

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 156</b>	<b>Date: August 2, 2013</b>
	<b>Change Request 8381</b>

**SUBJECT: Positron Emission Tomography**

**I. SUMMARY OF CHANGES:** Effective for dates of service on or after March 7, 2013, local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals for their Food and Drug Administration (FDA) approved labeled indications for oncologic imaging.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, 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: March 7, 2013**

**IMPLEMENTATION DATE: September 3, 2013**

*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.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	1/220.6/Positron Emission Tomography (PET) Scans

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

**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**

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

# Attachment - Business Requirements

<b>Pub. 100-03</b>	<b>Transmittal: 156</b>	<b>Date: August 2, 2013</b>	<b>Change Request: 8381</b>
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**SUBJECT: Positron Emission Tomography**

**EFFECTIVE DATE: March 7, 2013**

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## I. GENERAL INFORMATION

**A. Background:** On July 11, 2012, the Centers for Medicare & Medicaid Services (CMS) opened a reconsideration of Pub.100-03, the National Coverage Determinations (NCD) Manual, section 220.6, to review coverage of positron emission tomography (PET).

PET is a minimally-invasive diagnostic imaging procedure used to evaluate normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders.

Section 220.6 of the NCD currently identifies FDG (2-deoxy-2-[F-18] fluoro-D-Glucose (fluorodeoxyglucose)), NaF-18 (fluorine-18 labeled sodium fluoride), ammonia N-13, and rubidium-82 (Rb-82) as the only nationally covered radiopharmaceuticals (also known as radioisotopes or tracers) for certain defined uses in PET. All remaining uses of PET are nationally noncovered. CMS reconsidered Section 220.6 of the NCD manual regarding these remaining noncovered uses of PET.

**B. Policy:** Effective for dates of service on or after March 7, 2013, CMS has determined that, unless there is a specific NCD to the contrary, local Medicare Administrative Contractors (MACs) may determine coverage (or noncoverage) within their respective jurisdictions for PET using new, proprietary radiopharmaceuticals for their FDA-approved labeled indications *for oncologic imaging only*. This includes those radiopharmaceuticals that may be approved by FDA in the future.

This decision does not change coverage for any uses of PET using radiopharmaceuticals FDG (2-deoxy-2-[F-18] fluoro-D-Glucose (fluorodeoxyglucose)), NaF-18 (fluorine-18 labeled sodium fluoride), ammonia N-13, or rubidium-82 (Rb-82). This does not prevent CMS from determining national coverage for any uses of any radiopharmaceuticals in the future, and if such determinations are made, a future determination would supersede local contractor determination.

## II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility											
		A/B MAC			D M E M A C	F I R E R	C A R E R	R H I	Shared- System Maintainers				Other
		A	B	H H H					F I S S	M C S	V M S	C W F	
8381-03.1	Effective for dates of service on or after March 7, 2013, local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals for their Food and Drug	X	X			X	X						

Number	Requirement	Responsibility											
		A/B MAC			D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				Other
		A	B	H H H					F I S S	M C S	V M S	C W F	
	Administration (FDA) approved labeled indications for oncologic imaging.												

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility											
		A/B MAC			D M E M A C	F I	C A R R I E R	R H I	Other				
		A	B	H H H					F I S S	M C S	V M S	C W F	
8381-03.2	MLN Article : A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> 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				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):** Stuart Caplan, 410-786-8564 or Stuart.caplan@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocato-Simons@cms.hhs.gov (Coverage) , William Ruiz, 410-786-9283 or William.ruiz@cms.hhs.gov (Part A Institutional Claims) , Kathleen Kersell, 410-786-2033 or Kathleen.kersell@cms.hhs.gov (Part B Practitioner Claims Processing) , Wendy Knarr, 410-786-0843 or wendy.knarr@cms.hhs.gov (Part B Supplier Claims Processing)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

## VI. FUNDING

### **Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:**

No additional funding will be provided by CMS; Contractors activities are to be carried out with 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 do 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 - Positron Emission Tomography (PET) Scans**

*(Rev. 156, Issued: 08-02-13, Effective: 03-07-13, Implementation: 09-03-13)*

Positron Emission Tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate metabolism in normal tissues 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 to on the metabolism of the tissue being studied.

NOTE: This manual section, 220.6 lists all Medicare–covered uses of PET scans. Except as set forth below in cancer indications listed as “Coverage with Evidence Development,” a particular use of PET scans is not covered unless this manual specifically provides that such use is covered. Although this section, 220.6 lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all non-covered uses.

*Effective for dates of service on or after March 7, 2013, local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals for their Food and Drug Administration (FDA) approved labeled indications for oncologic imaging.*

*We emphasize each of the following points:*

- 1. Changing the ‘restrictive’ language of prior PET decisions will not by itself suffice to expand Medicare coverage to new PET radiopharmaceuticals.*
- 2. The scope of this change extends only to FDA-approved indications for oncologic uses of PET tracers.*
- 3. This change does not include screening uses of PET scanning.*

*The Centers for Medicare & Medicaid Services (CMS) acknowledges the advances relating to the assessment of diagnostic performance and patient safety, as pioneered by the FDA in its regulatory policies and guidelines for diagnostic PET imaging agents and systems during the past decade. We note for completeness that local coverage cannot be in conflict with NCDs or other national policies. Finally, we note that future CMS NCDs, if any, regarding diagnostic PET imaging would not be precluded by this NCD.*