

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 84	Date: JUNE 27, 2008
	Change Request 6099

SUBJECT: FDG PET for Infection and Inflammation

I. SUMMARY OF CHANGES: CMS reconsidered the current, de facto non-coverage for FDG PET imaging for off-label indications chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin, each in lieu of bone, leukocyte, and/or gallium scintigraphy. CMS determines it will continue its national non-coverage policy for FDG PET for the requested indications. Additionally, CMS determines that this request is not appropriate for the coverage with evidence development paradigm. This addition of section 220.6.16 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: MARCH 19, 2008

IMPLEMENTATION DATE: July 28, 2008

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
N	1/220.6.16/FDG PET for Infection and Inflammation (Effective March 19, 2008)

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.

Not Applicable.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 84	Date: June 27, 2008	Change Request: 6099
-------------	-----------------	---------------------	----------------------

SUBJECT: FDG PET for Infection and Inflammation

Effective Date: March 19, 2008

Implementation Date: July 28, 2008

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) received a request to reconsider the current, de facto non-coverage for FDG PET imaging at section 220.6, of Pub. 100-03, of the National Coverage Determinations (NCD) Manual, for the following off-label uses, each in lieu of bone, leukocyte, and/or gallium scintigraphy:

1. Suspected chronic osteomyelitis in patients with: (a) previously documented osteomyelitis with suspected recurrence, or, (b) symptoms of osteomyelitis for more than 6 weeks (including diabetic foot ulcers),
2. Investigation of patients with suspected infection of hip prosthesis, and,
3. Fever of unknown origin in patients with a febrile illness of >3 weeks duration, a temperature of >38.3 degrees Centigrade on at least two occasions, and uncertain diagnosis after a thorough history, physical examination, and one week of proper investigation.

B. Policy: CMS is continuing its national non-coverage of FDG PET for the requested indications. Based upon its review, CMS determines that the evidence is inadequate to conclude that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin improves health outcomes in the Medicare populations, and therefore has determined that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Additionally, CMS also determines that this request for coverage is not appropriate for the Coverage with Evidence Development (CED) paradigm.

NOTE: Current system edits and claims processing instructions shall continue – no changes should be necessary as a result of this instruction.

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 I E R	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
6099.1	Contractors shall be aware that effective for claims with dates of service March 19, 2008, and later, CMS is continuing its national non-coverage policy for the off-label indications of FDG PET for chronic osteomyelitis,	X		X	X						

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 H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	infection of hip arthroplasty, and fever of unknown origin.										
6099.2	Contractors shall be aware that effective for claims with dates of service March 19, 2008, and later, CMS determines that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin are not appropriate for coverage under the CED paradigm.	X		X	X						

III. PROVIDER EDUCATION TABLE

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 H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6099.3	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 provider community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

Section 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:
6099.1&2	Refer to section 220.6.16, of Pub. 100-03, of the NCD Manual when processing claims for these non-covered FDG PET indications.

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS:

Pre-Implementation Contact(s): Stuart Caplan, coverage, 410-786-8564, stuart.caplan@cms.hhs.gov, Patricia Brocato-Simons, coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov

Post-Implementation Contact(s): Appropriate regional office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Carriers (RHHIs)* use only one of the following statements:

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)*, use the following statement:

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. 84, 06-27-08)**

*220.6.16 – FDG PET for Infection and Inflammation (Effective March 19,
2008)*

220.6.16 – FDG PET for Infection and Inflammation (Effective March 19, 2008)

(Rev. 84; Issued: 06-27-08; Effective Date: 03-19-08; Implementation Date: 07-28-08)

A. General

The Centers for Medicare & Medicaid Services (CMS) received a formal, complete request to reconsider the current, de facto non-coverage for FDG PET imaging for the following off-label uses, each in lieu of bone, leukocyte, and/or gallium scintigraphy:

- 1. Suspected chronic osteomyelitis in patients with: (a) previously documented osteomyelitis with suspected recurrence, or, (b) symptoms of osteomyelitis for more than 6 weeks (including diabetic foot ulcers),*
- 2. Investigation of patients with suspected infection of hip prosthesis, and,*
- 3. Fever of unknown origin in patients with a febrile illness of >3 weeks duration, a temperature of >38.3 degrees Centigrade on at least two occasions, and uncertain diagnosis after a thorough history, physical examination, and one week of proper investigation.*

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

The CMS is continuing its national non-coverage of FDG PET for the requested indications. Based upon our review, CMS has determined that the evidence is inadequate to conclude that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin improves health outcomes in the Medicare populations, and therefore has determined that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

D. Other

The CMS has also determined that the request for coverage is not appropriate for the Coverage with Evidence Development (CED) paradigm.

(This NCD last reviewed March 2008.)