

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 107	Date: October 16, 2009
	Change Request 6672

SUBJECT: Magnetic Resonance Imaging (MRI)

I. SUMMARY OF CHANGES: Effective September 28, 2009, CMS finds that the blanket non-coverage of MRI for blood flow determination at section 220.2 of the NCD Manual is no longer supported by the available evidence. Therefore, CMS is removing the phrase blood flow measurement, from the NCD, giving local Medicare contractors discretion to cover (or not cover) this use. This revision is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW / REVISED MATERIAL

EFFECTIVE DATE: SEPTEMBER 28, 2009

IMPLEMENTATION DATE: JANUARY 4, 2010

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	1/220.2/Magnetic Resonance Imaging

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

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

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 107	Date: October 16, 2009	Change Request: 6672
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SUBJECT: Magnetic Resonance Imaging (MRI)

Effective Date: September 28, 2009

Implementation Date: January 4, 2010

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) received a request to delete the national non-coverage of blood flow measurement from the Magnetic Resonance Imaging (MRI) National Coverage Determination (NCD) at section 220.2 of the NCD Manual. The requestor points to an apparent contradiction between this non-coverage provision and the national coverage of MRI under the Magnetic Resonance Angiography NCD at section 220.3 of the NCD Manual.

The CMS also received a separate request to revise the reference to cardiac pacemakers to permit coverage for MRI when a beneficiary has an implanted device that has been designed, tested and Food and Drug Administration (FDA)-labeled for use in the MRI environment. Currently, the MRI is not covered for patients with cardiac pacemakers or with metallic clips on vascular aneurysms.

B. Policy: Effective September 28, 2009, CMS finds that the blanket non-coverage of MRI for blood flow determination at section 220.2 of the NCD Manual is no longer supported by the available evidence. Therefore, CMS is removing the phrase “blood flow measurement,” from the NCD, giving local Medicare contractors discretion to cover (or not cover) this use.

In addition, CMS has not found evidence that MRI improves health outcomes in beneficiaries who have an implanted cardioverter-defibrillator or cardiac pacemaker approved by FDA for use in an MRI environment. CMS also notes that there are currently no such devices. Therefore, CMS proposes no change in this provision of the NCD Manual, and will retain the current contraindications.

NOTE: Effective September 28, 2009, be advised that the following 4 CPT codes will be changed from non-covered to covered and will appear in the January 2010 Integrated Outpatient Code Editor (IOCE) Quarterly Updates:

75558, Cardiac MRI for morphology/function w/o contrast materials; w/flow/velocity quantification

75560, Cardiac MRI for morphology/function w/o contrast materials; w/flow/velocity quantification & stress

75562, Cardiac MRI for morphology/function w/o contrast materials; followed by contrast materials/further sequences, w/flow/velocity quantification

75564, Cardiac MRI for morphology/function w/o contrast materials; followed by contrast materials/further sequences, w/flow/velocity quantification & stress.

NOTE: All other uses of MRI noted in Pub. 100-03, NCD Manual, section 220.2, remain unchanged, including non-coverage of imaging of cortical bone and calcifications, procedures involving spatial resolution of bone and calcifications, for patients with FDA-approved (for an MRI environment) implanted cardioverter-defibrillators or cardiac pacemakers, or for patients with metallic clips on vascular aneurysms. Consult Pub. 100-03, NCD Manual, at section 220.2, for specific coverage and non-coverage indications associated with MRI and section 220.3, Magnetic Resonance Angiography, and Pub. 100-04, Claims Processing Manual, Chapter 13, Sections 40 and 40.1, MRI and MRA.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6672.1	Effective for claims with dates of service on and after September 28, 2009, local Medicare contractors have discretion to pay for MRI for blood flow measurement according to criteria contained in Pub. 100-03, NCD Manual, section 220.2.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6672. 2	<p>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.</p> <p>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.</p>	X		X	X						

IV. SUPPORTING INFORMATION

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

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
N/A	

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

V. CONTACTS

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Post-Implementation Contact(s):

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.

220.2 - Magnetic Resonance Imaging

(Rev. 107; Issued: 10-16-09; Effective Date: 09-28-09; Implementation Date: 01-04-10)

A. General

1. Method of Operation

Magnetic resonance imaging (MRI), formerly called nuclear magnetic resonance (NMR), is a noninvasive method of graphically representing the distribution of water and other hydrogen-rich molecules in the human body. In contrast to conventional radiographs or computed tomography (CT) scans, in which the image is produced by x-ray beam attenuation by an object, MRI is capable of producing images by several techniques. In fact, various combinations of MRI production methods may be employed to emphasize particular characteristics of the tissue or body part being examined. The basic elements by which MRI produces an image are the density of hydrogen nuclei in the object being examined, their motion, the relaxation times, and the period of time required for the nuclei to return to their original states in the main, static magnetic field after being subjected to a brief additional magnetic field. These relaxation times reflect the physical-chemical properties of tissue and the molecular environment of its hydrogen nuclei. Only hydrogen atoms are present in human tissues in sufficient concentration for current use in clinical MRI.

2. General Clinical Utility

Overall, MRI is a useful diagnostic imaging modality that is capable of demonstrating a wide variety of soft-tissue lesions with contrast resolution equal or superior to CT scanning in various parts of the body.

Among the advantages of MRI are the absence of ionizing radiation and the ability to achieve high levels of tissue contrast resolution without injected iodinated radiological contrast agents. Recent advances in technology have resulted in development and Food and Drug Administration (FDA) approval of new paramagnetic contrast agents for MRI that allow even better visualization in some instances. Multi-slice imaging and the ability to image in multiple planes, especially sagittal and coronal, have provided flexibility not easily available with other modalities. Because cortical (outer layer) bone and metallic prostheses do not cause distortion of MRI, it has been possible to visualize certain lesions and body regions with greater certainty than has been possible with CT. The use of MRI on certain soft tissue structures for the purpose of detecting disruptive, neoplastic, degenerative, or inflammatory lesions has now become established in medical practice.

B. Nationally Covered Indications (Effective November 22, 1985)

Although several uses of MRI are still considered investigational and some uses are clearly contraindicated, MRI is considered medically efficacious for a number of uses. Use the following descriptions as general guidelines or examples of what may be considered covered rather than as a restrictive list of specific covered indications. Coverage is limited to MRI units that have FDA premarket approval, and such units must be operated within the parameters

specified by the approval. In addition, the services must be reasonable and necessary for the diagnosis or treatment of the specific patient involved.

The MRI is useful in examining the head, central nervous system, and spine. Multiple sclerosis can be diagnosed with MRI and the contents of the posterior fossa are visible. The inherent tissue contrast resolution of MRI makes it an appropriate standard diagnostic modality for general neuroradiology.

The MRI can assist in the differential diagnosis of mediastinal and retroperitoneal masses, including abnormalities of the large vessels such as aneurysms and dissection. When a clinical need exists to visualize the parenchyma of solid organs to detect anatomic disruption or neoplasia, this can be accomplished in the liver, urogenital system, adrenals, and pelvic organs without the use of radiological contrast materials. When MRI is considered reasonable and necessary, the use of paramagnetic contrast materials may be covered as part of the study. MRI may also be used to detect and stage pelvic and retroperitoneal neoplasms and to evaluate disorders of cancellous bone and soft tissues. It may also be used in the detection of pericardial thickening. Primary and secondary bone neoplasm and aseptic necrosis can be detected at an early stage and monitored with MRI. Patients with metallic prostheses, especially of the hip, can be imaged in order to detect the early stages of infection of the bone to which the prosthesis is attached.

Disc Disease Diagnosis (Effective March 22, 1994)

The MRI may also be covered to diagnose disc disease without regard to whether radiological imaging has been tried first to diagnose the problem.

Gating Devices and Surface Coils (Effective March 4, 1991), and gating devices that eliminate distorted images caused by cardiac and respiratory movement cycles are now considered state-of-the-art techniques and may be covered. Surface and other specialty coils may also be covered, as they are used routinely for high resolution imaging where small limited regions of the body are studied. They produce high signal-to-noise ratios resulting in images of enhanced anatomic detail.

C. Contraindications and Nationally Non-Covered Indications

1. Contraindications

The MRI is not covered when the following patient-specific contraindications are present. It is not covered for patients with cardiac pacemakers or with metallic clips on vascular aneurysms. MRI during a viable pregnancy is also contraindicated at this time. The danger inherent in bringing ferromagnetic materials within range of MRI units generally constrains the use of MRI on acutely ill patients requiring life support systems and monitoring devices that employ ferromagnetic materials. In addition, the long imaging time and the enclosed position of the patient may result in claustrophobia, making patients who have a history of claustrophobia unsuitable candidates for MRI procedures.

2. Nationally Non-Covered Indications

The *Centers for Medicare & Medicaid Services (CMS)* has determined that imaging of cortical bone and calcifications, and procedures involving spatial resolution of bone and calcifications, are not considered reasonable and necessary indications within the meaning of section 1862(a)(1)(A) of the Social Security Act, and are therefore non-covered.

D. Other

All other uses of MRI for which CMS has not specifically indicated coverage or non-coverage continue to be eligible for coverage through individual local contractor discretion.

(This NCD last reviewed September 2009.)