

Understanding CMS coverage of MRI in patients with a CIED

The following information represents a summary* of the Centers for Medicare and Medicaid Services (CMS) covered indications for MRI in patients with an implanted Cardiovascular Implantable Electronic Device (CIED) based on the National Coverage Determination (NCD) for MRI effective April 10, 2018¹. For the purposes of this NCD, CMS uses the term CIED to refer to a pacemaker, implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy-pacemakers (CRT-P), and cardiac resynchronization therapy-defibrillators (CRT-D).

MRI in patients with CIED that **has** FDA labeling for use in an MRI environment

An MRI is covered when used **according to the FDA labeling** in an MRI environment for patients with an implanted CIED **with no further criteria or requirements**.

-OR-

MRI in patients with CIED that **does not have** FDA labeling for use in an MRI environment

An MRI for patients with an implanted CIED that **does not have** FDA labeling specific to use in an MRI environment is **only covered under certain conditions**:

- MRI field strength is 1.5 Tesla using Normal Operating Mode
- Implanted CIED has no fractured, epicardial, or abandoned leads
- Facility has implemented a checklist that includes:
 - Patient assessment is performed to identify presence of a CIED
 - Benefits and harms of the MRI are communicated with the patient or the patient's delegated decision-maker prior to the scan.
 - CIED is interrogated and programmed into the appropriate MRI scanning mode based on device and patient characteristics prior to the scan
 - MRI scan is directly supervised by a qualified physician, NP, or PA with expertise in CIEDs
 - Patient is observed by voice and visual contact throughout the MRI scan and monitored with equipment to assess vital signs and cardiac rhythm
 - Advanced cardiac life support provider is present for the duration of the scan
 - Discharge plan is established that includes, before being discharged from the hospital/facility: patient evaluation and re-interrogation of the CIED device immediately after the MRI scan to detect and correct abnormalities that may have developed during the scan

Coding for a Medicare patient receiving an MRI scan

Brief Background:

- Effective July 7, 2011 Medicare covers MRI scans for patients with implanted pacemakers when the pacemakers are used according to the FDA-approved labeling for use in the MRI environment²
- Effective October 2014, the Medtronic SureScan™ pacing system, which consists of an MRI SureScan device with two SureScan leads, is FDA approved for use in the MRI environment
- Medicare released a Claims Processing Transmittal and a National Coverage Determination Transmittal on September 20, 2011 that identified the recommended modifier and diagnosis codes to use when submitting a claim for an MRI scan if the Medicare patient has an FDA-approved pacemaker

MRI coding information when patient meets medical criteria:

| | |
|--|---|
| Dates of service: | On or after July 7, 2011 |
| CPT® code ³ : | Appropriate MRI procedure code |
| Modifier: | The KX modifier is appended (attached) to the MRI procedure code. KX indicates attestation by the provider that documentation is on file verifying that FDA-approved labeling requirements are met. This modifier does not apply to claims associated with clinical trials. |
| ICD-10-CM ³ diagnosis code: | Z95.0 (Presence of cardiac pacemaker) plus applicable MRI diagnosis code |
| Medicare denials: | Medicare contractors shall deny MRI line items when billed with an applicable MRI code and ICD code and ICD-10-CM ⁴ diagnosis code Z95.0 if modifier KX is not included |

Medtronic SureScan™ pacing systems are MR Conditional and as such are designed to allow patients to undergo MRI under the specified conditions for use. A complete SureScan pacing system, which consists of an MRI SureScan device with two SureScan leads, is required for use in the MRI environment.

Disclaimer: These coding suggestions do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third-party payers as to the correct form of billing or the amount that will be paid to providers of service.

Frequently asked questions

Q: How does a facility know whether a patient's device is FDA labeled as MR Conditional?

A: Information about FDA labeling for Medtronic devices can be obtained either from the patient's device card or from our Technology & Patient Services Hotline at 800-551-5544 or online at <https://www.medtronic.com/us-en/healthcare-professionals/mri-resources/implantable-cardiac-devices/product-listing.html>. Since information about any prior abandoned leads may impact the safety of an MRI scan, we suggest also contacting the clinician who would have the complete CIED history of the patient.

Q: Do private payers have the same indications as Medicare for coverage of MRI in patients with a CIED?

A: No. Consult the specific payer coverage policy to determine requirements for coverage.

Acronyms

APP: Advanced Practice Provider

CMS: Centers for Medicare & Medicaid Services

CIED: Cardiovascular Implantable Electronic Device

CRT-D: Cardiac Resynchronization Therapy - Defibrillator

CRT-P: Cardiac Resynchronization Therapy - Pacemaker

FDA: Food and Drug Administration

ICD: Implantable Cardioverter Defibrillator

MR: Magnetic Resonance

MR-Conditional Device: FDA-approved for an MR environment

MR Environment: Physical space where the MRI machine is located

MRI: Magnetic Resonance Imaging

NCD: National Coverage Determination

NP: Nurse Practitioner

PA: Physician Assistant

Contact

For more information, please contact the Medtronic Reimbursement Customer Support team by phone: 866-877-4102 or by email: rs.healthcareeconomics@medtronic.com.

References

*For the complete CMS NCD language, visit <https://www.cms.gov/medicare-coverage-database/view/nca.aspx?ncald=289>

¹ CMS National Coverage Determination for Magnetic Resonance Imaging (PUB100-3, Manual Section 200.2). Available at: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=177>. Accessed January 18, 2024.

² CMS Manual System Pub 100-03 and 100-04 Medicare Claims Processing transmittals are available at: <http://www.cms.gov/transmittals/downloads/R135NCD.pdf> MLN Matters® is available at: <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/MM7441.pdf> Accessed January 18, 2024.

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⁴ International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM). <https://www.cdc.gov/nchs/icd/icd-10-cm.htm>. Accessed January 18, 2024.

General Transvenous IPG, CRT-P, ICD, and CRT-D with MRI Brief Statement

Indications

Transvenous Implantable Pulse Generators (IPGs) are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Dual chamber SureScan pacing systems are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony.

Cardiac Resynchronization Therapy (CRT) IPGs are indicated for NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have a LVEF \leq 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF \leq 50%, are on stable, optimal heart failure medical therapy if indicated and have atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant.

Implantable cardioverter defibrillators (ICDs) are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Some ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

CRT ICDs are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications: New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction \leq 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration \geq 130 ms, left ventricular ejection fraction \leq 30%, and NYHA Functional Class II. NYHA Functional Class I, II, or III and who have left ventricular ejection fraction \leq 50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant. Some CRT ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

MRI SureScan IPGs, CRT IPGs, ICDs and CRT ICDs only:

Medtronic SureScan systems are MR Conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use. Patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging. When SureScan systems are programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. A complete SureScan system, which is a SureScan device with appropriate SureScan lead(s), is required for use in the MR environment. To verify that components are part of a SureScan system, visit <http://www.mrisurescan.com/>. Any other combination may result in a hazard to the patient during an MRI scan.

Contraindications

Transvenous IPGs and CRT-Ps are contraindicated for concomitant implantation with another bradycardia device or an implantable cardioverter defibrillator.

ICDs and CRT-Ds are contraindicated in patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis; patients who have a unipolar pacemaker implanted, patients with incessant ventricular tachycardia (VT) or ventricular fibrillation (VF), and patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

Warnings and Precautions

Changes in a patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset or device damage. Do not place transthoracic defibrillation paddles directly over the device.

Additionally, for CRT-Ds and CRT-Ps, certain programming and device operations may not provide cardiac resynchronization. Also for CRT-Ps, Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and/or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set. Use of the device should not change the application of established anticoagulation protocols.

MRI SureScan systems: Patients and their implanted systems must be screened to meet the following requirements for MRI: no lead extenders, lead adaptors or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history and the system must be implanted in the left or right pectoral region.

Potential Adverse Events

Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis. An additional complication for ICDs and CRT ICDs is the acceleration of ventricular tachycardia.

MRI SureScan Systems: Potential MRI complications for the SureScan system include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or MRI induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse; spontaneous tachyarrhythmia occurring during the scan that is not detected and treated because tachyarrhythmia detection is suspended while MRI SureScan is programmed to On; potential for VT/VF induction when the patient is programmed to an asynchronous pacing mode during MRI SureScan; device heating resulting in tissue damage in the implant pocket or patient discomfort or both; or damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer. See the MRI SureScan Technical Manual before performing an MRI Scan.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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