

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3162	Date: January 8, 2015
	Change Request 8739

Transmittal 2932, dated April 18, 2014 is being rescinded and replaced by Transmittal 3162, dated January 8, 2015 to remove Attachment A to the Pub. 100-04, Claims Processing Manual, and replaced with a web link in section 60.16A of the manual instruction that includes the list of appropriate diagnosis codes. Additionally, a diagnosis code 793.11 that was inadvertently left off has been included. All other information remains the same.

SUBJECT: Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors (This CR rescinds and fully replaces CR8468/TR2873 dated February 6, 2014)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is effective for claims with dates of service on and after June 11, 2013, CMS shall cover three FDG PET scans when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for the same cancer diagnosis. Coverage of any additional FDG PET scans (that is, beyond three) used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for the same diagnosis will be determined by the local Medicare Administrative Contractors.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all 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: June 11, 2013

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

IMPLEMENTATION DATE: May 19, 2014 - MAC Non-Shared System Edits; July 7, 2014 - CWF development/testing, FISS requirement development; October 6, 2014 - CWF, FISS, MCS Shared System Edits

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-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	13/60.15/Billing Requirements for CMS-Approved Clinical Trials and Coverage with Evidence Claims for PET Scans for Neurodegenerative Diseases, Previously Specified Cancer Indications, and All Other Cancer Indications Not Previously Specified
R	13/60.16/Billing and Coverage Changes for PET Scans

III. FUNDING:

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 obliged 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**

Attachment - Business Requirements

Pub. 100-04	Transmittal: 3162	Date: January 8, 2015	Change Request: 8739
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Transmittal 2932, dated April 18, 2014 is being rescinded and replaced by Transmittal 3162, dated January 8, 2015 to remove Attachment A to the Pub. 100-04, Claims Processing Manual, and replaced with a web link in section 60.16A of the manual instruction that includes the list of appropriate diagnosis codes. Additionally, a diagnosis code 793.11 that was inadvertently left off has been included. All other information remains the same.

SUBJECT: Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors (This CR rescinds and fully replaces CR8468/TR2873 dated February 6, 2014)

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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 FDG PET in the context of this document. The term FDG PET includes PET/computed tomography (CT) and PET/magnetic resonance (MRI).

The CMS is revising Pub. 100-03, NCD Manual, section 220.6, to reflect that CMS has ended the coverage with evidence development (CED) requirement for 18 fluorodeoxyglucose positron emission tomography (FDG PET) and PET/CT and PET/MRI for all oncologic indications contained in Section 220.6.17 of the NCD Manual. This removes the current requirement for prospective data collection by the National Oncologic PET Registry (NOPR) for oncologic indications for FDG (HCPCS A9552) only.

B. Policy: Effective for claims with dates of service on and after June 11, 2013, CMS shall cover three FDG PET scans when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for the same cancer diagnosis. Coverage of any additional FDG PET scans (that is, beyond three (3)) used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for the same diagnosis will be determined by the local Medicare Administrative Contractors.

Refer to CR6632, Transmittal (TR)1833 issued on October 16, 2009, and CR7148, TR124 issued September 24, 2010, for previous information on this coverage.

NOTE: For clarification purposes, as an example, each, different, cancer dx is allowed 1 initial treatment strategy (-PI modifier) FDG PET Scan and 3 subsequent treatment strategy (-PS modifier) FDG PET Scans without the -KX modifier. The 4th FDG PET Scan and beyond for subsequent treatment strategy for the same cancer dx will always require the -KX modifier. If a different cancer dx is reported, whether reported with a -PI modifier or a -PS modifier, that cancer dx will begin a new count for subsequent treatment strategy for that beneficiary.

NOTE: A beneficiary's file may or may not contain a claim for initial treatment strategy with a -PI modifier. The existence or non-existence of an initial treatment strategy claim has no bearing on the frequency count of the subsequent treatment strategy (-PS) claims.

Number	Requirement	Responsibility								
		A/B MAC		H H H M A C	D M E M A C S	Shared- System Maintainers				Other
		A	B			F I S S	M C S	V M S	C W F	
	<p>guide subsequent management of anti-tumor treatment strategy (-PS) after completion of initial anti-cancer therapy (-PI) for the same cancer dx code for the same beneficiary.</p> <p>NOTE: An initial treatment strategy claim denoting -PI may or may not be submitted for a beneficiary and does not impact the approval or frequency count of the subsequent treatment strategy (-PS) claims.</p>									
8739 - 04.4	<p>Effective for claims with dates of service on or after June 11, 2013, contractors shall pay oncologic FDG PET claims for subsequent management, identified by CPT codes 78608, 78811, 78812, 78813, 78814, 78815, or 78816, modifier -PS, HCPCS A9552, and the same cancer dx code (See Attachment A), which exceed 3 FDG PET scans when the -KX modifier is included on the claim line. (The use of the -KX modifier attests that: 1) the requirements specified in the MACs' medical policy have been met, and, 2) the claim is for >3 FDG oncologic PET scans.)</p>	X	X							
8739 -04.4.1	<p>CWF shall create two edits for oncologic FDG PET claims to reject to contractors when a beneficiary has reached 4 or greater FDG PET scans for subsequent treatment strategy (-PS) for the same cancer dx and the -KX modifier is not included on the claim line.</p> <p>-Edit 1 -will set when an incoming FDG PET scan claim (PS) contains a unit field with more than three (3), or the incoming claim FDG PET scan claim (PS) contains more than three (3) FDG PET scans (PS) detail lines with the same diagnosis.</p> <p>-Edit 2 – will set when the FDG PET scans (PS) on the incoming claim added to the FDG Pet scan (PS) services posted to the auxiliary file equal more than three (PS) services for the same diagnosis.</p>	X	X			X	X		X	
8739 -04.4.2	<p>Contractors shall deny subsequent treatment strategy (-PS) claims for oncologic FDG PET scans which exceed 3 when a -KX modifier is not included on the claim line using the following:</p>	X	X							

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
	PET services: ●TOB 13X ●TOB 85X when the revenue code is not 096X, 097X or 098X									
8739 -04.6.2	CWF shall identify all other oncologic FDG PET scan claims as professional service claims for screening services (professional claims and institutional claims with TOB 85X when the revenue code is 096X, 097X, or 098X).								X	
8739 -04.6.3	CWF shall identify the TECH (TC) and PROF (26) modifiers on claims for oncologic FDG PET services for physician claims. The absence of both the modifiers (TC and 26), qualifies the claim as a global for physicians. HUBC claims received without both the TC and 26 modifier will alert CWF that both components of the service have been received.								X	
8739 - 04.7	For FDG PET oncologic claims with dates of service June 11, 2013, or after, contractors shall not search their files. However, contractors shall adjust claims brought to their attention.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
8739 -04.8	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 sites 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 the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and	X	X			

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H	M A C	
	administering the Medicare program correctly.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
8739.2	CR6632 FDG PET for Solid Tumors and Myeloma

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): William Ruiz, 410-786-9283 or william.ruiz@cms.hhs.gov (Institutional Claims) , Chanelle Jones, 410-786-9668 or chanelle.jones@cms.hhs.gov (Practitioner Claims) , Yvette Cousar, 410-786-2160 or yvette.cousar@cms.hhs.gov (Practitioner Claims) , Stuart Caplan, 410-786-8564 or stuart.caplan@cms.hhs.gov (Coverage Policy) , Pat Brocato-Simons, 410-786-0261 or patricia.brocato-simons@cms.hhs.gov (Coverage Policy) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage Policy)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

60.15 - Billing Requirements for CMS-Approved Clinical Trials 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.3162, Issued: 01-08-15, Effective: 06-11-13, Implementation: 05-19-14- MAC Non-Shared System Edits; July 7, 2014 - CWF development/testing, FISS requirement development; October 6, 2014 - CWF, FISS, MCS Shared System Edits)

- Parts A and B Medicare Administrative Contractors (MACs)

Effective for services on or after January 28, 2005, contractors shall accept and pay for claims for *Positron Emission Tomography (PET)* scans for lung cancer, esophageal cancer, colorectal cancer, lymphoma, melanoma, head & neck cancer, breast cancer, thyroid cancer, soft tissue sarcoma, brain 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 *Centers for Medicare & Medicaid (CMS)*-approved clinical trial. (See Pub. 100-03, *National Coverage Determinations (NCD)* Manual, sections 220.6.13 and 220.6.17.)

Contractors shall also be aware that PET scans for all cancers not previously specified at Pub. 100-03, NCD Manual, section 220.6.17, remain nationally non-covered unless performed in conjunction with a CMS-approved clinical trial.

Effective for dates of service on or after June 11, 2013, Medicare has ended the coverage with evidence development (CED) requirement for FDG (2-[F18] fluoro-2-deoxy-D-glucose) PET and PET/computed tomography (CT) and PET/magnetic resonance imaging (MRI) for all oncologic indications contained in section 220.6.17 of the NCD Manual. Modifier -Q0 (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) or -Q1 (routine clinical service provided in a clinical research study that is in an approved clinical research study) is no longer mandatory for these services when performed on or after June 11, 2013.

- Part B MACs Only

Part B MACs shall pay claims for PET scans for beneficiaries participating in a CMS-approved clinical trial submitted with an appropriate current procedural terminology (CPT) code from section 60.3.1 of this chapter and *modifier -Q0/-Q1 for services performed on or after January 1, 2008, through June 10, 2013. (NOTE: Modifier -QR (Item or service provided in a Medicare specified study) and -QA (FDA investigational device exemption) were replaced by modifier -Q0 effective January 1, 2008.) Modifier -QV (item or service provided as routine care in a Medicare qualifying clinical trial) was replaced by modifier -Q1 effective January 1, 2008.) Beginning with services performed on or after June 11, 2013, modifier -Q0/-Q1 is no longer required for PET FDG services.*

- Part A MACs Only

In order to pay claims for PET scans on behalf of beneficiaries participating in a CMS-approved clinical trial, *Part A MACs* require providers to submit claims with *ICD-9/ICD-10* code V70.7/Z00.6 in the *primary/secondary* 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, *through December 31, 2007, A/BMAC (A)* shall accept claims with the *-QR, -QV, or -QA* modifier on other than inpatient claims. *Effective for services on or after January 1, 2008, through June 10, 2013, modifier -Q0 replaced the -QR and -QA modifier, modifier -Q1 replaced the -QV modifier. Modifier -Q0/-Q1 is no longer required for services performed on or after June 11, 2013.*

60.16 - Billing and Coverage Changes for PET Scans

(Rev.3162, Issued: 01-08-15, Effective: 06-11-13, Implementation: 05-19-14- MAC Non-Shared System Edits; July 7, 2014 - CWF development/testing, FISS requirement development; October 6, 2014 - CWF, FISS, MCS Shared System Edits)

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, and ovarian, unless the FDG PET is provided under the coverage with evidence development (CED) paradigm (billed with modifier -Q0/-Q1, see section 60.15 of this chapter).

Medicare will cover FDG PET imaging **for initial treatment strategy** for myeloma.

Effective for services performed on or after June 11, 2013, Medicare has ended the CED requirement for FDG PET and PET/CT and PET/MRI for all oncologic indications contained in section 220.6.17 of the NCD Manual. Effective for services on or after June 11, 2013, the -Q0/Q1 modifier is no longer required.

Beginning with services performed on or after June 11, 2013, contractors shall pay for up to three (3) FDG PET scans when used to guide subsequent management of anti-tumor treatment strategy (modifier –PS) after completion of initial anti-cancer therapy (modifier –PI) for the exact same cancer diagnosis.

Coverage of any additional FDG PET scans (that is, beyond 3) used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy for the same cancer diagnosis will be determined by the local MACs. Claims will include the –KX modifier indicating the coverage criteria is met for coverage of four or more FDG PET scans for subsequent treatment strategy for the same cancer diagnosis under this NCD.

A different cancer diagnosis whether submitted with a –PI or a –PS modifier will begin the count of one initial and three subsequent FDG PET scans not requiring the –KX modifier and four or more FDG PET scans for subsequent treatment strategy for the same cancer diagnosis requiring the –KX modifier.

NOTE: The presence or absence of an initial treatment strategy claim in a beneficiary's record does not impact the frequency criteria for subsequent treatment strategy claims for the same cancer diagnosis.

NOTE: Providers please refer to the following link for a list of appropriate diagnosis codes, http://cms.gov/medicare/coverage/determinationprocess/downloads/petforsolidtumorsoncologicdxcodesattachment_NCD220_6_17.pdf

For further information regarding the changes in coverage, refer to Pub.100-03, NCD Manual, section 220.6.17.

B. 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 for A/B MACs*

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 a 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 a cancer** diagnosis code **AND** modifier -Q0/Q1. *Effective for services performed on or after June 11, 2013, the CED requirement has ended and modifier -Q0/-Q1, along with condition code 30 (institutional claims only), or V70.7 (both institutional and practitioner claims) are no longer required*

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 (**CARC**) 4 – the procedure code is inconsistent with the modifier used or a required modifier is missing.

-Remittance Advice Remark Code (**RARC**) 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.

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

Also, effective for claims with dates of service on or after April 3, 2009, *through June 10, 2013*, 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** *a cancer* diagnosis code **AND** modifier *-Q0/-Q1*.

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

-CARC 4 – the procedure code is inconsistent with the modifier used or a required modifier is missing.

-RARC 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.

-RARC M16 - Alert: See our Web site, mailings, or bulletins for more details concerning this policy/procedure/decision.

Effective April 3, 2009, contractors shall **deny** claims with *ICD-9/ICD-10* diagnosis code *185/C61* for FDG PET imaging for the **initial treatment strategy** of patients with adenocarcinoma of the prostate.

For dates of service prior to June 11, 2013, 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, and ovarian, unless the FDG PET is provided under CED (submitted with the

-Q0/Q1 modifier) and use the following messages:

-Medicare Summary Notice 15.4 - Medicare 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.

-Contractors shall use Group Code CO (Contractual Obligation)

If the service is submitted with a -GA modifier indicating there is a signed Advance Beneficiary Notice (ABN) on file, the liability falls to the beneficiary. However, if the service is submitted with a -GZ modifier indicating no ABN was provided, the liability falls to the provider.

*Effective for dates of service on or after June 11, 2013, contractors shall use the following messages when denying claims in excess of **three** for PET FDG scans for subsequent treatment strategy when the **-KX** modifier is not included, identified by CPT codes 78608, 78811, 78812, 78813, 78814, 78815, or 78816, modifier **-PS**, HCPCS A9552, and the same cancer diagnosis code.*

CARC 96: “Non-Covered Charge(s). Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

RARC N435: “Exceeds number/frequency approved/allowed within time period without support documentation.”

MSN 23.17: “Medicare won’t cover these services because they are not considered medically necessary.”

Spanish Version: “Medicare no cubrirá estos servicios porque no son considerados necesarios por razones médicas.”

Contractors shall use Group Code PR assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.

Contractors shall use Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.