CMS Manual System	Department of Health & Human Services
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services
Transmittal 1833	Date: October 16, 2009
	Change Request 6632

This change request rescinds and replaces Transmittal 1817, dated September 18, 2009. The effective date has been changed to April 3, 2009 and the implementation date has been changed to October 30, 2009. Business Requirements (BR) 6632.6.1 and 6632.6.2 have been revised to clarify that they are subsets of BR 6632.6 and are specific to CED. All other information remains the same.

SUBJECT: FDG PET for Solid Tumors and Myeloma

I. SUMMARY OF CHANGES: CMS is adopting a coverage framework that replaces the four-part diagnosis, staging, restaging and monitoring response to treatment categories with a two-part framework that differentiates FDG PET imaging used to inform the initial antitumor treatment strategy from other uses related to guiding subsequent antitumor treatment strategies after the completion of initial treatment. CMS is making this change for all NCDs that address coverage of FDG PET for all oncologic conditions.

NEW / REVISED MATERIAL
EFFECTIVE DATE: APRIL 3, 2009
IMPLEMENTATION DATE: October 30, 2009

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/Positron Emission Tomography (PET) Scans - General Information
R	13/60.15/Billing Requirements for CMS - Approved Clinical Trial Claims for PET Scans for Neurodegenerative Diseases, Previously Specified Cancer Indications, and All Other Cancer Indications Not Previously Specified
N	13/60.16/Billing and Coverage Changes for PET Scans Effective for Services on or After April 3, 2009

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.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

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

Attachment – Business Requirements

Pub. 100-04	Transmittal: 1833	Date: October 16, 2009	Change Request: 6632

This change request rescinds and replaces Transmittal 1817, dated September 18, 2009. The effective date has been changed to April 3, 2009 and the implementation date has been changed to October 30, 2009. Business Requirements (BR) 6632.6.1 and 6632.6.2 have been revised to clarify that they are subsets of BR 6632.6 and are specific to CED. All other information remains the same.

SUBJECT: FDG PET for Solid Tumors and Myeloma

Effective Date: April 3, 2009
Implementation Date: October 30, 2009

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) was asked to reconsider section 220.6, of the National Coverage Determinations (NCD) Manual, to end the prospective data collection requirements across all oncologic indications of F-18 flouro-D-glucose (FDG) PET except for monitoring response to treatment. In the context of this document, the term FDG PET includes FDG PET/CT.

The CMS is revising Pub. 100-03, NCD Manual, section 220.6, to reflect a new framework for most solid tumor oncologic indications and for myeloma. The following 11 sections of the NCD Manual are deleted: 220.6.2 (FDG PET for Lung Cancer); 220.6.3 (FDG PET for Esophageal Cancer); 220.6.4 FDG PET for Colorectal Cancer): 220.6.5 (FDG PET for Lymphoma); 220.6.6 (FDG PET for Melanoma); 220.6.7 (FDG PET for Head and Neck Cancers Non-CNS/Thyroid); 220.6.10 (FDG PET for Breast Cancer); 220.6.11 (FDG PET for Thyroid Cancer); 220.6.12 (FDG PET for Soft Tissue Sarcoma); 220.6.14 (FDG PET for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung and Testicular Cancers), and 220.6.15 (FDG PET for All Other Cancer Indications) and replaced with section 220.6.17, Positron Emission Tomography (FDG) for Oncologic Conditions. See Pub. 100-03, NCD Manual, section 220.6.17, for specific coverage language.

B. Policy:

1. Framework

The CMS is adopting a coverage framework that replaces the 4-part diagnosis, staging, restaging, and monitoring response to treatment categories with a 2-part framework that differentiates FDG PET imaging used to inform the initial treatment strategy from other uses related to guiding subsequent treatment strategies after the completion of initial treatment. CMS is making this change for all NCDs that address coverage of FDG PET for oncologic conditions as noted below, inclusive of those indications that are coverable under CMS' coverage with evidence development (CED) paradigm.

Tumor Type	**Initial Treatment Strategy** (formerly "diagnosis" & "staging")	**Subsequent Treatment Strategy** (formerly "restaging" & "monitoring response to treatment")
Colorectal	Cover	Cover
Esophagus	Cover	Cover
Head & Neck (not Thyroid, CNS)	Cover	Cover
Lymphoma	Cover	Cover

Non-Small Cell Lung	Cover	Cover
Ovary	Cover	Cover*
Brain	Cover*	CED
Cervix	Cover** or CED	Cover*
Small Cell Lung	Cover*	CED
Soft Tissue Sarcoma	Cover*	CED
Pancreas	Cover*	CED
Testes	Cover*	CED
Breast (female and male)	Cover**	Cover
Melanoma	Cover**	Cover
Prostate	Non-Cover*	CED
Thyroid	Cover	Cover** or CED
All Other Solid Tumors	Cover*	CED
Myeloma	Cover*	Cover*
All other cancers not listed herein	CED*	CED*

***Coverage Change**
****Coverage w/Exceptions**

2. Initial Treatment Strategy

The CMS will cover one FDG PET study for beneficiaries who have solid tumors that are biopsy proven or strongly suspected based on other diagnostic testing when the beneficiary's treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial treatment strategy:

• To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or,

• To determine the optimal anatomic location for an invasive procedure; or,

• To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

New Coverage for Initial Treatment Strategy

Myeloma: CMS will nationally cover the use of FDG PET imaging to determine initial treatment strategy in patients with myeloma.

Prostate: CMS will nationally non-cover the use of FDG PET imaging to determine initial treatment strategy in patients with adenocarcinoma of the prostate.

All other cancers not listed herein: CMS will nationally cover the use of FDG PET imaging to determine initial treatment strategy in patients with all other cancers not listed herein provided under CED.

3. Subsequent Treatment Strategy

The CMS will non-cover FDG PET imaging for subsequent anti-tumor treatment strategy for tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, and thyroid, unless the FDG PET is provided under CED.

New Coverage for Subsequent Treatment Strategy

Ovarian: CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with ovarian cancer.

Cervical: CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with cervical cancer.

Myeloma: CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with myeloma.

All other cancers not listed herein: CMS will nationally cover the use of FDG PET imaging to determine subsequent treatment strategy in patients with all other cancers not listed herein provided under CED.

New Modifiers for PET

PI - Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing. Short descriptor: PET tumor init tx strat

PS - Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the subsequent treatment strategy of cancerous tumors when the beneficiary's treating physician determines that the PET study is needed to inform subsequent anti-tumor strategy. Short descriptor: PET tumor subsq tx strategy

NOTE: The two new PET FDG oncologic modifiers –PI and –PS are included in the July quarterly update of the IOCE, with an effective date of April 1, 2009. Upon implementation of this CR, all FDG PET oncologic-related claims received for dates of service on or after April 3, 2009, MUST include one of these two new modifiers in order for the claim to be processed correctly.

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	
6632.1	Effective for claims with dates of service on or after April 3, 2009, contractors shall **accept** and pay for FDG PET oncologic claims as specified in Pub. 100-03, NCD Manual, section 220.6.17, to inform **initial treatment strategy or subsequent treatment strategy** for suspected or biopsy proven solid tumors. **NOTE:** FDG PET also applies to FDG PET/CT.	X		X	X						
6632.1.1	Effective for claims with dates of service on or after April 3, 2009, received 10/30/2009, or later, contractors shall **return as unprocessable (professional) or return to provider (institutional)**	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	
	FDG PET oncologic claims to inform the **initial treatment strategy** for solid tumors that do not include: • -PI modifier **AND** • PET/PET/CT CPT code (78608, 78811, 78812, 78813, 78814, 78815,78816)										
6632.1.2	Effective for claims with dates of service on or after April 3, 2009, received 10/30/2009 or later, contractors shall **return as unprocessable** FDG PET oncologic claims for **subsequent treatment strategy** for solid tumors that do not include: • -PS modifier **AND** • PET/PET/CT CPT code in 6632.1.1 **AND** • ICD-9 cancer diagnosis code	X			X						
6632.1.2.1	Effective for claims with dates of service on or after April 3, 2009, received 10/30/2009 or later, contractors shall **return to provider** FDG PET oncologic claims for **subsequent treatment strategy** for solid tumors that do not include: • -PS modifier **AND** • PET/PET/CT CPT code in 6632.1.1 **AND** • ICD-9 cancer diagnosis code	X		X							
6632.1.3	Effective for claims with dates of service on or after April 3, 2009, received 10/30/2009 or later, when contractors **return as unprocessable** FDG PET oncologic claims billed without the -PI or -PS modifier use the following messages: Wrong/Lack of 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	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	
	bulletins for more details concerning this policy/procedure/decision.										
6632.1.4	Effective for claims with dates of service on or after April 3, 2009, received 10/30/2009, or later, contractors shall **deny** FDG PET oncologic claims for **subsequent treatment strategy** billed **with** the –PS modifier **without** an ICD-9 cancer diagnosis using the following message: MSN 15.4 – The information provided does not support the need for this service or item. CARC 167 – This (these) diagnosis(es) is(are) not covered. If an ABN is provided with a GA modifier indicating there is a signed ABN on file, contractors shall use Group Code PR (Patient Responsibility) and the liability falls to the beneficiary. If an ABN is provided 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						
6632.2	Effective for claims with dates of service on or after April 3, 2009, contractors shall **accept** FDG PET oncologic claims for **subsequent treatment strategy** of ovarian cancer with: • -PS modifier **AND** • PET/PET/CT CPT code in 6632.1.1 **AND** • ICD-9 cancer diagnosis code	X		X	X						
6632.3	Effective for claims with dates of service on or after April 3, 2009, contractors shall **accept** FDG PET oncologic claims for **subsequent treatment strategy** of cervical cancer with: • -PS modifier **AND** • PET/PET/CT CPT code in 6632.1.1 **AND** • ICD-9 cancer diagnosis code	X		X	X						
6632.4	Effective for claims with dates of service on or after April 3, 2009, contractors shall **accept** FDG PET oncologic claims for **initial or subsequent treatment strategy** of myeloma with:	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	
	• -PI modifier **OR** • -PS modifier **AND** ICD-9 cancer diagnosis code **AND** • PET/PET/CT CPT code in 6632.1.1										
6632.5	Effective for claims with dates of service on or after April 3, 2009, contractors shall **deny** FDG PET oncologic claims for **initial treatment strategy** with: • -PI modifier **AND** • PET/PET/CT CPT code in 6632.1.1 **AND** • ICD-9 cancer diagnosis code 185 for adenocarcinoma of the prostate.	X		X	X						
6632.5.1	When denying the above FDG PET oncologic claims, contractors shall use the following messages: MSN 15.4 – The information provided does not support the need for this service or item. CARC 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer. If an ABN is provided with a GA modifier indicating there is a signed ABN on file, contractors shall use Group Code PR (Patient Responsibility) and the liability falls to the beneficiary. If an ABN is provided 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						
6632.6	Effective for claims with dates of service on or after April 3, 2009, contractors shall **accept** FDG PET oncologic claims billed to inform **initial treatment strategy or subsequent treatment strategy** when performed under CED only when the following are present: • PET/PET/CT CPT code in 6632.1.1 **AND** • -PI modifier **OR** • -PS modifier **AND** ICD-9 cancer diagnosis code **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.	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	
	NOTE: For institutional claims, continue to include diagnosis code V70.7 and condition code 30 to denote a clinical trial.										
6632.6.1	Effective for claims with dates of service on or after April 3, 2009, received 10/30/2009, or later, contractors shall **return as unprocessable** FDG PET oncologic claims billed to inform **initial treatment strategy or subsequent treatment strategy** when performed under CED without • PET/PET/CT CPT code in 6632.1.1 **AND** • -PI modifier **OR** • -PS modifier **AND** an ICD-9 cancer code diagnosis code **AND** • -Q0 modifier Use the following messages: Wrong/Lack of 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						
6632.6.2	Effective for claims with dates of service on or after April 3, 2009, received 10/30/2009, or later, contractors shall **return to provider** FDG PET oncologic claims billed to inform **initial treatment strategy or subsequent treatment strategy** when performed under CED without • PET/PET/CT CPT code in 6632.1.1 **AND** • -PI modifier **OR** • -PS modifier **AND** an ICD-9 cancer code diagnosis code **AND** • -Q0 modifier	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	
6632.7	For FDG PET oncologic claims with dates of service April 3, 2009 or after, contractors shall not search their files. 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	
6632.8	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:
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:

V. CONTACTS

Pre-Implementation Contact(s): Stuart Caplan, coverage, 410-786-8564, stuart.caplan@cms.hhs.gov; Katherine Tillman, coverage, 410-786-9252, Katherine.tillman@cms.hhs.gov; Pat Brocato-Simons, coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov; Michelle Atkinson, 410-786-2881, michelle.atkinosn@cms.hhs.gov; Yvette Cousar, practitioner claims processing, 410-786-2160, yvette.cousar@cms.hhs.gov; Cynthia Glover, practitioner claims processing, 410-786-2589, cynthia.glover@cms.hhs.gov; Bill Ruiz, institutional claims processing, 410-786-9283, William.ruiz@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

Table of Contents
(Rev. 1833, 10-16-09)

60 - Positron Emission Tomography (PET) Scans – General Information

(Rev. 1833; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

Positron emission tomography (PET) is a noninvasive imaging procedure that assesses perfusion and the level of metabolic activity in various organ systems of the human body. A positron camera (tomograph) is used to produce cross-sectional tomographic images which are obtained by detecting radioactivity from a radioactive tracer substance (radiopharmaceutical) that emits a radioactive tracer substance (radiopharmaceutical FDG) such as 2 –[F-18] flouro-D-glucose FDG, that is administered intravenously to the patient.

The Medicare National Coverage Determinations (NCD) Manual, chapter 1, §220.6, contains additional coverage instructions to indicate the conditions under which a PET scan is performed.

A. Definitions

For all uses of PET, excluding Rubidium 82 for perfusion of the heart, myocardial viability and refractory seizures, the following definitions apply:

- **Diagnosis**: PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are generally performed for the purpose of staging, rather than diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers, as well as in melanoma, should be rare. PET is not covered for other diagnostic uses, and is not covered for screening (testing of patients without specific signs and symptoms of disease).

- **Staging**: PET is covered in clinical situations in which (1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or, (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and, (2) clinical management of the patient would differ depending on the stage of the cancer identified.

NOTE: *Effective for services on or after April 3, 2009, the terms "diagnosis" and "staging" will be replaced with "Initial Treatment Strategy." For further information on this new term, refer to Pub. 100-03, NCD Manual, section 220.6.17.*

- **Restaging**: PET will be covered for restaging: (1) after the completion of treatment for the purpose of detecting residual disease, (2) for detecting suspected recurrence, or metastasis, (3) to determine the extent of a known recurrence, or (4) if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is to determine the extent of a known recurrence, or if study information is insufficient for the clinical management of the patient. Restaging applies to testing after a course of treatment is completed and is covered subject to the conditions above.

- **Monitoring**: Use of PET to monitor tumor response to treatment during the planned course of therapy (i.e., when a change in therapy is anticipated).

NOTE: *Effective for services on or after April 3, 2009, the terms "restaging" and "monitoring" will be replaced with "Subsequent Treatment Strategy." For further information on this new term, refer to Pub. 100-03, NCD Manual, section 220.6.17.*

B. Limitations

For staging and restaging: PET is covered in either/or both of the following circumstances:

- The stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound); and/or

- The clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

The PET is not covered for other diagnostic uses, and is not covered for screening (testing of patients without specific symptoms). Use of PET to monitor tumor response during the planned course of therapy (i.e., when no change in therapy is being contemplated) is not covered.

60.15 - Billing Requirements for CMS - Approved Clinical Trial *and Coverage With Evidence Development* Claims for PET Scans for Neurodegenerative Diseases, Previously Specified Cancer Indications, and All Other Cancer Indications Not Previously Specified

(Rev. 1833; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

- Carriers and FIs

Effective for services on or after January 28, 2005, contractors shall accept and pay for claims for PET scans for lung cancer, esophageal cancer, colorectal cancer, lymphoma, melanoma, head & neck cancer, breast cancer, thyroid cancer, soft tissue sarcoma, brain cancer, cervical cancer, ovarian cancer, pancreatic cancer, small cell lung cancer, and testicular cancer, as well as for neurodegenerative diseases and all other cancer indications not previously mentioned in this chapter, if these scans were performed as part of a CMS-approved clinical trial. (See Pub. 100-03, NCD Manual, sections 220.6.2-220.6.7 and 220.6.10-220.6.15.)

Contractors shall also be aware that PET scans for all cancers not previously specified at Pub. 100-03, NCD Manual, section 220.6.15, remain nationally non-covered unless performed in conjunction with a CMS-approved clinical trial.

- **Carriers Only**

Carriers shall pay claims for PET scans for beneficiaries participating in a CMS-approved clinical trial submitted with an appropriate CPT code from *section* 60.3.1, *of this chapter* and the **QR (Item or Service Provided in a Medicare Specified Study)** modifier.

- FIs Only

In order to pay claims for PET scans on behalf of beneficiaries participating in a CMS-approved clinical trial, FIs require providers to submit claims with ICD-9 code V70.7 in the second diagnosis position on the CMS-1450 (UB-*04*), or the electronic equivalent, with the appropriate principal diagnosis code and an appropriate CPT code from section 60.3.1. Effective for PET scan claims for dates of service on or after January 28, 2005, FIs shall accept claims with the QR modifier on other than inpatient claims.

NOTE: *Effective for services on or after January 1, 2008, -Q0 (investigational clinical service provided in a clinical research study that is in an approved clinical research study) replaces the -QR modifier.*

60.16 - Billing and Coverage Changes for PET Scans Effective for Services on or After April 3, 2009

(Rev. 1833; Issued: 10-16-09; Effective Date: 04-03-09; Implementation Date: 10-30-09)

A. Summary of Changes

Effective for services on or after April 3, 2009, Medicare will ***not cover*** *the use of FDG PET imaging to determine* ***initial treatment strategy*** *in patients with adenocarcinoma of the prostate.*

*Medicare will also not cover FDG PET imaging for **subsequent treatment strategy** for tumor types other than breast, cervical, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, myeloma, non-small cell lung, ovarian, and thyroid, unless the FDG PET is provided under the coverage with evidence development (CED) paradigm (billed with modifier -Q0, see section 60.15 of this chapter).*

*Last, Medicare will cover FDG PET imaging **for initial treatment strategy** for myeloma. For further information regarding the changes in coverage, refer to Pub.100-03,NCD Manual, section 220.6.17.*

B. New Modifiers for PET Scans

*Effective for claims with dates of service on or after April 3, 2009, the following modifiers have been created for use to inform for **the initial treatment strategy** of biopsy-proven or strongly suspected tumors or **subsequent treatment strategy** of cancerous tumors:*

***PI** -Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing.*
Short descriptor: PET tumor init tx strat

***PS** - Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the subsequent treatment strategy of cancerous tumors when the beneficiary's treatment physician determines that the PET study is needed to inform subsequent anti-tumor strategy.*
Short descriptor: PS - PET tumor subsq tx strategy

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

*Effective for claims with dates of service on or after April 3, 2009, contractors shall accept FDG PET claims billed to inform **initial treatment strategy** with the following CPT codes **AND** modifier –PI: 78608, 78811, 78812, 78813, 78814, 78815, 78816.*

*Effective for claims with dates of service on or after April 3, 2009, contractors shall accept FDG PET claims with modifier –PS for the **subsequent treatment strategy** for solid tumors using a CPT code above **AND** an ICD-9 cancer diagnosis code.*

*Contractors shall also accept FDG PET claims billed to **inform initial treatment strategy or subsequent treatment strategy** when performed under CED with one of the PET or PET/CT CPT codes above **AND** modifier -PI **OR** modifier -PS **AND** an ICD-9 cancer diagnosis code **AND** modifier Q0 (Investigational clinical service provided in a clinical research study that is in an approved clinical research study).*

***NOTE:** For institutional claims continue to use diagnosis code V70.7 and condition code 30 on the claim.*

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

*Effective for dates of service on or after April 3, 2009, contractors shall **return as unprocessable/return to provider** claims that do not include the -PI modifier with one of the PET/PET/CT CPT codes listed in subsection C. above when billing for **the initial treatment strategy** for solid tumors in accordance with Pub.100-03, NCD Manual, section 220.6.17. In addition, contractors shall **return as unprocessable/return to provider** claims that do not include the -PS modifier with one of the CPT codes listed in subsection C. above when billing for the **subsequent treatment strategy** for solid tumors in accordance with Pub.100-03, NCD Manual, section 220.6.17.*

The following messages apply:

-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.

If an ABN is provided with a GA modifier indicating there is a signed ABN on file, contractors shall use Group Code PR (Patient Responsibility) and the liability falls to the beneficiary.

If an ABN is provided with a GZ modifier indicating no ABN was provided, contractors shall use Group Code CO (Contractual Obligation) and the liability falls to the provider.

*Also, effective for claims with dates of service on or after April 3, 2009, contractors shall **return as unprocessable/return to provider** FDG PET claims billed to **inform initial treatment strategy or subsequent treatment strategy** when performed under CED without one of the PET/PET CT CPT codes listed in subsection C. above **AND** modifier –PI **OR** modifier –PS **AND** an ICD-9 cancer diagnosis code **AND** modifier –Q0.*

*The following messages apply to **return as unprocessable** claims:*

-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.

If an ABN is provided with a GA modifier indicating there is a signed ABN on file, contractors shall use Group Code PR (Patient Responsibility) and the liability falls to the beneficiary.

If an ABN is provided with a GZ modifier indicating no ABN was provided, contractors shall use Group Code CO (Contractual Obligation) and the liability falls to the provider.

*Effective April 3, 2009, contractors shall **deny** claims with ICD-9 diagnosis code 185 for FDG PET imaging for the **initial treatment strategy** of patients with adenocarcinoma of the prostate. Contractors shall also **deny** claims for FDG PET imaging for **subsequent treatment strategy** for tumor types other than breast, cervical, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, myeloma, non-small cell lung, ovarian, and thyroid unless the FDG PET is provided under CED (submitted with the -Q0 modifier) and use the following messages:*

-Medicare Summary Notice 15.4 - Medicare does not support the need for this service or item

-Claim Adjustment Reason Code 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer.

- Contractors shall use Group Code CO (Contractual Obligation)