

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 135	Date: September 22, 2011
	Change Request 7441

NOTE: Transmittal 134, dated August 26, 2011, is being rescinded and replaced by Transmittal 135, dated September 22, 2011 to include carrier responsibility in BR 7441-03.2. 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.

This revision to the Medicare NCD manual is a national coverage determination. NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, 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.)

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/revise 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	1/220.2/Magnetic Resonance Imaging (MRI) (Various Effective Dates Below)

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. 100-03	Transmittal:135	Date: September 22, 2011	Change Request: 7441
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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 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. See Pub. 100-04.

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.

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 claims processing instructions.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B M A C	D M M A C	F I I E R	C A R I E R	R H R I	Shared-System Maintainers			
					F I S S	M C S	V M S	C W F		
7441-03.1	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. Refer to Pub. 100-04 for detailed Business Requirements.	X		X	X					
7441-03.2	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					

III. PROVIDER EDUCATION TABLE

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

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I I E R	C A R I E R	R H H I	Shared-System Maintainers				OTH ER
					F I S S	M C S	V M S	C W F			
7441-03.3	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.brocato-simons@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, 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.

220.2 - Magnetic Resonance Imaging (MRI) (Various Effective Dates Below)

(Rev.135, Issued: 09-22-11, Effective: 07-07-11/02-24-11(CR 7296), Implementation: 09-26-11)

A. General

1. Method of Operation

Magnetic Resonance Imaging (MRI), formerly called nuclear magnetic resonance (NMR), is a non-invasive 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 image 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, and 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.

Magnetic Resonance Angiography (MRA) is a non-invasive diagnostic test that is an application of 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.

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 which allow even better visualization in some instances. Multislice 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 MR images, 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.

Phase contrast (PC) and time-of-flight (TOF) are some of 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.

B. Nationally Covered MRI and MRA Indications

1. MRI

Although several uses of MRI are still considered investigational and some uses are clearly contraindicated (see subsection C), 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 received 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.

a. Effective November 22, 1985, 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.

b. Effective November 22, 1985, 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.

c. Effective March 22, 1994, MRI may also be covered to diagnose disc disease without regard to whether radiological imaging has been tried first to diagnose the problem.

d. Effective March 4, 1991, MRI with gating devices and surface coils, 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.

2. MRA (MRI for Blood Flow)

Currently covered indications include using MRA for specific conditions to evaluate flow in internal carotid vessels of the head and neck, peripheral arteries of lower extremities, abdomen and pelvis, and the chest. Coverage is limited to MRA units that have received 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.

a. Head and Neck

Effective April 15, 2003, 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:

- 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;

- MRA is performed on patients with conditions of the head and neck for which surgery is anticipated and may be found to be appropriate based on the MRA. These conditions 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 in specific diseases. The medical records should clearly justify and demonstrate the existence of medical necessity; and

- MRA and 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.

b. Peripheral Arteries of Lower Extremities

Effective April 15, 2003, 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 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

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

c. Abdomen and Pelvis

i. Pre-operative Evaluation of Patients Undergoing Elective Abdominal Aortic Aneurysm (AAA) Repair

Effective July 1, 1999, 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.

ii. Imaging the Renal Arteries and the Aortoiliac Arteries in the Absence of AAA or Aortic Dissection

Effective July 1, 2003, 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.

d. Chest

i. 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 when it is contraindicated for the patient to receive intravascular iodinated contrast material.

ii. 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 may be 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, require evidence of the need to perform both MRA and CA.

C. Contraindications and Nationally Non-Covered Indications

1. Contraindications

The MRI is not covered when the following patient-specific contraindications are present:

MRI is not covered for patients with cardiac pacemakers or with metallic clips on vascular aneurysms unless the Medicare beneficiary meets the provisions of the following exceptions:

Effective July 7, 2011, the contraindications will not apply to pacemakers when used according to the FDA-approved labeling in an MRI environment, or

Effective February 24, 2011, CMS believes that the evidence is promising although not yet convincing that MRI will improve patient health outcomes if certain safeguards are in place to ensure that the exposure of the device to an MRI environment adversely affects neither the interpretation of the MRI result nor the proper functioning of the implanted device itself. We believe that specific precautions (as listed below) could maximize benefits of MRI exposure for beneficiaries enrolled in clinical trials designed to assess the utility and safety of MRI exposure. Therefore, CMS determines that MRI will be covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) (consistent with section 1142 of the Act) through the Coverage with Study Participation (CSP) form of Coverage with Evidence Development (CED) if the study meets the criteria in each of the three paragraphs below:

The approved prospective clinical study of MRI must, with appropriate methodology, address one or more aspects of the following questions:

1. Do results of MRI in implanted permanent pacemaker (PM)/implantable cardioverter defibrillator (ICD) beneficiaries with implanted cardiac devices affect physician decision making related to:
 - a. Clinical management strategy (e.g., in oncology, toward palliative or curative care)?
 - b. Planning of treatment interventions?; or
 - c. Prevention of unneeded diagnostic studies or interventions, or preventable exposures?
2. Do results of MRI in PM/ICD beneficiaries with implanted cardiac devices affect patient outcomes related to:
 - a. Survival?
 - b. Quality of life?; or
 - c. Adverse events during and after MR scanning?

In addition, the prospective clinical study of MRI must include safety criteria for all participants. Such required safety measures for such studies, as further explained in guidance documents from professional societies must include, but are not limited to:

1. MRI should be done on a case-by-case and site-by-site basis.
2. MRI scan sequences, field intensity, and field(s) of exposure should be selected to minimize risk to the patient while gaining needed diagnostic information for diagnosis or for managing therapy.
3. MRI scanning should be done only if the site is staffed with individuals with the appropriate radiology and cardiology knowledge and expertise on hand.
4. Implanted device patients who are candidates for recruitment for an MRI clinical study should be advised that life-threatening arrhythmias might occur during MRI and serious device malfunction might occur, requiring replacement of the device.
5. Radiology and cardiology personnel and a fully stocked crash cart should be readily available throughout the procedure in case a significant arrhythmia develops during the examination that does not terminate with the cessation of the MRI study. The cardiologist should be familiar with the patient's arrhythmia history and the implanted device. A programmer that can be used to adjust the device as necessary should be readily available.
6. All such patients should be actively monitored for cardiac and respiratory function throughout the examination. At a minimum, ECG and pulse oximetry should be used. Visual and verbal contact with the patient must be maintained throughout the MRI scan. The patient should be instructed to alert the MRI staff on hand to any unusual sensations, pains, or to any problems.
7. At the conclusion of the examination, the cardiologist should examine the device to confirm that the function is consistent with its pre-examination state.
8. Follow-up should include a check of the patient's device at a time remote (1–6 weeks) after the scan to confirm appropriate function.
9. If the implanted device manufacturer has indicated additional safety precautions appropriate for safe MRI performance, these must be included in the study protocol.

The clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- c. The research study does not unjustifiably duplicate existing studies.
- d. The research study design is appropriate to answer the research question being asked in the study.
- e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the FDA, it must be in compliance with 21 CFR Parts 50 and 56.
- g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).
- h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
- i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
- j. The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
- k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured, including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (<http://www.icmje.org>). However, a full report of the outcomes must be made public no later than three (3) years after the end of data collection.
- l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

- 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

CMS has determined that MRI 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 Act, and are therefore non-covered.

D. Other

Effective June 3, 2010, all other uses of MRI or MRA 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 *July* 2011.)