CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3227	**Date: April 2, 2015**
	Change Request 8614

Transmittal 3091, dated March 7, 2014, is being rescinded and replaced by Transmittal 3227 to incorporate information from CRs 8526 and 8739 that was erroneously overwritten. All other information remains the same.

SUBJECT: Update to Pub. 100-04 Chapter 13 to Provide Language-Only Changes for Updating ICD-10 and ASC X12

I. SUMMARY OF CHANGES: This CR contains language-only changes for updating ICD-10 and ASC X12 language in Pub 100-04, Chapter 13. Also, references to MACs replace the references to old contractor types in the chapter sections that are included in this CR. There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

EFFECTIVE DATE:

ICD-10: Upon Implementation of ICD-10
ASC-X12: January 1, 2012
Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013

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

IMPLEMENTATION DATE:

ICD-10: Upon Implementation of ICD-10
ASC X12: November 10, 2014
Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	13/Table of Contents
R	13/10/ICD Coding for Diagnostic Tests
R	13/30.1.3.1/A/B MAC (A)Payment for Low Osmolar Contrast Material (LOCM) (Radiology)

R	13/40.1.3/Special Billing Instructions for RHCs and FQHCs
R	13/40.1.4/Payment Requirements
R	13/40.2/Medicare Summary Notices (MSN), Reason Codes, and Remark Codes
R	13/60.1/Billing Instructions
R	13/60.12/Coverage for PET Scans for Dementia and Neurodegenerative Diseases
R	13/60.15/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
R	13/60.16/Billing and Coverage Changes for PET Scans
R	13/60.17/Billing and Coverage Changes for PET Scans for Cervical Cancer Effective for Services on or After November 10, 2009
R	13/60.18/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
R	13/130/EMC Formats
R	13/140.1/Payment Methodology and HCPCS Coding
R	13/150/Place of Service (POS) Instructions for the Professional Component (PC or Interpretation) and the Technical Component (TC) of Diagnostic Tests

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 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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 3227	Date: April 2, 2015	Change Request: 8614

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SUBJECT: Update to Pub. 100-04 Chapter 13 to Provide Language-Only Changes for Updating ICD-10 and ASC X12

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IMPLEMENTATION DATE: October 1, 2014

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I. GENERAL INFORMATION

A. Background: This CR contains language-only changes for updating ICD-10 and ASC X12 language in Pub 100-04, Chapter 13. Also, references to MACs replace the references to old contractor types in the chapter sections that are included in this CR.

B. Policy: There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

III. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
8614.1	A/B MACs shall be aware of the updated language for ICD-10 and for ASC X12 in Pub. 100 - 04, Chapter 13.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	H H H		
	None					

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Not applicable

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.

Medicare Claims Processing Manual
Chapter 13 - Radiology Services and Other Diagnostic Procedures

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(Rev. 3227, Issued 04-02-15)

10 - ICD Coding for Diagnostic Tests

(Rev. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

The ICD Coding Guidelines for Outpatient Services (hospital-based and physician office) have instructed physicians to report diagnoses based on test results. Instructions and examples for coding specialists, contractors, physicians, hospitals, and other health care providers to use in determining the use of ICD codes for coding diagnostic test results is found in chapter 23.

30.1.3.1 – *A/B MAC (A)* Payment for Low Osmolar Contrast Material (LOCM) (Radiology)

(Rev. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

The LOCM is paid on a reasonable cost basis when rendered by a SNF to its Part B patients (in addition to payment for the radiology procedure) when it is used in one of the situations listed below.

The following HCPCS are used when billing for LOCM.

HCPCS Code	Description (January 1. 1994, and later)
A4644	Supply of low osmolar contrast material (100-199 mgs of iodine);
A4645	Supply of low osmolar contrast material (200-299 mgs of iodine); or
A4646	Supply of low osmolar contrast material (300-399 mgs of iodine).

When billing for LOCM, SNFs use revenue code 0636. If the SNF charge for the radiology procedure includes a charge for contrast material, the SNF must adjust the charge for the radiology procedure to exclude any amount for the contrast material.

NOTE: LOCM is never billed with revenue code 0255 or as part of the radiology procedure.

The *A/B MAC (A)* will edit for the intrathecal procedure codes and the following codes to determine if payment for LOCM is to be made. If an intrathecal procedure code is not present, or one of the ICD codes is not present to indicate that a required medical condition is met, the *A/B MAC (A)* will deny payment for LOCM. In these instances, LOCM is not covered and should not be billed to Medicare.

When LOCM Is Separately Billable and Related Coding Requirements

- In all intrathecal injections. HCPCS codes that indicate intrathecal injections are:

  70010 70015 72240 72255 72265 72270 72285 72295

  One of these must be included on the claim; or

- In intravenous and intra-arterial injections only when certain medical conditions are present in an outpatient. The SNF must verify the existence of at least one of the following medical conditions, and report the applicable diagnosis code(s) either as a principal diagnosis code or other diagnosis codes on the claim:

  - A history of previous adverse reaction to contrast material. The applicable ICD-9-CM codes are V14.8 and V14.9. *The applicable ICD-10-CM codes are Z88.8 and Z88.9.* The conditions which should not be considered adverse reactions are a sensation of heat, flushing, or a single episode of nausea or vomiting. If the adverse reaction occurs on that visit with the induction of contrast material, codes describing hives, urticaria, etc. should also be present, as well as a code describing the external cause of injury and poisoning, *ICD-9-CM code* E947.8. *The applicable ICD-10 CM codes are: T50.8X5A Adverse effect of diagnostic agents, initial encounter, T50.8X5S Adverse effect of diagnostic agents, sequela , T50.995A Adverse effect of other drugs, medicaments and biological substances, initial encounter, or T50.995S Adverse effect of other drugs, medicaments and biological substances, sequela;*

  - A history or condition of asthma or allergy. The applicable ICD-9-CM codes are V07.1, V14.0 through V14.9, V15.0, 493.00, 493.01, 493.10, 493.11, 493.20, 493.21, 493.90, 493.91, 495.0, 495.1, 495.2, 495.3, 495.4, 495.5, 495.6, 495.7, 495.8, 495.9, 995.0, 995.1, 995.2, and 995.3. *The applicable ICD-10-CM codes are in the table below:*

ICD-10-CM Codes						
J44.0	*J44.9*	*J45.20*	*J45.22*	*J45.30*	*J45.32*	*J45.40*
J45.42	*J45.50*	*J45.52*	*J45.902*	*J45.909*	*J45.998*	*J67.0*
J67.1	*JJ67.2*	*J67.3*	*J67.4*	*J67.5*	*J67.6*	*J67.7*
J67.8	*J67.9*	*J96.00*	*J96.01*	*J96.02*	*J96.90*	*J96.91*
J96.92	*T36.0X5A*	*T36.1X5A*	*T36.2X5A*	*T36.3X5A*	*T36.4X5A*	*T36.5X5A*
T36. 6X5A	*T36.7X5A*	*T36.8X5A*	*T36.95XA*	*T37.0X5A*	*T37.1X5A*	*T37.2X5A*

ICD-10-CM Codes						
T37.3X5A	*T37.8X5A*	*T37.95XA*	*T38.0X5A*	*T38.1X5A*	*T38.2X5A*	*T38.3X5A*
T38.4X5A	*T38.6X5A*	*T38.7X5A*	*T38.805A*	*T38.815A*	*T38.895A*	*T38.905A*
T38.995A	*T39.015A*	*T39.095A*	*T39.1X5A*	*T39.2X5A*	*T39.2X5A*	*T39.315A*
T39.395A	*T39.4X5A*	*T39.8X5A*	*T39.95XA*	*T40.0X5A*	*T40.1X5A*	*T40.2X5A*
T40.3X5A	*T40.4X5A*	*T40.5X5A*	*T40.605A*	*T40.695A*	*T40.7X5A*	*T40.8X5A*
T40.905A	*T40.995A*	*T41.0X5A*	*T41.1X5A*	*T41.205A*	*T41.295A*	*T41.3X5A*
T41.4X5A	*T41.X5A*	*T41.5X5A*	*T42.0X5A*	*T42.1X5A*	*T42.2X5A*	*T42.3X5A*
T42.4X5A	*T42.5X5A*	*T42.6X5A*	*427.5XA*	*428.X5A*	*T43.015A*	*T43.025A*
T43.1X5A	*T43.205A*	*T43.215A*	*T43.225A*	*T43.295A*	*T43.3X5A*	*T43.4X5A*
T43.505A	*T43.595A*	*T43.605A*	*T43.615A*	*T43.625A*	*T43.635A*	*T43.695A*
T43.8X5A	*T43.95XA*	*T44.0X5A*	*T44.1X5A*	*T44.2X5A*	*T44.3X5A*	*T44.6X5A*
T44.7X5A	*T44.8X5A*	*T44.905A*	*T44.995A*	*T45.0X5A*	*T45.1X5A*	*T45.2X5A*
T45.3X5A	*T45.4X5A*	*T45.515A*	*T45.525A*	*T45.605A*	*T45.615A*	*T45.625A*
T45.695A	*T45.7X5A*	*T45.8X5A*	*T45.95XA*	*T46.0X5A*	*T46.1X5A*	*T46.2X5A*
T46.3X5A	*T46.4X5A*	*T46.5X5A*	*T46.6X5A*	*T46.7X5A*	*T46.8X5A*	*T46.905A*
T46.995A	*T47.0X5A*	*T47.1X5A*	*T47.2X5A*	*T47.3X5A*	*T47.4X5A*	*T47.5X5A*
T47.6X5A	*T47.7X5A*	*T47.8X5A*	*T47.95XA*	*T48.0X5A*	*T48.1X5A*	*T48.205A*
T48.295A	*T48.3X5A*	*T48.4X5A*	*T48.5X5A*	*T48.6X5A*	*T48.905A*	*T48.995A*
T49.0X5A	*T49.1X5A*	*T49.2X5A*	*T49.3X5A*	*T49.4X5A*	*T49.5X5A*	*T49.6X5A*
T49.6X5A	*T47.X5A9*	*T49.8X5A*	*T49.95XA*	*T50.0X5A*	*T50.1X5A*	*T50.2X5A*
T50.3X5A	*T50.4X5A*	*T50.5X5A*	*T50.6X5A*	*T50.7X5A*	*T50.8X5A*	*T50.905a*
T50.995A	*T50.A15A*	*T50.A25A*	*T50.A95A*	*T50.B15A*	*T50.B95A*	*T50.Z15A*
T50.Z95A	*T78.2XXA*	*T78.3XXA*	*T78.40XA*	*T78.41XA*	*T88.52XA*	*T88.59XA*
T88.6XXA	*Z51.89*	*Z88.0*	*Z88.1*	*Z88.2*	*Z88.3*	*Z88.4*
Z88.5	*Z88.6*	*Z88.7*	*Z88.8*	*Z88.9*	*Z91.010*	

- Significant cardiac dysfunction including recent or imminent cardiac decompensation, severe arrhythmia, unstable angina pectoris, recent myocardial infarction, and pulmonary hypertension. *The applicable ICD-9-CM codes are*:

ICD-9-CM							
402.00	402.01	402.10	402.11	402.90	402.91		
404.00	404.01	404.02	404.03				
404.10	404.11	404.12	404.13				
404.90	404.91	404.92	404.93				
410.00	410.01	410.02	410.10	410.11	410.12		
410.20	410.21	410.22	410.30	410.31	410.32		
410.40	410.41	410.42	410.50	410.51	410.52		
410.60	410.61	410.62	410.70	410.71	410.72		
410.80	410.81	410.82	410.90	410.91	410.92		
411.1	415.0	416.0	416.1	416.8	416.9		
420.0	420.90	420.91	420.99	424.90	424.91		
424.99	427.0	427.1	427.2	427.31	427.32		

ICD-9-CM							
427.41	427.42	427.5	427.60	427.61	427.69		
427.81	427.89	427.9	428.0	428.1	428.9	429.0	
429.1	429.2	429.3	429.4	429.5	429.6	429.71	
429.79	429.81	429.82	429.89	429.9	785.50	785.51	785.59

- *The applicable ICD-10-CM codes are in the table below:*

ICD-10-CM Codes						
A18.84	*I11.0*	*I11.9*	*I13.0*	*I13.10*	*I13.11*	*I13.2*
I20.0	*I21.01*	*I21.02*	*I21.09*	*I21.11*	*I21.19*	*I21.21*
I21.29	*I21.3*	*I21.4*	*I22.1*	*I22.2*	*I22.8*	*I23.0*
I23.1	*I23.2*	*I23.3*	*I23.4*	*I23.5*	*I23.6*	*I23.7*
I23.8	*I25.10*	*I25.110*	*I25.700*	*I25.710*	*I25.720*	*I25.730*
I25.750	*I25.760*	*I25.790*	*I26.01*	*I26.02*	*I26.09*	*I27.0*
I27.1	*I27.2*	*I27.81*	*I27.89*	*I27.9*	*I30.0*	*I30.1*
I30.8	*I30.9*	*I32*	*I38*	*I39*	*I46.2*	*I46.8*
I46.9	*I47.0*	*I471*	*I472*	*I47.9*	*I48.0*	*I48.1*
I48.1	*I48.2*	*I48.3*	*I48.4*	*I48.91*	*I48.92*	*I49.01*
I49.02	*I49.1*	*I49.2*	*I49.3*	*I49.40*	*I49.49*	*I49.5*
I49.8	*I49.9*	*I50.1*	*I50.20*	*I50.21*	*I50.22*	*I50.23*
I50.30	*I50.31*	*I50.32*	*I50.33*	*I50.40*	*I50.41*	*I50.42*
I50.43	*I50.9*	*I51*	*I51.0*	*I51.1*	*I51.2*	*I51.3*
I51.4	*I51.5*	*I51.7*	*I51.89*	*I51.9*	*I52*	*I97.0*
I97.110	*I97.111*	*I97.120*	*I97.121*	*I97.130*	*I97.131*	*I97.190*
I97.191	*M32.11*	*M32.12*	*R00.1*	*R57.0*	*R57.8*	*R57.9*

- Generalized severe debilitation. The applicable ICD-9-CM codes are: 203.00, 203.01, all codes for diabetes mellitus, 518.81, 585, 586, 799.3, 799.4, and V46.1. *The applicable ICD-10-CM codes are: J96.850, J96.00 through J96.02, J96.90 through J96.91, N18.1 through N19, R53.81, R64, and Z99.11 through Z99.12.* Or

- Sickle Cell disease. The applicable ICD-9-CM codes are 282.4, 282.60, 282.61, 282.62, 282.63, and 282.69. *The applicable ICD-10-CM codes are D56.0 through D56.3, D56.5 through D56.9, D57.00 through D57.1, D57.20, D57.411 through D57.419, and D57.811 through D57.819.*

40.1.3 - Special Billing Instructions for RHCs and FQHCs

(Rev. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

Independent RHCs and free-standing FQHCs bill under bill type 71X and 73X for the professional component utilizing revenue codes 520 and 521 as appropriate. HCPCS coding is not required. The technical component is outside the scope of the RHC/FQHC benefit. The provider of the technical service bills *using the ASC X12 837 professional claim format or* on Form CMS-1500.

The technical component for a provider based RHC/FQHC is typically furnished by the provider. The provider of that service bills under bill type 13X or 85X as appropriate using its outpatient provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services). Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for radiology services.

40.1.4 - Payment Requirements

(Rev. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

For claims with dates of service on and after February 24, 2011, the following diagnosis code and modifier shall be reported on MRI claims for beneficiaries with implanted PMs, that are outside FDA-approved labeling for use in an MRI environment (in a Medicare-approved clinical study):

- Appropriate MRI code
- Q0 modifier
- Condition code 30 (for institutional claims)
- ***If ICD-9-CM is applicable***
    - ICD-9 code V70.7- Examination of participant in clinical trial (for institutional claims)
    - ICD-9 code V45.02 (automatic implantable cardiac defibrillator) or
    - ICD-9 code V45.01 (cardiac pacemaker)

- ***If ICD-10-CM is applicable***
    - Z00.6 - Encounter for examination for normal comparison and control in clinical research program
    - Z95.810 - Presence of automatic (implantable) cardiac defibrillator or
    - Z95.0 - Presence of cardiac pacemaker

For claims with dates of services on and after July 7, 2011, the following codes shall be reported on MRI claims for beneficiaries with implanted PMs that have FDA-approved labeling for use in an MRI environment:

- Appropriate MRI code
- KX modifier
- ***If ICD-9-CM is applicable***
    - ICD-9 code V45.01 (cardiac pacemaker)
- ***If ICD-10-CM is applicable***
    - ICD-10 code Z95.0 (cardiac pacemaker)

Payment is as follows:

- Professional claims (practitioners and suppliers) - based on the Medicare Physician Fee Schedule (MPFS)

- Inpatient (11x) - Prospective payment system (PPS), based on the diagnosis-related group

- Hospital outpatient departments (13x) - Outpatient PPS, based on the ambulatory payment classification

- Rural Health Clinics/Federally Qualified Health Centers (RHCs/FQHCs) (71x/77x) - All-inclusive rate, professional component only, based on the visit furnished to the RHC/FQHC beneficiary to receive the MRI. The technical component is outside the scope of the RHC/FQHC benefit. Therefore the provider of the technical service bills their *A/B MAC (B)* on the *ASC X12 837 professional claim format* or hardcopy Form CMS-1500 and payment is made under the MPFS.

- Critical access hospitals (CAHs) (85x) –

    - For CAHs that elected the optional method of payment for outpatient services, the payment for technical services would be the same as the CAHs that did not elect the optional method - Reasonable cost.

    - The *A/B MAC (A)* pays the professional component at 115% of the MPFS.

Deductible and coinsurance apply.

40.2 - Medicare Summary Notices (MSN), Reason Codes, and Remark Codes

(Rev. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron

Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

When denying MRI line items on institutional claims when billed with the appropriate MRI code and modifier KX is not present, use the following messages:

If ICD-9-CM is applicable, ICD-9 code V45.01

If ICD-10-CM is applicable, ICD-10 code Z95.0

- CARC 188 – This product/procedure is only covered when used according to the FDA recommendations

- MSN 21.8 – Services performed using equipment that has not been approved by the Food and Drug Administration are not covered. Spanish Version - "Servicios rendidos usando equipo que no es aprobado por la Administración de Alimentos y Drogas no son cubiertos".

When denying MRI line items on professional claims and modifier KX is not present, use the following messages*:*

If ICD-9-CM is applicable, ICD-9 code V45.01

If ICD-10-CM is applicable, ICD-10 code Z95.0

- CARC 188 - This product/procedure is only covered when used according to the FDA recommendations

- MSN 21.8 - Services performed using equipment that has not been approved by the Food and Drug Administration are not covered

When denying MRI line items that do not include all of the following line items:

- An appropriate MRI code,

- *If ICD-9-CM is applicable,* ICD-9 code V45.02 (automatic implantable cardiac defibrillator) or ICD-9 code V45.01 (cardiac pacemaker),

- *ICD-10-CM is applicable, ICD-10 code Z95.810* (automatic implantable cardiac defibrillator)*or ICD-10 code Z95.0* (cardiac pacemaker),

- Modifier Q0,

- *If ICD-9-CM is applicable, ICD-9 code V70.7 Examination of participant in clinical trial (for institutional claims only)or*

- *If ICD-10-CM is applicable, ICD-10 code Z00.6 – Examination of participant in clinical trial (for institutional claims only), and*

- Condition code 30 (for institutional claims only), use the following messages:

  - CARC B5 - Coverage/program guidelines were not met or exceeded

  - RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

  - MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances. Spanish Version - Este servicio fue denegado porque Medicare solamente lo cubre bajo ciertas circunstancias.

60.1 - Billing Instructions

(Rev. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

A. Billing and Payment Instructions or Responsibilities for *A/B MACs (B)*

Claims for PET scan services must be billed *using the ASC X12 837 professional claim format or* on Form-CMS 1500 with the appropriate HCPCS or CPT code and diagnosis codes to the *A/B MAC (B)*. Effective for claims received on or after July 1, 2001, PET modifiers were discontinued and are no longer a claims processing requirement for PET scan claims. Therefore, July 1, 2001, and after the MSN messages regarding the use of PET modifiers can be discontinued. The type of service (TOS) for the new PET scan procedure codes is TOS 4, Diagnostic Radiology. Payment is based on the Medicare Physician Fee Schedule.

B. Billing and Payment Instructions or Responsibilities for *A/B MACs (A)*

Claims for PET scan procedures must be billed to the *A/B MAC (A)* on the ASC X12 837 institutional claim format or on Form CMS-1450 with the appropriate diagnosis and HCPCS “G” code or CPT code to indicate the conditions under which a PET scan was

done. These codes represent the technical component costs associated with these procedures when furnished to hospital and SNF outpatients. They are paid as follows:

- under OPPS for hospitals subject to OPPS
- under current payment methodologies for hospitals not subject to OPPS
- on a reasonable cost basis for critical access hospitals.
- on a reasonable cost basis for skilled nursing facilities.

Institutional providers bill these codes under Revenue Code 0404 (PET Scan).

Medicare contractors shall pay claims submitted for services provided by a critical access hospital (CAH) as follows: Method I technical services are paid at 101% of reasonable cost; Method II technical services are paid at 101% of reasonable cost, and professional services are paid at 115% of the Medicare Physician Fee Schedule Data Base.

C. Frequency

In the absence of national frequency limitations, for all indications covered on and after July 1, 2001, contractors can, if necessary, develop frequency limitations on any or all covered PET scan services.

D. Post-Payment Review for PET Scans

As with any claim, but particularly in view of the limitations on this coverage, Medicare may decide to conduct post-payment reviews to determine that the use of PET scans is consistent with coverage instructions. Pet scanning facilities must keep patient record information on file for each Medicare patient for whom a PET scan claim is made. These medical records can be used in any post-payment reviews and must include the information necessary to substantiate the need for the PET scan. These records must include standard information (e.g., age, sex, and height) along with sufficient patient histories to allow determination that the steps required in the coverage instructions were followed. Such information must include, but is not limited to, the date, place and results of previous diagnostic tests (e.g., cytopathology and surgical pathology reports, CT), as well as the results and reports of the PET scan(s) performed at the center. If available, such records should include the prognosis derived from the PET scan, together with information regarding the physician or institution to which the patient proceeded following the scan for treatment or evaluation. The ordering physician is responsible for forwarding appropriate clinical data to the PET scan facility.

Effective for claims received on or after July 1, 2001, CMS no longer requires paper documentation to be submitted up front with PET scan claims. Contractors shall be aware and advise providers of the specific documentation requirements for PET scans for dementia and neurodegenerative diseases. This information is outlined in section 60.12. Documentation requirements such as physician referral and medical necessity determination are to be maintained by the provider as part of the beneficiary's medical

record. This information must be made available to the *A/B MAC (A or B)* upon request of additional documentation to determine appropriate payment of an individual claim.

60.12 - Coverage for PET Scans for Dementia and Neurodegenerative Diseases

(Rev. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

Effective for dates of service on or after September 15, 2004, Medicare will cover FDG PET scans for a differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease OR; its use in a CMS-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases. Refer to Pub. 100-03, NCD Manual, section 220.6.13, for complete coverage conditions and clinical trial requirements and section 60.15 of this manual for claims processing information.

A. *A/B MAC (A and B)* Billing Requirements for PET Scan Claims for FDG-PET for the Differential Diagnosis of Fronto-temporal Dementia and Alzheimer's Disease:

CPT Code for PET Scans for Dementia and Neurodegenerative Diseases

Contractors shall advise providers to use the appropriate CPT code from section 60.3.1 for dementia and neurodegenerative diseases for services performed on or after January 28, 2005.

Diagnosis Codes for PET Scans for Dementia and Neurodegenerative Diseases

The contractor shall ensure one of the following appropriate diagnosis codes is present on claims for PET Scans for AD:

- *If ICD-9-CM is applicable, ICD-9 codes are:* 290.0, 290.10 - 290.13, 290.20 - 290, 21, 290.3, 331.0, 331.11, 331.19, 331.2, 331.9, 780.93

- *If ICD-10-CM is applicable, ICD-10 codes are: F03.90, F03.90 plus F05, G30.9, G31.01, G31.9, R41.2 or R41.3*

Medicare contractors shall use an appropriate Medicare Summary Notice (MSN) message such as 16.48, "Medicare does not pay for this item or service for this condition" to deny claims when submitted with an appropriate CPT code from section 60.3.1 and with a

diagnosis code other than the range of codes listed above. Also, contractors shall use an appropriate Remittance Advice (RA) such as 11, “The diagnosis is inconsistent with the procedure."

Medicare contractors shall instruct providers to issue an Advanced Beneficiary Notice to beneficiaries advising them of potential financial liability prior to delivering the service if one of the appropriate diagnosis codes will not be present on the claim.

Provider Documentation Required with the PET Scan Claim

Medicare contractors shall inform providers to ensure the conditions mentioned in the NCD Manual, section 220.6.13, have been met. The information must also be maintained in the beneficiary's medical record:

- Date of onset of symptoms;
- Diagnosis of clinical syndrome (normal aging, mild cognitive impairment or MCI: mild, moderate, or severe dementia);
- Mini mental status exam (MMSE) or similar test score;
- Presumptive cause (possible, probably, uncertain AD);
- Any neuropsychological testing performed;
- Results of any structural imaging (MRI, CT) performed;
- Relevant laboratory tests (B12, thyroid hormone); and,
- Number and name of prescribed medications.

B. Billing Requirements for Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease:

Effective for claims with dates of service on and after September 27, 2013, Medicare will only allow coverage with evidence development (CED) for Positron Emission Tomography (PET) beta amyloid (also referred to as amyloid-beta (Aβ)) imaging (HCPCS A9586)or (HCPCS **A9599)** (one PET Aβ scan per patient).

NOTE: Please note that effective January 1, 2014 the following code A9599 will be updated in the IOCE and HCPCS update. This code will be contractor priced.

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

Effective for dates of service on or after September 27, 2013, contractors shall **return as unprocessable/return to provider** claims for PET Aβ imaging, through CED during a clinical trial, not containing the following:

- Condition code 30, (FI only)
- Modifier Q0 and/or modifier Q1 as appropriate

- ICD-9 dx code V70.7/ICD-10 dx code Z00.6 (on either the primary/secondary position)
- A PET HCPCS code (78811 or 78814)
- At least, one Dx code from the table below,

ICD-9 Codes	**Corresponding ICD-10 Codes**
290.0 Senile dementia, uncomplicated	F03.90 Unspecified dementia without behavioral disturbance
290.10 Presenile dementia, uncomplicated	F03.90 Unspecified dementia without behavioral disturbance
290.11 Presenile dementia with delirium	F03.90 Unspecified dementia without behavioral disturbance
290.12 Presenile dementia with delusional features	F03.90 Unspecified dementia without behavioral disturbance
290.13 Presenile dementia with depressive features	F03.90 Unspecified dementia without behavioral disturbance
290.20 Senile dementia with delusional features	F03.90 Unspecified dementia without behavioral disturbance
290.21 Senile dementia with depressive features	F03.90 Unspecified dementia without behavioral disturbance
290.3 Senile dementia with delirium	F03.90 Unspecified dementia without behavioral disturbance
290.40 Vascular dementia, uncomplicated	F01.50 Vascular dementia without behavioral disturbance
290.41 Vascular dementia with delirium	F01.51 Vascular dementia with behavioral disturbance
290.42 Vascular dementia with delusions	F01.51 Vascular dementia with behavioral disturbance
290.43 Vascular dementia with depressed mood	F01.51 Vascular dementia with behavioral disturbance
294.10 Dementia in conditions classified elsewhere without behavioral disturbance	F02.80 Dementia in other diseases classified elsewhere without behavioral disturbance
294.11 Dementia in conditions classified elsewhere with behavioral disturbance	F02.81 Dementia in other diseases classified elsewhere with behavioral disturbance
294.20 Dementia, unspecified, without behavioral disturbance	F03.90 Unspecified dementia without behavioral

	disturbance
294.21 Dementia, unspecified, with behavioral disturbance	F03.91 Unspecified dementia with behavioral disturbance
331.11 Pick's Disease	G31.01 Pick's disease
331.19 Other Frontotemporal dementia	G31.09 Other frontotemporal dementia
331.6 Corticobasal degeneration	G31.85 Corticobasal degeneration
331.82 Dementia with Lewy Bodies	G31.83 Dementia with Lewy bodies
331.83 Mild cognitive impairment, so stated	G31.84 Mild cognitive impairment, so stated
780.93 Memory Loss	R41.1 Anterograde amnesia R41.2 Retrograde amnesia R41.3 Other amnesia (Amnesia NOS, Memory loss NOS)
V70.7 Examination for normal comparison or control in clinical	Z00.6 Encounter for examination for normal comparison and control in clinical research program

and

- Aβ HCPCS code A9586 or A9599

Contractors shall return as unprocessable claims for PET Aβ imaging using 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 N517 - Resubmit a new claim with the requested information.

- Remittance Advice Remark Code N519 - Invalid combination of HCPCS modifiers.

Contractors shall line-item **deny** claims for PET Aβ , HCPCS code A9586 or A9599 , where a previous PET Aβ, HCPCS code A9586 or A9599 is paid in history using the following messages:

- CARC 149: "Lifetime benefit maximum has been reached for this service/benefit category."

- RARC N587: "Policy benefits have been exhausted".

- MSN 20.12: “This service was denied because Medicare only covers this service once a lifetime.”

- Spanish Version: “Este servicio fue negado porque Medicare sólo cubre este servicio una vez en la vida.”

- Group Code: PR, if a claim is received with a GA modifier

- Group Code: CO, if a claim is received with a GZ modifier

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. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

A/B MACs (A and B)

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.

A/B MACs (B) Only

A/B MACs (B) 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.

A/B MACs (A) Only

In order to pay claims for PET scans on behalf of beneficiaries participating in a CMS-approved clinical trial, *A/B* MACs *(A)* require providers to submit claims with, *if ICD-9-CM is applicable,* ICD-9 code V70.7; *if ICD-10-CM is applicable*, ICD-10 code Z00.6 in the primary/secondary diagnosis position *using the ASC X12 837 institutional claim format* or on *Form* CMS-1450, 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/B MACs (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. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

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 *A/B* MACs *(A or B)*. 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 *(A and B)*

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 *ICD-9 code* 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.

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.

60.17 – Billing and Coverage Changes for PET Scans for Cervical Cancer Effective for Services on or After November 10, 2009

(Rev. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

A. Billing Changes for A/B MACs *(A and B)*

Effective for claims with dates of service on or after November 10, 2009, contractors shall accept FDG PET oncologic claims billed to inform initial treatment strategy; specifically for staging in beneficiaries who have biopsy-proven cervical cancer when the beneficiary's treating physician determines the FDG PET study is needed to determine the location and/or extent of the tumor as specified in Pub. 100-03, section 220.6.17.

EXCEPTION: CMS continues to non-cover FDG PET for initial diagnosis of cervical cancer related to initial treatment strategy.

NOTE: Effective for claims with dates of service on and after November 10, 2009, the –Q0 modifier is no longer necessary for FDG PET for cervical cancer.

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

Adjustment Reason Codes
Additionally, contractors shall return as unprocessable /return to provider for FDG PET for cervical cancer for initial treatment strategy billed without the following: one of the PET/PET/ CT CPT codes listed in 60.16 C above **AND** modifier PI **AND** *a* cervical cancer diagnosis code.
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.

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. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

A. Billing Changes for A/B MACs *(A and B)*

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 *A/B MACs (A)* 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
- *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 *ICD-9* diagnosis code V70.7 *or ICD-10 diagnosis code Z00.6* 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 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
- *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 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.

130 - EMC Formats

(Rev. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

Billing instructions for *the ASC X12 837 institutional claim format can be found in chapter 24 of this manual or, for* Form CMS-1450 can be found in chapter 25 of this manual. Each revenue code requires a HCPCS code, modifier if applicable, units, line-item date of service, and charge.

Billing instructions for *the ASC X12 837 professional claim format can be found in chapter 24 of this manual or for* Form CMS-1500 can be found in *this* manual, *Chapter* 26, “Instructions for Completing Form CMS-1500."

140.1 - Payment Methodology and HCPCS Coding

(Rev. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

A/B MAC (B) pay for BMM procedures based on the Medicare physician fee schedule. Claims from physicians, other practitioners, or suppliers where assignment was not taken are subject to the Medicare limiting charge.

The *A/B MACs (A)* pay for BMM procedures under the current payment methodologies for radiology services according to the type of provider.

Do not pay BMM procedure claims for dual photon absorptiometry, CPT procedure code 78351.

Deductible and coinsurance apply.

Any of the following CPT procedure codes may be used when billing for BMMs through December 31, 2006. All of these codes are bone densitometry measurements except code 76977, which is bone sonometry measurements. CPT procedure codes are applicable to billing *A/B MACs (A and B)*.

76070 76071 76075 76076 76078 76977 78350 G0130

Effective for dates of services on and after January 1, 2007, the following changes apply to BMM:

- New 2007 CPT bone mass procedure codes have been assigned for BMM. The following codes will replace current codes, however the CPT descriptors for the services remain the same:

  77078 replaces 76070
  77079 replaces 76071
  77080 replaces 76075
  77081 replaces 76076
  77083 replaces 76078

- Certain BMM tests are covered when used to screen patients for osteoporosis subject to the frequency standards described in chapter 15, section 80.5.5 of the Medicare Benefit Policy Manual.

    - Contractors will pay claims for screening tests when coded as follows:

        - Contains CPT procedure code 77078, 77079, 77080, 77081, 77083, 76977 or G0130, and

        - Contains a valid diagnosis code indicating the reason for the test is postmenopausal female, vertebral fracture, hyperparathyroidism, or steroid therapy. Contractors are to maintain local lists of valid codes for the benefit's screening categories.

    - Contractors will deny claims for screening tests when coded as follows:

        - Contains CPT procedure code 77078, 77079, 77081, 77083, 76977 or G0130, but

        - Does not contain a valid diagnosis code from the local lists of valid diagnosis codes maintained by the contractor for the benefit's screening categories indicating the reason for the test is postmenopausal female, vertebral fracture, hyperparathyroidism, or steroid therapy.

- Dual-energy x-ray absorptiometry (axial) tests are covered when used to monitor FDA-approved osteoporosis drug therapy subject to the 2-year frequency standards described in chapter 15, section 80.5.5 of the Medicare Benefit Policy Manual.

    - Contractors will pay claims for monitoring tests when coded as follows:

        - Contains CPT procedure code 77080, and

        - Contains 733.00, 733.01, 733.02, 733.03, 733.09, 733.90, or 255.0 as the ICD-9-CM diagnosis code *or M81.0, M81.8, M81.6 or M94.9 as the ICD-10-CM diagnosis code.*

    - Contractors will deny claims for monitoring tests when coded as follows:

        - Contains CPT procedure code 77078, 77079, 77081, 77083, 76977 or G0130, and

        - Contains 733.00, 733.01, 733.02, 733.03, 733.09, 733.90, or 255.0 as the ICD-9-CM diagnosis code, but

- Does not contain a valid ICD-9-CM diagnosis code from the local lists of valid ICD-9-CM diagnosis codes maintained by the contractor for the benefit's screening categories indicating the reason for the test is postmenopausal female, vertebral fracture, hyperparathyroidism, or steroid therapy.

- *Does not contain a valid ICD-10-CM diagnosis code from the local lists of valid ICD-10-CM diagnosis codes maintained by the contractor for the benefit's screening categories indicating the reason for the test is postmenopausal female, vertebral fracture, hyperparathyroidism, or steroid therapy.*

- Single photon absorptiometry tests are not covered. Contractors will deny CPT procedure code 78350.

The *A/B MACs (A)* are billed using the *ASC X12 837 institutional claim format* or hardcopy Form CMS-1450. The appropriate bill types are: 12X, 13X, 22X, 23X, 34X, 71X (Provider-based and independent), 72X, 73X (Provider-based and freestanding), 83X, and 85X. Effective April 1, 2006, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for bone mass measurements. Information regarding the claim form locators that correspond to the HCPCS/CPT code or Type of Bill are found in chapter 25.

Providers must report HCPCS codes for bone mass measurements under revenue code 320 with number of units and line item dates of service per revenue code line for each bone mass measurement reported.

A/B MACs (B) are billed for bone mass measurement procedures using the *ASC X12 837 professional claim format* or hardcopy Form CMS-1500.

150 - Place of Service (POS) Instructions for the Professional Component (PC or Interpretation) and the Technical Component (TC) of Diagnostic Tests

(Rev. 3227, Issued: 04-02-15, Effective; ASC-X12: January 1, 2012 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: June 11, 2013, ICD-10: Upon Implementation of ICD-10 Implementation: ASC X12: November 10, 2014 Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors: 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), ICD-10: Upon Implementation of ICD-10)

Many of the diagnostic services, including radiology services, provided by physicians/practitioners contain both a technical component (TC) and a professional component (PC). Often, the PC and TC of diagnostic services are furnished in different settings. As a general policy, the POS code assigned by the physician/practitioner for the

PC of a diagnostic service shall be the setting in which the beneficiary received the TC service.

A. Interpretation Provided Telephonically by Wireless Remote

Teleradiology services (radiology services that do not require a face-to-face encounter with the patient furnished through the use of a telecommunications system) are discussed in Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 30. The interpretation of an x-ray, electrocardiogram, electroencephalogram and tissue samples are listed as examples of these services.

In cases where the face-to-face requirement is obviated such as those when a physician/practitioner provides the PC/interpretation of a diagnostic test, from a distant site, the POS code assigned by the physician /practitioner shall be the setting in which the beneficiary received the TC service. The POS code for a teleradiology interpretation is generally the place where the beneficiary received the TC, or face-to-face encounter. The POS code representing the setting where the beneficiary received the TC is entered *in the ASC X12 837 professional claim format or in* item 24B on the paper claim Form CMS 1500. In cases where it is unclear which POS code applies, the Medicare contractor can provide guidance.

For example: A beneficiary receives an MRI at an outpatient hospital near his/her home. The outpatient hospital submits a claim that would correspond to the TC portion of the MRI. The physician furnishes the PC portion of the beneficiary's MRI from his/her office location - POS code 22(Outpatient Hospital) shall be used on the physician's claim to indicate that the beneficiary received the face-to-face portion of the MRI, the TC, at the outpatient hospital.

B. Interpretation Provided Outside of the United States

Generally, Medicare will not pay for health care or supplies that are performed outside the United States (U.S.). The term "outside the U.S." means anywhere other than the 50 states of the U.S., the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. See Pub. 100-02, chapter 16, section 60, for exceptions to the "outside the U.S." exclusions.

C. Interpretation Provided Under Arrangement --To A Hospital

Separate TC and PC

If a diagnostic test which has a separate TC and PC is provided under arrangement to a hospital, the physician who reads the test can bill and be paid for the professional component. Both the technical and professional components of the test are also subject to the physician self-referral prohibition.

The appropriate POS code for the interpretation (or PC) is the setting where the beneficiary received the TC service. If the interpretation is performed in the physician's office and the patient received the TC service in the provider-based outpatient hospital setting, the physician assigns POS code 22, for outpatient hospital, on the claim for the interpretation or PC.

Global Service

When a physician performs a diagnostic test under arrangement to a hospital and the test and the interpretation are not separately billable, the interpretation cannot be billed by the physician. In this scenario, the hospital is the only entity that can bill for the diagnostic test which encompasses the interpretation. There is no POS code for the interpretation since a physician claim is not generated.

D. Global Billing

Billing globally for services that are split into PC and TC components is only possible when the TC and the physician who provides the PC of the diagnostic service are furnished by the same physician or supplier entity and the PC and TC components are furnished within the same Medicare physician fee schedule payment locality. Merely applying the same POS code to the PC as that of the TC (as described in "A" above) does not permit global billing for any diagnostic procedure.

E. Determination of Payment Locality

Under the Medicare physician fee schedule (MPFS), payment amounts are based on the relative resources required to provide services and vary among payment localities as resource costs vary geographically as measured by the geographic practice cost indices (GPCIs). The payment locality is determined based on the location where a specific service code was furnished. For purposes of determining the appropriate payment locality, CMS requires that the address, including the ZIP code for each service code be included on the claim form in order to determine the appropriate payment locality. The location in which the service code was furnished is entered *on the ASC X12 837 professional claim format or* in Item 32 on the paper claim Form CMS 1500.

Global Service Code

If the global diagnostic service code is billed, the biller (either the entity that took the test, physician who interpreted the test, or separate billing agent) must report the address and ZIP code of where the test was furnished on the bill for the global diagnostic service code. In other words, when the global diagnostic service code is billed, for example, chest x-ray as described by HCPCS code 71010 (no modifier TC and no modifier -26), the locality is determined by the ZIP code applicable to the testing facility, i.e. where the TC of the chest x-ray was furnished. The testing facility (or its billing agent) enters the address and ZIP code of the setting/location where the test took place. This practice location is entered *using the ASC X12 837 professional claim format or* in Item 32 on the

paper claim Form CMS 1500. As explained in D above, in order to bill for a global diagnostic service code, the same physician or supplier entity must furnish both the TC and the PC of the diagnostic service and the TC and PC must be furnished within the same MPFS payment locality.

Separate Billing of Professional Interpretation

If the same physician or other supplier entity does not furnish both the TC and PC of the diagnostic service, or if the same physician or other supplier entity furnishes both the TC and PC but the professional interpretation was furnished in a different payment locality from where the TC was furnished, the professional interpretation of a diagnostic test must be separately billed with modifier -26 by the interpreting physician.

When the physician's interpretation of a diagnostic test is billed separately from the technical component, as identified by modifier -26, the interpreting physician (or his or her billing agent) must report the address and ZIP code of the interpreting physician's location on the claim form. If the professional interpretation was furnished at an unusual and infrequent location for example, a hotel, the locality of the professional interpretation is determined based on the Medicare enrolled location where the interpreting physician most commonly practices. The address and ZIP code of this practice location is entered using the ASC X12 837 professional claim format or in Item 32 on the paper claim Form CMS 1500.