

<b>CMS Manual System</b>	Department of Health & Human Services (DHHS)
<b>Pub 100-04 Medicare Claims Processing</b>	Centers for Medicare & Medicaid Services (CMS)
<b>Transmittal 2096</b>	<b>Date: November 19, 2010</b>
	<b>Change Request 7125</b>

**SUBJECT: Billing Clarification for Positron Emission Tomography (Sodium Fluoride -18) (NaF-18) PET for Identify Bone Metastasis of Cancer in Context of a Clinical Trial**

**I. SUMMARY OF CHANGES:** This change request (CR) is being issued to clarify a requirement in Transmittal 1937, CR 6861, dated March 26, 2010, in regards to how these claims should be billed. In Business Requirement 6861.1.1, the requirement was vague and did not include proper billing and claims handling instructions for claims submitted for the professional component, technical or global components. This instruction will break down the specific claims handling instructions for claims submitted for each of these components. This CR also corrects an error contained in Business Requirement 6861.1.1, in the listing of HCPCS codes that can be billed with PET for NaF-18.

**EFFECTIVE DATE: FEBRUARY 26, 2010**

**IMPLEMENTATION DATE: FEBRUARY 22, 2011**

*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:**

**R=REVISED, N=NEW, D=DELETED-Only One Per Row.**

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
<b>R</b>	13/60.3.2/Tracer Codes Required for PET Scans
<b>R</b>	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: 2096	Date: November 19, 2010	Change Request: 7125
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**SUBJECT: Billing Clarification for Positron Emission Tomography (Sodium Fluoride -18) (NaF-18) PET for Identify Bone Metastasis of Cancer in Context of a Clinical Trial**

**EFFECTIVE DATE: FEBRUARY 26, 2010**

**IMPLEMENTATION DATE: FEBRUARY 22, 2011**

## I. GENERAL INFORMATION

**A. Background:** This instruction clarifies a requirement originally created in Pub. 100-04, Transmittal 1937, CR 6861, dated March 26, 2010. This CR also serves to ensure consistency among contractors. Business Requirement 6861.1.1, is being amended to state only claims for the technical component (TC) or global service require the radioactive tracer, HCPCS A9580. Claims for the professional component (PC) do not require HCPCS A9580 but must contain the appropriate –PI or –PS modifier, PET/with computed tomography (CT) HCPCS procedure code, diagnosis code and the Q0 modifier.

This CR also corrects the list of applicable PET or PET with CT CPT codes that can be used for bone metastasis on the claim and to remove HCPCS 78608 and HCPCS 78459 as they cannot be paid for bone metastasis with NaF-18. Lastly, modifier **KX** (Requirements specified in the medical policy have been met) shall be accepted for professional component claims (modifier 26) for PET for bone metastasis (PET NaF-18) to differentiate these claims from PET for FDG in the context of a clinical trial. This modifier is **not** required on claims submitted to FIs nor is it required on claims for the technical or global service. When modifier KX is present on a PET professional component service, process the service as PET NaF-18 rather than PET with FDG.

**B. Policy:** Pub. 100-03, Chapter 1, National Claims Determination Manual, Section 220.6, provides the coverage policy related information for this CR.

## 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 M A C	F I I E R	C A R I E R	R H H I S S	Shared-System Maintainers				OTH ER	
		F	M	V	C	M	S	S	W	F		
7125.1	Effective for claims with dates of service on or after February 26, 2010, contractors shall return as unprocessable NaF-18 PET oncologic claims billed with HCPCS A9580 and <b>modifier TC or globally</b> to inform the initial treatment strategy or subsequent treatment strategy for bone metastasis that do not include ALL of the following:	X			X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				OTH ER	
							F I S S	M C S	V M S	C W F		
	<ul style="list-style-type: none"> <li>• -PI or -PS modifier AND</li> <li>• PET or PET/CT CPT code (78811, 78812, 78813, 78814, 78815, 78816) AND</li> <li>• ICD-9 cancer diagnosis code AND</li> <li>• Q0 modifier – Investigational clinical service provided in a clinical research study, are present on the claim.</li> </ul>											
7125.1.1	<p>Effective for claims with dates of service on or after February 26, 2010, contractors shall return to provider NaF-18 PET oncologic claims billed with HCPCS A9580 and to inform the initial treatment strategy or subsequent treatment strategy for bone metastasis that do not include ALL of the following:</p> <ul style="list-style-type: none"> <li>• -PI or -PS modifier AND</li> <li>• PET or PET/CT CPT code (78811, 78812, 78813, 78814, 78815, 78816) AND</li> <li>• ICD-9 cancer diagnosis code AND</li> <li>• Q0 modifier – Investigational clinical service provided in a clinical research study, are present on the claim.</li> </ul> <p><b>NOTE:</b> For institutional claims, continue to include diagnosis code V70.7 and condition code 30 to denote a clinical study.</p>	X		X								
7125.1.2	Contractors shall refer to Transmittal 1937, Change Request 6861, dated March 26, 2010, Business Requirement 6861.1.2, for messaging returning these claims as unprocessable.	X			X							
7125.2	<p>Effective for claims with dates of service on or after February 26, 2010, contractors shall accept PET oncologic claims billed with <b>modifier 26</b> and modifier <b>KX</b> to inform the initial treatment strategy or strategy or subsequent treatment strategy for bone metastasis that include the following:</p> <ul style="list-style-type: none"> <li>• -PI or -PS modifier AND</li> <li>• PET or PET/CT CPT code (, 78811, 78812, 78813, 78814, 78815, 78816) AND</li> <li>• ICD-9 cancer diagnosis code AND</li> <li>• Q0 modifier – Investigational clinical service provided</li> </ul>	X			X							

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				OTH ER
		M A C	M A C				I S S	M S	V S	C W F	
	in a clinical research study, are present on the claim.  <b>NOTE:</b> Contractors shall treat professional component PET claims (modifier 26) that include modifier KX as PET NaF-18 rather than PET with FDG.										
7125.3	Contractors shall also return as unprocessable NaF-18 PET oncologic professional component claims (i.e., claims billed with <b>modifiers 26</b> and KX) to inform the initial treatment strategy or strategy or subsequent treatment strategy for bone metastasis billed with HCPCS A9580 and use the following messages:  Claim Adjustment Reason Code 97 – The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated.  <b>NOTE:</b> Refer to the 835 Healthcare Policy identification Segment (loop 2110 Service Payment Information REF), if present.	X			X						

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				OTH ER
		M A C	M A C				I S S	M S	V S	C W F	
7125.4	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/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 site and include information about it	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  I E R	C A R I E R	R H H I  I S S	Shared-System Maintainers			
						F I S S	M C S	V M S	C W F	
	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.									

#### 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:
	Pub. 100-04, Transmittal 1937, CR 6861, dated March 26, 2010, Business Requirement 6861.1.1, is being corrected.

**Section B: For all other recommendations and supporting information, use this space: N/A**

#### V. CONTACTS

**Pre-Implementation Contact(s):** For claims processing issues, contact Yvette Cousar at [Yvette.cousar@cms.hhs.gov](mailto:Yvette.cousar@cms.hhs.gov) or (410) 786-2160. For institutional claims processing issues, contact Antoinette Johnson at [Antoinette.Johnson@cms.hhs.gov](mailto:Antoinette.Johnson@cms.hhs.gov) or (410) 786-9326

**Post-Implementation Contact(s):** Appropriate project officer or contractor manager

#### VI. FUNDING

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

### 60.3.2 - Tracer Codes Required for PET Scans

*(Rev.2096, Issued: 11-19-10, Effective: 02-26-10, Implementation: 02-22-11)*

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	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Fluorodeoxyglucose F18, (2-Deoxy-2-18F Fluoro-D-Glucose), Per dose (4-40 Mci/MI)



12/31/05)	
**A4641	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Not Otherwise Classified

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

<i>A9580</i>	<i>Sodium Fluoride F-18, Diagnostic, per study dose, up to 30 Millicuries</i>
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**NOTE:** For claims with dates of service prior to 1/01/06, OPSS hospitals report C1775 for supply of radiopharmaceutical diagnostic imaging agent, Fluorodeoxyglucose F18. For claims with dates of service 1/01/06 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

**The following tracer code is applicable only to 78811-78816. They can not be reported with any other code:**

<i>A9580</i>	<i>Sodium Fluoride F-18, Diagnostic, per study dose, up to 30 Millicuries</i>
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**\*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.*

***Positron Emission Tomography Reference Table***

<b><i>CPT</i></b>	<b><i>Short Descriptor</i></b>	<b><i>Tracer/Code</i></b>	<b><i>or</i></b>	<b><i>Tracer/Code</i></b>	<b><i>Comment</i></b>
78459	<i>Myocardial imaging, positron emission tomography (PET), metabolic imaging</i>	<i>FDG A9552</i>	--	--	<i>N/A</i>
78491	<i>Myocardial imaging, positron emission tomography (PET), perfusion; single study at rest or stress</i>	<i>N-13 A9526</i>	<i>or</i>	<i>Rb-82 A9555</i>	<i>N/A</i>
78492	<i>Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest and/or stress</i>	<i>N-13 A9526</i>	<i>or</i>	<i>Rb-82 A9555</i>	<i>N/A</i>
78608	<i>Brain imaging, positron emission tomography (PET); metabolic evaluation</i>	<i>FDG A9552</i>	--	--	<i>Covered indications: Alzheimer's disease/dementias, intractable seizures  Note: This code is also covered for dedicated PET brain tumor imaging.</i>
78609	<i>Brain imaging, positron emission tomography (PET); perfusion evaluation</i>	--	--	--	<i>Nationally noncovered</i>
78811	<i>Positron emission tomography (PET) imaging; limited area (e.g, chest, head/neck)</i>	<i>FDG A9552</i>	<i>or</i>	<i>NaF-18 A9580</i>	<i>NaF-18 PET is covered only to identify bone metastasis of cancer.</i>

78812	<i>Positron emission tomography (PET) imaging, skull base to mid-thigh</i>	<i>FDG A9552</i>	<i>or</i>	<i>NaF-18 A9580</i>	<i>NaF-18 PET is covered only to identify bone metastasis of cancer.</i>
78813	<i>Positron emission tomography (PET) imaging, whole body</i>	<i>FDG A9552</i>	<i>or</i>	<i>NaF-18 A9580</i>	<i>NaF-18 PET s covered only to identify bone metastasis of cancer.</i>
78814	<i>PET/CT imaging, limited area (e.g., chest, head/neck)</i>	<i>FDG A9552</i>	<i>or</i>	<i>NaF-18 A9580</i>	<i>NaF-18 PET is covered only to identify bone metastasis of cancer.</i>
78815	<i>PET/CT imaging , skull base to mid-thigh</i>	<i>FDG A9552</i>	<i>or</i>	<i>NaF-18 A9580</i>	<i>NaF-18 PET is covered only to identify bone metastasis of cancer.</i>
78816	<i>PET/CT imaging, whole body</i>	<i>FDG A9552</i>	<i>or</i>	<i>NaF-18 A9580</i>	<i>NaF-18 PET is covered only to identify bone metastasis of cancer.</i>

**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. 2096, Issued: 11-19-10, Effective: 02-26-10, Implementation: 02-22-11)*

**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**

*Effective for claims with dates of service on or after February 26, 2010, contractors shall return as unprocessable NaF-18 PET oncologic claims billed with **modifier TC or globally (for FIs modifier TC or globally does not apply)** and HCPCS A9580 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 (78811, 78812, 78813, 78814, 78815, 78816) AND*
- ICD-9 cancer diagnosis code AND
- Q0 modifier – Investigational clinical service provided in a 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.

Use the following messages:

- Claim Adjustment Reason Code 4 – The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- 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.

*Effective for claims with dates of service on or after February 26, 2010, contractors shall accept PET oncologic claims billed with **modifier 26** and modifier **KX** to inform the initial treatment strategy or strategy or subsequent treatment strategy for bone metastasis that include the following:*

- *PI or –PS modifier AND*
- *PET or PET/CT CPT code (78811, 78812, 78813, 78814, 78815, 78816) AND*
- *ICD-9 cancer diagnosis code AND*
- *Q0 modifier – Investigational clinical service provided in a clinical research study, are present on the claim.*

***NOTE:*** If modifier ***KX*** is present on the professional component service, Contractors shall process the service as ***PET NaF-18*** rather than ***PET with FDG***.

Contractors shall also return as unprocessable ***NaF-18 PET oncologic professional component claims*** (i.e., claims billed with ***modifiers 26 and KX***) to inform the initial treatment strategy or strategy or subsequent treatment strategy for bone metastasis billed with ***HCPCS A9580*** and use the following message:

*Claim Adjustment Reason Code 97 – The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated.*

***NOTE:*** Refer to the ***835 Healthcare Policy identification Segment (loop 2110 Service Payment Information REF)***, if present.