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# CMS Manual System

## Pub. 100-03 Medicare National Coverage Determinations

Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

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Transmittal 21

Date: September 10, 2004

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CHANGE REQUEST 3425

### **SUBJECT: Magnetic Resonance Spectroscopy for Diagnosing Brain Tumors**

**I. SUMMARY OF CHANGES:** Upon reconsideration of existing noncoverage policy, CMS determines that Magnetic Resonance Spectroscopy (MRS) used as a diagnostic tool for distinguishing indeterminate brain lesions and/or as an aid in conducting brain biopsies is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Therefore, CMS reaffirms its existing noncoverage policy at section 220.2.1, of the National Coverage Determinations Manual (NCD) for all indications of MRS. In addition, sections 220.2, Magnetic Resonance Imaging, and 220.3, Magnetic Resonance Angiography, are revised and reprinted with clerical/technical edits/clarifications. There are no substantive revisions and no changes to existing NCD policy.

(This addition of §220.2.1 of Pub. 100-03 is an NCD. The NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on Medicare Advantage Organizations. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

**NEW/REVISED MATERIAL - EFFECTIVE DATE: 09/10/04**

**\*IMPLEMENTATION DATE: 09/10/04**

### **II. CHANGES IN MANUAL INSTRUCTIONS:**

**(R = REVISED, N = NEW, D = DELETED)**

| <b>R/N/D</b> | <b>CHAPTER/SECTION/SUBSECTION/TITLE</b>                                  |
|--------------|--|
| <b>R</b>     | 1/Table of Contents  |
| <b>R</b>     | 1/220.2/Magnetic Resonance Imaging (See Effective Dates Below)           |
| <b>N</b>     | 1/220.2.1/Magnetic Resonance Spectroscopy (Effective September 10, 2004) |
| <b>R</b>     | 1/220.3/Magnetic Resonance Angiography (See Effective Dates Below)       |

### **\*III. FUNDING:**

**These instructions shall be implemented within your current operating budget.**

### **IV. ATTACHMENTS:**

|          |                                      |
|----------|--------------------------------------|
| <b>X</b> | <b>Business Requirements</b>         |
| <b>X</b> | <b>Manual Instruction</b>            |
|          | <b>Confidential Requirements</b>     |
|          | <b>One-Time Notification</b>         |
|          | <b>Recurring Update Notification</b> |

**\*Medicare contractors only**

# Attachment - Business Requirements

|             |              |                          |                     |
|-------------|--------------|--------------------------|---------------------|
| Pub. 100-03 | Transmittal: | Date: September 10, 2004 | Change Request 3425 |
|-------------|--------------|--------------------------|---------------------|

**SUBJECT: Magnetic Resonance Spectroscopy for Diagnosing Brain Tumors**

## I. GENERAL INFORMATION

**A. Background:** Magnetic Resonance Spectroscopy (MRS) is an application of magnetic resonance imaging. It is a non-invasive diagnostic test that uses strong magnetic fields to measure and analyze the chemical composition of human tissues. On March 22, 1994, CMS considered MRS an investigational procedure and issued a national noncoverage determination for all indications of MRS.

**B. Policy:** Upon reconsideration of existing noncoverage policy, CMS determines that the evidence is not adequate to conclude that MRS used as a diagnostic tool for distinguishing indeterminate brain lesions and/or as an aid in conducting brain biopsies is reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Therefore, CMS reaffirms its existing noncoverage policy at section 220.2.1 of the NCD Manual for all indications of MRS. In addition, sections 220.2, Magnetic Resonance Imaging, and 220.3, Magnetic Resonance Angiography, are revised and reprinted with clerical/technical edits/clarifications. There are no substantive revisions, and no changes to existing NCD policy.

**C. Provider Education:** A Medlearn Matters provider education article related to this instruction will be available at [www.cms.hhs.gov/medlearn/matters](http://www.cms.hhs.gov/medlearn/matters) shortly after the CR is released. You will receive notification of the article release via the established “medlearn 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 1 week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.

## II. BUSINESS REQUIREMENTS

*“Shall” denotes a mandatory requirement*

*“Should” denotes an optional requirement*

| Requirement # | Requirements   | Responsibility                |
|---------------|--|-------------------------------|
| 3425.1        | Magnetic Resonance Spectroscopy (MRS) used as a diagnostic tool for distinguishing indeterminate brain lesions is not considered a reasonable and necessary treatment and is not nationally covered by the Medicare program. | FIs and local Part B carriers |
| 3425.2        | MRS used as an aid in conducting brain biopsies is not considered a reasonable and   | FIs and local Part B carriers |

|        |  |                               |
|--------|--|-------------------------------|
|        | necessary treatment and is not nationally covered by the Medicare program.   |                               |
| 3425.3 | All other indications of MRS are not considered reasonable and necessary treatment and are not nationally covered by the Medicare program. | FIs and local Part B carriers |

### III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

#### A. Other Instructions: N/A

| X-Ref Requirement # | Instructions |
|---------------------|--------------|
|                     |              |

#### B. Design Considerations: N/A

| X-Ref Requirement # | Recommendation for Medicare System Requirements |
|---------------------|---|
|                     |   |

#### C. Interfaces: N/A

#### D. Contractor Financial Reporting /Workload Impact: N/A

#### E. Dependencies: N/A

#### F. Testing Considerations: N/A

### IV. SCHEDULE, CONTACTS, AND FUNDING

|   |   |
|---|---|
| <p><b>Effective Date:</b> September 10, 2004</p> <p><b>Implementation Date:</b> September 10, 2004</p> <p><b>Pre-Implementation Contact(s):</b> Stuart Caplan, 410-786-8564, Pat Brocato-Simons, 410-786-0261</p> <p><b>Post-Implementation Contact(s):</b> CMS ROs</p> | <p><b>These instructions shall be implemented within your current operating budget.</b></p> |
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# Medicare National Coverage Determinations Manual

## Chapter 1 - Coverage Determinations

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### Table of Contents

*(Rev.21, 09-10-04)*

*220.2 – Magnetic Resonance Imaging (See Effective Dates Below)*

*220.2.1 - Magnetic Resonance Spectroscopy (Effective September 10,  
2004)*

*220.3 – Magnetic Resonance Angiography (See Effective Dates Below)*

## 220.2 - Magnetic Resonance Imaging (*See Effective Dates Below*)

*(Rev.21, Issued: 09-10-04, Effective: 09-10-04, Implementation: 09-10-04)*

### 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)*

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 Noncovered 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 Noncovered Indications

*The CMS has determined that blood flow measurement, 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 noncovered.*

D. Other

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

*(This NCD last reviewed September 2004.)*

**220.2.1 - Magnetic Resonance Spectroscopy (Effective September 10, 2004)**

***(Rev.21, Issued: 09-10-04, Effective: 09-10-04, Implementation: 09-10-04)***

A. General

*Magnetic Resonance Spectroscopy (MRS) is an application of magnetic resonance imaging (MRI). It is a non-invasive diagnostic test that uses strong magnetic fields to measure and analyze the chemical composition of human tissues. On March 22, 1994, CMS considered MRS an investigational procedure and issued a national noncoverage determination for all indications of MRS.*

B. Nationally Covered Indications

*Not applicable.*

C. Nationally Noncovered Indications

*After thorough review and reconsideration of the existing national noncoverage determination for MRS, as well as the available evidence for the use of MRS as a diagnostic tool for distinguishing indeterminate brain lesions, and/or as an aid in conducting brain biopsies, CMS has determined that the evidence is not adequate to conclude that MRS is reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act, for use in the diagnosis of brain tumors.*

*Therefore, CMS reaffirms its current national noncoverage determination for all indications of MRS.*

*D. Other*

*Not applicable.*

*(This NCD last reviewed September 2004.)*

**220.3 - Magnetic Resonance Angiography (See Effective Dates Below)**

***(Rev.21, Issued: 09-10-04, Effective: 09-10-04, Implementation: 09-10-04)***

*A. General*

Magnetic resonance angiography (MRA) is a non-invasive diagnostic test that is an application of magnetic resonance imaging (MRI). By analyzing the amount of energy released from tissues exposed to a strong magnetic field, MRA provides images of normal and diseased blood vessels as well as visualization and quantification of blood flow through these vessels.

Phase contrast (PC) and time-of-flight (TOF) are the available MRA techniques at the time these instructions are being issued. PC measures the difference between the phases of proton spins in tissue and blood and measures both the venous and arterial blood flow at any point in the cardiac cycle. TOF measures the difference between the amount of magnetization of tissue and blood and provides information on the structure of blood vessels, thus indirectly indicating blood flow. Two-dimensional (2D) and three-dimensional (3D) images can be obtained using each method.

Contrast-enhanced MRA (CE-MRA) involves blood flow imaging after the patient receives an intravenous injection of a contrast agent. Gadolinium, a non-ionic element, is the foundation of all contrast agents currently in use. Gadolinium affects the way in which tissues respond to magnetization, resulting in better visualization of structures when compared to un-enhanced studies. Unlike ionic (i.e., iodine-based) contrast agents used in conventional contrast angiography (CA), allergic reactions to gadolinium are extremely rare. Additionally, gadolinium does not cause the kidney failure occasionally seen with ionic contrast agents. Digital subtraction angiography (DSA) is a computer-augmented form of CA that obtains digital blood flow images as contrast agent courses through a blood vessel. The computer “subtracts” bone and other tissue from the image, thereby improving visualization of blood vessels. Physicians elect to use a specific MRA or CA technique based upon clinical information from each patient.

In a National Coverage Analysis Decision Memorandum issued on April 15, 2003, CMS reviewed scientific and clinical literature on MRA, and set forth its basis for the

following coverage policy. Below are the only indications for which Medicare coverage is allowed for MRA.

## *B. Nationally Covered Indications*

### *1. Head and Neck*

Studies have proven that MRA is effective for evaluating flow in internal carotid vessels of the head and neck. However, not all potential applications of MRA have been shown to be reasonable and necessary. All of the following criteria must apply in order for Medicare to provide coverage for MRA of the head and neck:

*a.* MRA is used to evaluate the carotid arteries, the circle of Willis, the anterior, middle or posterior cerebral arteries, the vertebral or basilar arteries or the venous sinuses;

*b.* MRA is used to verify the need for anticipated surgery for conditions that include, but are not limited to, tumor, aneurysms, vascular malformations, vascular occlusion, or thrombosis. Within this broad category of disorders, medical necessity is the underlying determinant of the need for an MRA. Because MRA and CA perform the same diagnostic function, the medical records should clearly justify and demonstrate the existence of medical necessity; *and*

*c.* MRA and contrast angiography (CA) are not expected to be performed on the same patient for diagnostic purposes prior to the application of anticipated therapy. Only one of these tests will be covered routinely unless the physician can demonstrate the medical need to perform both tests.

### *2. Peripheral Arteries of Lower Extremities*

Studies have proven that MRA of peripheral arteries is useful in determining the presence and extent of peripheral vascular disease in lower extremities. This procedure is non-invasive and has been shown to find occult vessels in some patients for which those vessels were not apparent when CA was performed. Medicare will cover either MRA *or* CA to evaluate peripheral arteries of the lower extremities. However, both MRA and CA may be useful in some cases, such as:

*a.* A patient has had CA and this test was unable to identify a viable run-off vessel for bypass. When exploratory surgery is not believed to be a reasonable medical course of action for this patient, MRA may be performed to identify the viable runoff vessel; *or*

*b.* A patient has had MRA, but the results are inconclusive.

### *3. Abdomen and Pelvis*

*a. Pre-operative Evaluation of Patients Undergoing Elective Abdominal Aortic Aneurysm (AAA) Repair (Effective July 1, 1999)*

*The MRA is covered for pre-operative evaluation of patients undergoing elective AAA repair if the scientific evidence reveals MRA is considered comparable to CA in determining the extent of AAA, as well as in evaluating aortoiliac occlusion disease and renal artery pathology that may be necessary in the surgical planning of AAA repair. These studies also reveal that MRA could provide a net benefit to the patient. If preoperative CA is avoided, then patients are not exposed to the risks associated with invasive procedures, contrast media, end-organ damage, or arterial injury.*

*b. Imaging the Renal Arteries and the Aortoiliac Arteries in the Absence of AAA or Aortic Dissection (Effective July 1, 2003)*

*The MRA coverage is expanded to include imaging the renal arteries and the aortoiliac arteries in the absence of AAA or aortic dissection. MRA should be obtained in those circumstances in which using MRA is expected to avoid obtaining CA, when physician history, physical examination, and standard assessment tools provide insufficient information for patient management, and obtaining an MRA has a high probability of positively affecting patient management. However, CA may be ordered after obtaining the results of an MRA in those rare instances where medical necessity is demonstrated.*

**4. Chest**

*a. Diagnosis of Pulmonary Embolism*

Current scientific data has shown that diagnostic pulmonary MRAs are improving due to recent developments such as faster imaging capabilities and gadolinium-enhancement. However, these advances in MRA are not significant enough to warrant replacement of pulmonary angiography in the diagnosis of pulmonary embolism for patients who have no contraindication to receiving intravenous iodinated contrast material. Patients who are allergic to iodinated contrast material face a high risk of developing complications if they undergo pulmonary angiography or computed tomography angiography. Therefore, Medicare will cover MRA of the chest for diagnosing a suspected pulmonary embolism only when it is contraindicated for the patient to receive intravascular iodinated contrast material.

*b. Evaluation of Thoracic Aortic Dissection and Aneurysm*

Studies have shown that MRA of the chest has a high level of diagnostic accuracy for pre-operative and post-operative evaluation of aortic dissection or aneurysm. Depending on the clinical presentation, MRA is used as an alternative to other non-invasive imaging technologies, such as transesophageal echocardiography and CT. Generally, Medicare will provide coverage only for MRA or for CA when used as a diagnostic test. However, if both MRA and CA of the chest are used, the physician must demonstrate the medical need for performing these tests.

While the intent of this policy is to provide reimbursement for either MRA or CA, CMS is also allowing flexibility for physicians to make appropriate decisions concerning the use of these tests based on the needs of individual patients. CMS anticipates, however, low utilization of the combined use of MRA and CA. As a result, CMS encourages contractors to monitor the use of these tests and, where indicated, requires evidence of the need to perform both MRA and CA.

*C. Nationally Noncovered Indications*

*All other uses of MRA for which CMS has not specifically indicated coverage continue to be noncovered.*

*D. Other*

*Not applicable.*

*(This NCD last reviewed September 2004.)*