CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2307	**Date: September 22, 2011**
	Change Request 7441

NOTE: Transmittal 2293, dated August 26, 2011, is being rescinded and replaced by Transmittal 2307, dated September 22, 2011 to include carrier responsibility in BR's 7441-04.2, 7441-04.2.1, and 7441-04.2.2. All other information remains the same.

SUBJECT: Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with FDA-Approved Implanted Permanent Pacemakers (PMs) for use in an MRI Environment

I. SUMMARY OF CHANGES: Effective for claims with dates of service on or after July 7, 2011, CMS believes that the evidence is adequate to conclude that magnetic resonance imaging (MRI) improves health outcomes for Medicare beneficiaries with implanted permanent pacemakers (PMs) when the PMs are used according to the FDA-approved labeling for use in an MRI environment. Other contraindications that may be present in any given beneficiary would continue to apply in patients with PMs. These other contraindications are listed in section 220.2.C.1 of the National Coverage Determinations (NCD) manual and referenced in CR 7296.

EFFECTIVE DATE: July 7, 2011
February 24, 2011 (CR 7296)
IMPLEMENTATION DATE: September 26, 2011

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (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	13/40/Magnetic Resonance Imaging (MRI) Procedures
R	13/40.1.4/Payment Requirements
N	13/40.2/Medicare Summary Notices (MSN), Reason Codes, and Remark Codes

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically

authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 2307	Date: September 22, 2011	Change Request: 7441

NOTE: Transmittal 2293, dated August 26, 2011, is being rescinded and replaced by Transmittal 2307, dated September 22, 2011 to include carrier responsibility in BR's 7441-04.2, 7441-04.2.1, and 7441-04.2.2. All other information remains the same.

SUBJECT: Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with FDA-Approved Implanted Permanent Pacemakers (PMs) for use in the MRI Environment

EFFECTIVE DATE: July 7, 2011
February 24, 2011 (CR 7296)

IMPLEMENTATION DATE: September 26, 2011

I. GENERAL INFORMATION

A. Background: The Centers for Medicare and Medicaid Services (CMS) recently issued a 2010 National Coverage Decision (NCD) that merged the Magnetic Resonance Angiography (MRA) NCD at section 220.3 under the NCD for Magnetic Resonance Imaging (MRI) at section 220.2 in Chapter 1 of Publication 100-03 of the NCD Manual. In addition, a 2009 NCD removed a contraindication from 220.2.C.2 of the NCD Manual concerning blood flow measurement. Currently, coverage is limited to MRI units that have received Food and Drug Administration (FDA) premarket approval, and such units must be operated within the parameters specified by the approval. Other uses of MRI for which CMS has not specifically indicated national coverage or national non-coverage are at the discretion of Medicare's local contractors.

On February 8, 2011, the FDA granted approval of the first pacemaker designed for use in the MR environment for certain MRI exams.

On February 24, 2011, CMS issued a NCD that provided coverage of MRI for beneficiaries with implanted PMs or ICDs through Coverage with Evidence Development (CED)/Coverage with Study Participation (CSP) in approved clinical studies of MRI. Besides the one exception for coverage of MRI in clinical trials, CMS retained the current general contraindications at 220.2.C.1 in the NCD Manual. The FDA approval came after the public comment period and was too late for CMS to adequately review the evidence to address coverage for MRI for patients that may obtain this device.

On February 25, 2011, Medtronic (the requester and manufacturer of this pacemaker) asked that CMS remove completely the contraindication in the MRI policy for patients with pacemaker devices that have been approved by the FDA for use in the MRI environment.

B. Policy: Effective for claims with dates and services on or after July 7, 2011, CMS believes that the evidence is adequate to conclude that magnetic resonance imaging (MRI) improves health outcomes for Medicare beneficiaries with implanted permanent pacemakers (PMs) when the PMs are used according to the FDA-approved labeling for use in an MRI environment. Therefore we believe that this use of MRI is reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act.)

CMS will change the language in section 220.2.C.1 of the NCD Manual to remove the contraindication for Medicare coverage of MRI in beneficiaries with implanted PMs when the PMs are used according to the FDA-approved labeling for use in an MRI environment. Other contraindications that may be present in any given

beneficiary would continue to apply in patients with PMs. These other contraindications are listed in section 220.2.C.1 of the NCD manual.

NOTE: Contractors shall follow CR 7296, TR 2171, issued 3/4/11, implemented 4/4/11, for instructions on other contraindications related to pacemakers. CR 7441 is adding ICD-9 code V45.01, cardiac pacemaker, and ICD-9 code V45.02, automatic implantable cardiac defibrillator, to claims instructions in CR 7296.

NOTE: Contractors shall accept the inclusion of the KX modifier on the claim line(s) as an attestation by the provider of the service that documentation is on file verifying that FDA-approved labeling requirements are met. This is only necessary for claims not associated with clinical trials.

NOTE: Contractors should refer to the business requirements below as well as general clinical trial billing requirements at Pub. 100-03, chapter 1, section 310, and Pub. 100-04, chapter 32, section 69. See Pub. 100-03, NCD Manual, section 220.2 for the MRI coverage policy, and Pub. 100-04, Claims Processing Manual, chapter 13, section 40, for claim processing instructions.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7441-04.1	Effective for claims with dates of service on and after July 7, 2011, Medicare will allow for coverage of MRI for beneficiaries with implanted PMs when the PMs are used according to the FDA-approved labeling for use in an MRI environment. See section 220.2.C.1 of the NCD Manual.	X		X	X						
7441-04.1.1	Effective for claims with dates of service on and after July 7, 2011, contractors shall deny MRI line items on institutional claims when billed with an appropriate MRI code and ICD-9 code V45.01 (cardiac pacemaker), if modifier KX is not also present on the line or the conditions of requirement 7441-04.2.1 are not met.	X		X							
7441-04.1.2	Effective for claims with dates of service on and after July 7, 2011, contractors shall deny MRI line items on professional claims when billed with ICD-9 diagnosis code V45.01 if modifier KX is not also present on the line or the conditions of requirement 7441-04.2.1 are not met.	X			X						
7441-04.1.3	Contractors shall deny line items identified in requirement 7441-04.1.1 and 7441-04.1.2 using the following remittance advice coding: Group code - CO	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	CARC 188 - This product/procedure is only covered when used according to 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".										
7441-04.2	Effective for claims with dates of service on and after February 24, 2011, Medicare will allow for coverage of MRI for beneficiaries with implanted PMs or cardioverter defibrillators (ICDs) for use in an MRI environment in a Medicare-approved clinical study.	X		X	X						
7441-04.2.1	Effective for claims with dates of service on and after February 24, 2011, contractors shall deny line items that do not include all of the following line items: • An appropriate MRI code • ICD-9 code V45.02 (automatic implantable cardiac defibrillator) or ICD-9 code V45.01 (cardiac pacemaker) • Modifer Q0 • ICD-9 code V70.7 - Examination of participant in clinical trial (for institutional claims only), and • Condition code 30 - (for institutional claims only).	X		X	X						
7441-04.2.2	Contractors shall deny line items identified in requirement 7441-04.2.1 using the following remittance advice coding: Group code - CO CARC B5 - Coverage/program guidelines were not met or were 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.	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	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.										
7441-04.3	Contractors shall note that the appropriate ICD-10 codes are listed below. Contractors shall track these ICD-10 codes and ensure that the updated edits are turned on as part of the ICD-10 implementation October 1, 2013. NOTE: You will not receive a separate change request instructing you to implement the updated edits. • ICD-10 - Z006 - Encounter for examination for normal comparison and control in clinical research program • ICD-10- Z950 - Presence of cardiac pacemaker • ICD-10- Z95810 - Presence of automatic implantable cardiac defibrillator	X		X	X						
7441-04.4	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 (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 carrier on the ANSI X12N 837P or hardcopy Form CMS-1500 and payment is made under the MPFS. • Critical Access Hospitals (85x) -	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	o 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. o The fiscal intermediary pays the professional component at 115% of the MPFS										
7441-04.5	Contractors need not search their files to recoup payment for claims already paid prior the implementation of this CR. However contractors shall adjust claims brought to their attention.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7441-04.6	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: NA

V. CONTACTS

Pre-Implementation Contact(s): Brijet Burton (coverage), 410-786-7364, brijet.burton2@cms.hhs.gov, Sarah Meisenberg (coverage), 410-786-5323, sarah.meisenberg@cms.hhs.gov, Patricia Brocato-Simons (coverage), 410-786-0261, patricia.brocatosimons@cms.hhs.gov, Wanda Belle (coverage), wanda.belle@cms.hhs.gov, 410-786-7491, Cynthia Glover (Division of Practitioner Claims Processing), 410-786-2589, cynthia.glover@cms.hhs.gov, Felicia Rowe (supplier claims processing), 410-786-5655 or felicia.rowe@cms.hhs.gov, and Bill Ruiz (institutional claims processing), 410-786-9283, william.ruiz@cmes.gov.

Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers:* No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*: The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

40 - Magnetic Resonance Imaging (MRI) Procedures

(Rev.2307, Issued: 09-22-11, Effective: 07-07-11/02-24-11(CR 7296), Implementation: 09-26-11)

Effective September 28, 2009

The *Centers for Medicare & Medicaid Services (*CMS) finds that the non-coverage of *magnetic resonance imaging (*MRI) for blood flow determination is no longer supported by the available evidence. CMS is removing the phrase "blood flow measurement" and local Medicare contractors will have the discretion to cover (or not cover).

Consult *Publication (*Pub.) 100-03, *National Coverage Determinations (*NCD) Manual, chapter 1, section 220.2, for specific coverage and non-coverage indications associated with MRI and MRA (Magnetic Resonance Angiography).

Prior to January 1, 2007

Carriers do not make additional payments for three or more MRI sequences. The *relative value units (*RVUs) reflect payment levels for two sequences.

The technical component *(TC)* RVUs for MRI procedures that specify "with contrast" include payment for paramagnetic contrast media. Carriers do not make separate payment under code A4647.

A diagnostic technique has been developed under which an MRI of the brain or spine is first performed without contrast material, then another MRI is performed with a standard (0.1mmol/kg) dose of contrast material and, based on the need to achieve a better image, a third MRI is performed with an additional double dosage (0.2mmol/kg) of contrast material. When the high-dose contrast technique is utilized, carriers:

- Do not pay separately for the contrast material used in the second MRI procedure;

- Pay for the contrast material given for the third MRI procedure through supply code Q9952, the replacement code for A4643, when billed with *Current Procedural Terminology (*CPT) codes 70553, 72156, 72157, and 72158;

- Do not pay for the third MRI procedure. For example, in the case of an MRI of the brain, if CPT code 70553 (without contrast material, followed by with contrast material(s) and further sequences) is billed, make no payment for CPT code 70551 (without contrast material(s)), the additional procedure given for the purpose of administering the double dosage, furnished during the same session. Medicare does not pay for the third procedure (as distinguished from the contrast material) because the CPT definition of code 70553 includes all further sequences; and

- Do not apply the payment criteria for low osmolar contrast media in §30.1.2 to billings for code Q9952, the replacement code for A4643.

Effective January 1, 2007

With the implementation for calendar year 2007 of a bottom-up methodology, which utilizes the direct inputs to determine the practice expense (PE) relative value units (RVUs), the cost of the contrast media is not included in the PE RVUs. Therefore, a separate payment for the contrast media used in various imaging procedures is paid. In addition to the CPT code representing the imaging procedure, separately bill the appropriate HCPCS "Q" code (Q9945 – Q9954; Q9958-Q9964) for the contrast medium utilized in performing the service.

Effective February 24, 2011

Medicare will allow for coverage of MRI for beneficiaries with implanted PMs or cardioverter defibrillators (ICDs) for use in an MRI environment in a Medicare-approved clinical study as described in section 220.C.1 of the NCD manual.

Effective July 7, 2011

Medicare will allow for coverage of MRI for beneficiaries with implanted pacemakers (PMs) when the PMs are used according to the Food and Drug Administration (FDA)-approved labeling for use in an MRI environment as described in section 220.2.C.1 of the NCD Manual.

40.1.4 – Payment Requirements

(Rev.2307, Issued: 09-22-11, Effective: 07-07-11/02-24-11(CR 7296), Implementation: 09-26-11)

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*
- *ICD-9 code V70.7- Examination of participant in clinical trial (for institutional claims)*
- *Condition code 30 (for institutional claims)*
- *ICD-9 code V45.02 (automatic implantable cardiac defibrillator) or ICD-9 code V45.01 (cardiac pacemaker)*

NOTE: *Effective for claims with dates of service on and after October 1, 2013, providers report the following ICD-10 codes instead of the ICD-9 codes referenced above:*

- *Z006 – Encounter for examination for normal comparison and control in clinical research program*
- *Z95810 – Presence of automatic (implantable) cardiac defibrillator*
- *Z950 – 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*
- *ICD-9 code V45.01 (cardiac pacemaker)*
- *KX modifier*

NOTE: *Effective for claims with dates of service on and after October 1, 2013, providers report ICD-10 code Z950 instead of the ICD-9 code referenced above for patients with a 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 carrier on the ANSI X12N 837P or hardcopy Form CMS-1500 and payment is made under the MPFS.
- Critical access hospital*s* (CAH*s*) *(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 *fiscal intermediary* pays the professional component at 115*% of the MPFS*.

eductible and coinsurance apply.

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

(Rev.2307, Issued: 09-22-11, Effective: 07-07-11/02-24-11(CR 7296), Implementation: 09-26-11)

When denying MRI line items on institutional claims when billed with the appropriate MRI code and ICD-9 code V45.01 and modifier KX is not present, use the following messages:

- *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 when billed with ICD-9 code V45.01 and modifier KX is not present, use the following messages:

- *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,*
- *ICD-9 code V45.02 (automatic implantable cardiac defibrillator) or ICD-9 code V45.01 (cardiac pacemaker),*
- *Modifier Q0,*
- *ICD-9 code V70.7 – 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.*