CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 119	Date: March 26, 2010
	Change Request 6861

SUBJECT: Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer

I. SUMMARY OF CHANGES: On June 4, 2009, CMS opened a reconsideration in Pub. 100-03, the National Coverage Determinations (NCD) Manual, section 220.6, to review evidence on the use of NaF-18 (sodium fluoride-18) imaging (NaF-18 PET) to identify bone metastasis of cancer. CMS proposes that the evidence is not sufficient to determine that the results of NaF-18 PET imaging to identify bone metastases improve health outcomes of beneficiaries with cancer. Therefore CMS proposes that this use is not reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act (the Act).

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: FEBRUARY 26, 2010
IMPLEMENTATION DATE: JULY 6, 2010

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	1/220.6.19/Positron Emission Tomography NaF-18 (NaF-18 PET) to Identify Bone Metastasis of Cancer (Effective February 26, 2010)

III. FUNDING:

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.

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: 119	Date: March 26, 2010	Change Request: 6861

SUBJECT: Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer

EFFECTIVE DATE: FEBRUARY 26, 2010
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I. GENERAL INFORMATION

A. Background: On June 4, 2009, the Centers for Medicare & Medicaid Services (CMS) opened a reconsideration of Pub. 100-03, NCD Manual, section 220.6, to review evidence on the use of NaF-18 (sodium fluoride-18) imaging (NaF-18 PET) to identify bone metastasis of cancer. CMS proposes that the evidence is not sufficient to determine that the results of NaF-18 PET imaging to identify bone metastases improve health outcomes of beneficiaries with cancer. Therefore CMS proposes that this use is not reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act).

However, CMS proposes that the available evidence is sufficient to determine that NaF-18 PET imaging, to identify symptomatic or strongly suspected bone metastasis of cancer to inform the initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after the completion of initial treatment, is reasonable and necessary under §1862(a)(1)(E) through Coverage with Evidence Development (CED) when the beneficiary's treating physician determines that the NaF-18 PET study is needed, and when the beneficiary is enrolled in, and the NaF-18 PET provider is participating in, specific types of prospective clinical studies as outlined in Pub. 100-03, NCD Manual, section 220.6.

B. Policy: Effective for claims with dates of service on and after February 26, 2010, contractors shall be aware that NaF-18 PET oncologic claims to inform initial treatment strategy (PI) or subsequent treatment strategy (PS) for suspected or biopsy proven bone metastasis are covered, BUT ONLY IN THE CONTEXT OF A CLINICAL STUDY. All other claims for NaF-18 PET oncology claims are non-covered.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6861.1	Effective for claims with dates of service on or after February 26, 2010, contractors shall accept and pay for NAF-18 PET oncologic claims as specified in Pub. 100-03, NCD Manual, section 220.6, to inform initial treatment strategy or subsequent treatment strategy for suspected or biopsy proven bone metastasis ONLY IN THE CONTEXT OF A CLINICAL STUDY. **NOTE:** NaF-18 PET also applies to NaF-18	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	PET/CT.										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6861.2	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 local information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below: N/A
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: N/A

V. CONTACTS

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786-2160, yvette.cousar@cms.hhs.gov; Antoinette Johnson, institutional claims processing, 410-786-9326, Antoinette.johnson@cms.hhs.gov.

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.119, 03-26-10)

220.6.19 – Positron Emission Tomography NaF-18 (NaF-18 PET) to Identify Bone Metastasis of Cancer (Effective February 26, 2010)

(Rev.119, Issued: 03-26-10, Effective: 02-26-10, Implementation: 07-06-10)

A. General

Positron Emission Tomography (PET) is a non-invasive, diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the body. A positron camera (tomograph) is used to produce cross-sectional tomographic images, which are obtained from positron-emitting radioactive tracer substances (radiopharmaceuticals) such as F-18 sodium fluoride. NaF-18 PET has been recognized as an excellent technique for imaging areas of altered osteogenic activity in bone. The clinical value of detecting and assessing the initial extent of metastatic cancer in bone is attested by a number of professional guidelines for oncology. Imaging to detect bone metastases is also recommended when a patient, following completion of initial treatment, is symptomatic with bone pain suspicious for metastases from a known primary tumor.

B. Nationally Covered Indications

Effective February 26, 2010, the Centers for Medicare & Medicaid Services (CMS) will cover NaF-18 PET imaging when the beneficiary's treating physician determines that the NaF-18 PET study is needed to inform to inform the initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after the completion of initial treatment, and when the beneficiary is enrolled in, and the NaF-18 PET provider is participating in, the following type of prospective clinical study:

> *A NaF-18 PET clinical study that is designed to collect additional information at the time of the scan to assist in initial antitumor treatment planning or to guide subsequent treatment strategy by the identification, location and quantification of bone metastases in beneficiaries in whom bone metastases are strongly suspected based on clinical symptoms or the results of other diagnostic studies. 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 Medicare will provide coverage must answer one or more of the following questions:

Prospectively, in Medicare beneficiaries whose treating physician determines that the NaF-18 PET study results are needed to inform the initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after the completion of initial treatment, does the addition of NaF-18 PET imaging lead to:

- *A change in patient management to more appropriate palliative care; or*
- *A change in patient management to more appropriate curative care; or*
- *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 three (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 Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that the Centers for Medicare and Medicaid Services (CMS) determines meet the above-listed standards and address the above-listed research questions.

C. Nationally Non-Covered Indications

Effective February 26, 2010, CMS determines that the evidence is not sufficient to determine that the results of NaF-18 PET imaging to identify bone metastases improve health outcomes of beneficiaries with cancer and is not reasonable and necessary under §1862(a)(1)(A) of the Act unless it is to inform initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after completion of initial treatment, and then only under CED. All other uses and clinical indications of NaF-18 PET are nationally non-covered.

D. Other

The only radiopharmaceutical diagnostic imaging agents covered by Medicare for PET cancer imaging are 2-[F-18] Fluoro-D-Glucose (FDG) and NaF-18 (sodium fluoride-18). All other PET radiopharmaceutical diagnostic imaging agents are non-covered for this indication.

(This NCD was last reviewed in February 2010.)