CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2171	**Date: March 4, 2011**
	Change Request 7296

SUBJECT: Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with Implanted Permanent Pacemakers (PMs) or Implantable Cardioverter Defibrillators (ICDs)

I. SUMMARY OF CHANGES: Effective for claims with dates of service on or after February 24, 2011, CMS will allow for coverage of MRI for Medicare beneficiaries with implanted PMs or ICDs when those beneficiaries are enrolled in clinical studies that are approved by CMS for the purpose of gaining further evidence about the utility and safety of MRI exposure. Coverage under the CED paradigm is also contingent on all the criteria at section 220.2.C.1 of the NCD Manual being met.

EFFECTIVE DATE: February 24, 2011
IMPLEMENTATION DATE: April 4, 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	13/40.1/ Magnetic Resonance Angiography (MRA)
R	13/40.1.1/Magnetic Resonance Angiography (MRA) Coverage Summary

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: 2171	Date: March 4, 2011	Change Request: 7296

SUBJECT: Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with Implanted Permanent Pacemakers (PMs) or Implantable Cardioverter Defibrillators (ICDs)

EFFECTIVE DATE: February 24, 2011

IMPLEMENTATION DATE: April 4, 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.

In June 2010, CMS received an external request to remove the contraindications for MRI for patients with implanted permanent pacemakers (PMs), as well as to provide Medicare coverage for patients who undergo MRI with an implantable cardioverter defibrillator (ICD). In addition (and as noted by the requester), payment for an MRI examination is not currently covered by Medicare if certain contraindications are present. These include cardiac PMs.

B. Policy: After careful reconsideration, effective for claims with dates of service on or after February 24, 2011, CMS believes the evidence is inadequate to determine that the use of MRI in patients with PMs and ICDs is reasonable and necessary. Therefore, Medicare will continue to retain the current contraindications at section 220.2.C.1 of the NCD Manual. However, CMS believes the evidence is promising, although not yet convincing, that MRI can improve health outcomes in patients with PMs and ICDs if certain safeguards are in place, and therefore will allow for coverage of MRI for Medicare beneficiaries with implanted PMs or ICDs when those beneficiaries are enrolled in clinical studies that are approved by CMS for the purpose of gaining further evidence about the utility and safety of MRI exposure. Coverage under the coverage with evidence development (CED) paradigm is also contingent on all the criteria at section 220.2.C.1 of the NCD Manual being met.

NOTE: Contractors shall use existing clinical trial coding conventions to identify on a claim that MRI for beneficiaries with implanted PMs or ICDs was provided pursuant to a Medicare-approved clinical study under CED. Currently, there is a clinical trial pending approval for this purpose.

NOTE: Subject to this one exception for beneficiaries with implanted PMs or ICDs, contractors will continue to non-cover the current general contraindications at 220.2.C.1 in the NCD Manual.

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 40.1, 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	
7296.1	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 ICDs only if those beneficiaries are enrolled in an approved clinical study under CED as specified at chapter 1, section 220.2.C.1, Pub. 100-03 of the NCD Manual.	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	
7296.2	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
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

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, Bridgitte Davis (practitioner claims processing), 410-786-4573, Bridgitte.davis@cms.hhs.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.

Medicare Claims Processing Manual
Chapter 13 - Radiology Services and Other Diagnostic Procedures
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(Rev. 2171, 03-04-11)

40.1 – Magnetic Resonance Angiography *(MRA)*
(Rev. 2171, Issued: 03-04-11, Effective: 02-24-11, Implementation: 04-04-11)

40.1.1 – Magnetic Resonance Angiography *(MRA)* Coverage Summary
(Rev. 2171, Issued: 03-04-11, Effective: 02-24-11, Implementation: 04-04-11)

Section 1861(s)(2)(C) of the *Social Security* Act provides for coverage of diagnostic testing. Coverage of magnetic resonance angiography (MRA) of the head and neck, and MRA of the peripheral vessels of the lower extremities is limited as described in *Publication (Pub.) 100-03,* the Medicare National Coverage Determinations *(NCD)* Manual. This instruction has been revised as of July 1, 2003, based on a determination that coverage is reasonable and necessary in additional circumstances. Under that instruction, MRA is generally covered only to the extent that it is used as a substitute for contrast angiography, except to the extent that there are documented circumstances consistent with that instruction that demonstrate*s* the medical necessity of both tests. Prior to June 3, 2010, there was no coverage of MRA outside of the indications and circumstances described in that instruction.

Effective for claims with dates of service on or after June 3, 2010, contractors have the discretion to cover or not cover all indications of MRA (and *magnetic resonance imaging (MRI)*) that are not specifically nationally covered or nationally non-covered as stated in section 220.2 of the NCD Manual.

Because the status codes for HCPCS codes 71555, 71555-TC, 71555-26, 74185, 74185-TC, and 74185-26 were changed in the *Medicare Physician Fee Schedule Database* from *'N' to 'R'* on April 1, 1998, any MRA claims with those HCPCS codes with dates of service between April 1, 1998, and June 30, 1999, are to be processed according to the contractor's discretionary authority to determine payment in the absence of national policy.

Effective for claims with dates of service on or after February 24, 201l, Medicare will provide coverage for MRIs for beneficiaries with implanted cardiac pacemakers or implantable cardioverter defibrillators if the beneficiary is enrolled in an approved clinical study under the Coverage with Study Participation form of Coverage with Evidence Development that meets specific criteria per Pub. 100-03, the NCD Manual, chapter 1, section 220.2.C.1.