

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 208	Date: October 19, 2018
	Change Request 10877

SUBJECT: Magnetic Resonance Imaging (MRI)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that effective for claims with dates of service on and after April 10, 2018 Medicare will allow for coverage of MRI for beneficiaries under certain conditions.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all Medicare Administrative Contractors (MACs) 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: April 10, 2018

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

IMPLEMENTATION DATE: December 10, 2018

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	1/220.2/Magnetic Resonance Imaging (MRI)

III. FUNDING:

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**

Attachment - Business Requirements

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SUBJECT: Magnetic Resonance Imaging (MRI)

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I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) opened this national coverage analysis (NCA) to reconsider coverage indications for Magnetic Resonance Imaging (MRI), specifically section 220.2(C)(1) Contraindications. This NCA focused on the contraindications for implanted pacemaker (PM), implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy pacemaker (CRT-P), or cardiac resynchronization therapy defibrillator (CRT-D) in patients undergoing MRIs both on and off Food & Drug Administration (FDA) label. The Coverage with Evidence Development (CED) requirement has been effective since 2011 and generated numerous data collection.

B. Policy: Effective for claims with dates of service on or after April 10, 2018, CMS determined the evidence is sufficient to conclude that MRI for Medicare beneficiaries with an implanted PM, ICD, CRT-P, or CRT-D is reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act (the Act) under certain circumstances. We are modifying our national coverage determination (NCD) to eliminate the collection of additional information under the CED paradigm under section 1862(a)(1)(E) of the Act.

CMS is revising the language in the NCD Manual sections as follows:

- (1) remove the contraindication for Medicare coverage of MRI in a beneficiary who has an implanted PM or ICD under section 220(C)(1);
- (2) expand coverage to include CRT-P or CRT-D devices under section 220.2(B)(3);
- (3) expand coverage for beneficiaries who have an implanted FDA-approved, ICD, CRT-P, or CRT-D correspondingly under section 220.2(B)(3);
- (4) expand coverage for beneficiaries with an implanted PM, ICD, CRT-P, or CRT-D device that does not have FDA labeling specific for an MRI under certain conditions under section 220.2(B)(3); and,
- (5) remove the CED requirement.

NOTE: Medicare coverage for MRIs performed on Medicare beneficiaries without implanted PMs, implanted ICDs, CRT-Ps, and CRT-Ds is not affected by this CR.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility									
		A/B MAC		H H H	D M E M A C	Shared-System Maintainers				Other	
		A	B			F I S S	M C S	V M S	C W F		
10877 - 03.1	Effective for claims with dates of service on and after April 10, 2018, contractors shall allow for coverage of MRI for beneficiaries with implanted PMs, implantable ICDs, CRT-Ps, and CRT-Ds in patients undergoing MRIs both on and off FDA label. See section 220.2.B.3 of the NCD Manual.	X	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC			H H H	D M E M A C	C E D I	
		A	B					
10877 - 03.2	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Kimberly Long, 410-786-5702 or Kimberly.Long@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage) , William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Institutional Claims Processing) , Thomas Dorsey, 410-786-7434 or Thomas.Dorsey@cms.hhs.gov (Practitioner Claims Processing)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1) Coverage Determinations

Table of Contents *(Rev.208, Issued: 10-19-18)*

220.2 - Magnetic Resonance Imaging (MRI)

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

d. 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

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

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

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

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 RA or CA, the Centers for Medicare & Medicaid Services (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 the Medicare Administrative Contractors (MACs) to monitor the use of these tests and, where indicated, require evidence of the need to perform both MRA and CA.

3. MRI for Patients with an Implanted Pacemaker, Implantable Cardioverter Defibrillator (ICD), Cardiac Resynchronization Therapy Pacemaker (CRT-P), or Cardiac Resynchronization Therapy Defibrillators (CRT-D)

- i. *An MRI is covered when used according to the FDA labeling in an MRI environment for patients with an implanted pacemaker, implantable cardioverter defibrillator (ICD) cardiac resynchronization therapy pacemaker (CRT-P), or cardiac resynchronization therapy defibrillator (CRT-D).*
- ii. *Any MRI for patients with an implanted pacemaker, ICD, CRT-P, or CRT-D that does not have FDA labeling specific to use in an MRI environment is only covered under the following conditions:*
 - a. *MRI field strength is 1.5 Tesla using Normal Operating Mode;*
 - b. *The implanted pacemaker, ICD, CRT-P, or CRT-D system has no fractured, epicardial, or abandoned leads;*
 - c. *The facility has implemented a checklist which includes the following:*
 - *patient assessment is performed to identify the presence of an implanted pacemaker, ICD, CRT-P, or CRT-D;*
 - *before the scan benefits and harms of the MRI scan are communicated with the patient or the patient's delegated decision-maker;*
 - *prior to the MRI scan, the implanted pacemaker, ICD, CRT-P, or CRT-D is interrogated and programmed into the appropriate MRI scanning mode;*
 - *a qualified physician, nurse practitioner, or physician assistant with expertise with implanted pacemakers, ICDs, CRT-Ps, or CRT-Ds must directly supervise the MRI scan as defined in 42 CFR § 410.28 and 410.32;*

- *patients are observed throughout the MRI scan via visual and voice contact and monitored with equipment to assess vital signs and cardiac rhythm;*
- *an advanced cardiac life support provider must be present for the duration of the MRI scan;*
- *a discharge plan that includes before being discharged from the hospital/facility, the patient is evaluated and the implanted pacemaker, ICD, CRT-P, or CRT-D is reinterrogated immediately after the MRI scan to detect and correct any abnormalities that might have developed.*

C. Contraindications and Nationally Non-Covered Indications

1. Contraindications

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

- MRI during a viable pregnancy.
- 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.
- 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.

MRI is not covered for patients with metallic clips on vascular aneurysms.

D. Other

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 MAC discretion.

(This NCD last reviewed April 2018.)