

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2750	Date: August 2, 2013
	Change Request 8381

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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	13/60.19/Local Coverage Determination for PET Using New, Proprietary Radiopharmaceuticals for their FDA-Approved Labeled Indications for Oncologic Imaging Only

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

Pub. 100-04	Transmittal: 2750	Date: August 2, 2013	Change Request: 8381
--------------------	--------------------------	-----------------------------	-----------------------------

SUBJECT: Positron Emission Tomography

EFFECTIVE DATE: March 7, 2013

IMPLEMENTATION DATE: September 3, 2013

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 E R	Shared- System Maintainers				Other
		A	B	H H H					F I S S	M C S	V M S	C W F	
8381-04.1	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 R E R	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.												
8381-04.1.1	<p>When the local MAC determines that a claim for PET using radiopharmaceuticals for their FDA approved labeled indications for oncologic imaging is noncovered, the following messages shall be used to deny the claim:</p> <p>Claim Adjustment Reason Code (CARC) 167: This (these) diagnosis(es) is(are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>Medicare Summary Notice (MSN) 15.4: The information provided does not support the need for this service or item.</p>	X	X			X	X						
8381-04.1.2	If the service is submitted with a GA modifier indicating there is a signed Advance Beneficiary Notice (ABN) on file, contractors shall use group code PR (patient responsibility) and the liability falls to the beneficiary.	X	X			X	X						
8381-04.1.3	If the service is submitted with a GZ modifier indicating no ABN was provided, contractors shall use group code CO (contractual obligation) and the liability falls to the provider.	X	X			X	X						
8381-04.2	For claims with dates of service on or after March 7, 2013, contractors shall not search their files, but contractors will adjust claims brought to their attention	X	X			X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility							
		A/B MAC			D M E M A C	F I M A C	C A R R I E R	R H H I	Other
		A	B	H H H					
8381-04.3	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			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) , Wendy Knarr, 410-786-0843 or wendy.knarr@cms.hhs.gov (Part B supplier claims processing) , 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 processing) , Kathleen Kersell, 410-786-2033 or Kathleen.kersell@cms.hhs.gov (Part B practitioner 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.

Medicare Claims Processing Manual

Chapter 13 - Radiology Services and Other Diagnostic Procedures

Table of Contents
(Rev.2750, Issued: 08-02-13)

Transmittals for Chapter 13

60.19 – Local Coverage Determination for PET Using New, Proprietary Radiopharmaceuticals for their FDA-Approved Labeled Indications for Oncologic Imaging Only

60.19 – Local Coverage Determination for PET Using New, Proprietary Radiopharmaceuticals for their FDA-Approved Labeled Indications for Oncologic Imaging Only

(Rev. 2750; Issued: 08-02-13; Effective Date: 03-07-13, Implementation Date: 09-03-13)

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. When the local MAC determines that a claim is noncovered, the following messages apply:

Claim Adjustment Reason Code (CARC) 167: This (these) diagnosis(es) is(are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

Medicare Summary Notice (MSN) 15.4: The information provided does not support the need for this service or item.

If the service is submitted with a GA modifier indicating there is a signed Advance Beneficiary Notice (ABN) on file, the liability falls to the beneficiary. However, if the service is submitted with a GZ modifier indicating no ABN was provided, the liability falls to the provider.