover</i>	<i>Cover</i>
<i>Lymphoma</i>	<i>Cover</i>	<i>Cover</i>

<i>Non-small cell lung</i>	<i>Cover</i>	<i>Cover</i>
<i>Ovary</i>	<i>Cover</i>	<i>Cover</i>
<i>Brain</i>	<i>Cover</i>	<i>CED</i>
<i>Cervix</i>	<i>1 or CED</i>	<i>Cover</i>
<i>Small cell lung</i>	<i>Cover</i>	<i>CED</i>
<i>Soft Tissue Sarcoma</i>	<i>Cover</i>	<i>CED</i>
<i>Pancreas</i>	<i>Cover</i>	<i>CED</i>
<i>Testes</i>	<i>Cover</i>	<i>CED</i>
<i>Breast (female and male)</i>	<i>2</i>	<i>Cover</i>
<i>Melanoma</i>	<i>3</i>	<i>Cover</i>
<i>Prostate</i>	<i>N/C</i>	<i>CED</i>
<i>Thyroid</i>	<i>Cover</i>	<i>4 or CED</i>
<i>All other solid tumors</i>	<i>Cover</i>	<i>CED</i>
<i>Myeloma</i>	<i>Cover</i>	<i>Cover</i>
<i>All other cancers not listed herein</i>	<i>CED</i>	<i>CED</i>

* Formerly “diagnosis” and “staging”

** Formerly “restaging” and “monitoring response to treatment”

N/C = noncover

(1) *Cervix: Covered for the detection of pre-treatment metastases (i.e., staging) in newly diagnosed cervical cancer subsequent to conventional imaging that is negative for extra-pelvic metastasis. All other uses are CED.*

(2) *Breast: Non-covered for initial diagnosis and/or staging of axillary lymph nodes. Covered for initial staging of metastatic disease.*

(3) *Melanoma: Non-covered for initial staging of regional lymph nodes. All other uses for initial staging are covered.*

(4) *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 uses for subsequent treatment strategy are CED.*

(This NCD last reviewed April 2009.)