CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1937	**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 Section1862(a)(1)(A) of the Social Security Act (the 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	13/Table of Contents
R	13/60.3.2/Tracer Codes Required for PET Scans
N	13/60.18/Billing and Coverage Changes for PET (NaF-18) Scans to Identify Bone Metastasis of Cancer Effective for Claims With Dates of Service on or After 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. 100-04	Transmittal: 1937	Date: March 26, 2010	Change Request: 6861

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

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

I. GENERAL INFORMATION

A. Background: On June 4, 2009, the Centers for Medicare & Medicaid Services (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 §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 noncovered.

NOTE: Effective for claims with dates of service on and after February 26, 2010, HCPCS A9580, sodium fluoride F-18, diagnostic, per study dose, up to 30 millicuries, effective January 1, 2009, shall be used for all NaF-18 PET oncology claims.

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	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	
	metastasis ONLY IN THE CONTEXT OF A CLINICAL STUDY. **NOTE:** NaF-18 PET also applies to NaF-18 PET/CT.										
6861.1.1	Effective for claims with dates of service on or after February 26, 2010, contractors shall return as unprocessable NaF-18 PET oncologic claims to inform the initial treatment strategy or subsequent treatment strategy for bone metastasis that do not include **ALL** of the following: • -PI or –PS modifier **AND** • PET or PET/CT CPT code (78608, 78811, 78812, 78813, 78814, 78815,78816) **AND** • ICD-9 cancer diagnosis code **AND** • HCPCS A9580 **AND** • -Q0 modifier - Investigational clinical service provided in a clinical research study that is in an approved clinical research study, are present on the claim. **NOTE:** For institutional claims, continue to include diagnosis code V70.7 and condition code 30 to denote a clinical study.	X		X	X		X				
6861.1.2	Effective for claims with dates of service on or after February 26, 2010, when contractors return as unprocessable or return to provider NaF-18 PET oncologic claims for bone metastasis using the following messages, if appropriate: Without PI/PS or Q0 modifier: Claim Adjustment Reason Code (CARC) 4 – The procedure code is inconsistent with the modifier used or a required modifier is missing. Remittance Advice Remark Code (RARC) MA130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Submit a new claim with the complete/correct information. RARC M16 - Alert: See our Web site, mailings, or bulletins for more details concerning this policy/procedure/decision.	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	
	Without HCPCS A9580: RARC M20 – Missing/incomplete/invalid HCPCS. Without ICD-9 cancer diagnosis code: CARC 167 – This (these) diagnosis(es) is (are) not covered.										
6861.2	Contractors shall not search their files for NaF-18 PET oncologic claims with dates of service between February 26, 2010, and July 6, 2010. However, contractors shall adjust claims brought to their attention.	X		X	X						

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	
6861.3	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 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

Pre-Implementation Contact(s): Stuart Caplan, coverage, 410-786-8564, stuart.caplan@cms.hhs.gov; Pat Brocato-Simons, coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov; Michelle Atkinson, coverage, 410-786-2881, michelle.atkinson@cms.hhs.gov; Yvette Cousar, professional claims processing, 410-786-2160, 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 Claims Processing Manual
Chapter 13 - Radiology Services and Other Diagnostic Procedures

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(Rev.1937, 03-26-10)

60.18 – Billing and Coverage Changes for PET (NaF-18) Scans to Identify Bone Metastasis of Cancer Effective for Claims With Dates of Services on or After February 26, 2010.

60.3.2 - Tracer Codes Required for PET Scans

(Rev. 1937, Issued: 03-26-10, Effective: 02-26-10, Implementation: 07-06-10)

The following tracer codes are applicable only to CPT 78491 and 78492. They can not be reported with any other code.

Institutional providers billing the fiscal intermediary

HCPCS	Description
*A9555	Rubidium Rb-82, Diagnostic, Per study dose, Up To 60 Millicuries
* Q3000 (Deleted effective 12/31/05)	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Rubidium Rb-82, per dose
A9526	Nitrogen N-13 Ammonia, Diagnostic, Per study dose, Up To 40 Millicuries

NOTE: For claims with dates of service prior to 1/01/06, providers report Q3000 for supply of radiopharmaceutical diagnostic imaging agent, Rubidium Rb-82. For claims with dates of service 1/01/06 and later, providers report A9555 for radiopharmaceutical diagnostic imaging agent, Rubidium Rb-82 in place of Q3000.

Physicians / practitioners billing the carrier:

*A4641	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Not Otherwise Classified
A9526	Nitrogen N-13 Ammonia, Diagnostic, Per study dose, Up To 40 Millicuries
A9555	Rubidium Rb-82, Diagnostic, Per study dose, Up To 60 Millicuries

***NOTE:** Effective January 1, 2008, tracer code A4641 is not applicable for PET Scans.

The following tracer codes are applicable only to CPT 78459, 78608, 78811-78816. They can not be reported with any other code:

Institutional providers billing the fiscal intermediary:

* A9552	Fluorodeoxyglucose F18, FDG, Diagnostic, Per study dose, Up to 45 Millicuries
* C1775 (Deleted effective 12/31/05)	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Fluorodeoxyglucose F18, (2-Deoxy-2-18F Fluoro-D-Glucose), Per dose (4-40 Mci/Ml)

**A4641	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Not Otherwise Classified
A9580	*Sodium Fluoride F-18, Diagnostic, per study dose, up to 30 Millicuries*

NOTE: For claims with dates of service prior to 1/01/06, OPPS hospitals report C1775 for supply of radiopharmaceutical diagnostic imaging agent, Fluorodeoxyglucose F18. For claims with dates of service January 1, 2006 and later, providers report A9552 for radiopharmaceutical diagnostic imaging agent, Fluorodeoxyglucose F18 in place of C1775.

** **NOTE:** Effective January 1, 2008, tracer code A4641 is not applicable for PET Scans.

******NOTE: Effective for claims with dates of service February 26, 2010 and later, tracer code A9580 is applicable for PET Scans.***

Physicians / practitioners billing the carrier:

A9552	Fluorodeoxyglucose F18, FDG, Diagnostic, Per study dose, Up to 45 Millicuries
*A4641	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Not Otherwise Classified
A9580	*Sodium Fluoride F-18, Diagnostic, per study dose, up to 30 Millicuries*

***NOTE:** Effective January 1, 2008, tracer code A4641 is not applicable for PET Scans.
******NOTE: Effective for claims with dates of service February 26, 2010 and later, tracer code A9580 is applicable for PET Scans.***

60.18 – Billing and Coverage Changes for PET (NaF-18) Scans to Identify Bone Metastasis of Cancer Effective for Claims With Dates of Services on or After February 26, 2010.

(Rev. 1937, Issued: 03-26-10, Effective: 02-26-10, Implementation: 07-06-10)

A. Billing Changes for A/B MACs, FIs, and Carriers

*Effective for claims with dates of service on and after February 26, 2010, contractors shall pay for NaF-18 PET oncologic claims to inform of initial treatment strategy (PI) or subsequent treatment strategy (PS) for suspected or biopsy proven bone metastasis **ONLY** in the context of a clinical study and as specified in Pub. 100-03, section 220.6. All other claims for NaF-18 PET oncology claims remain non-covered.*

B. Medicare Summary Notices, Remittance Advice Remark Codes, and Claim Adjustment Reason Codes

*Additionally, contractors shall **return as unprocessable /return to provider** NaF-18 PET oncologic claims for bone metastasis billed without HCPCS A9580, one of the PET/PET/ CT*

CPT codes listed in 60.16 C above, modifier –PI or –PS, an ICD-9 cancer diagnosis code and modifier -Q0. For Institutional claims, V70.7 and condition code 30 must also be included on the claim.

Use the following messages:

- *Claim Adjustment Reason Code 4 – the procedure code is inconsistent with the modifier used or a required modifier is missing.*

- *Remittance Advice Remark Code MA-130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Submit a new claim with the complete/correct information.*

- *Remittance Advice Remark Code M16 - Alert: See our Web site, mailings, or bulletins for more details concerning this policy/procedure/decision.*

- *Claim Adjustment Reason Code 167 – This (these) diagnosis(es) is (are) not covered.*