

### 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, 2018<sup>1</sup>. 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

## Frequently asked questions

### Q: What has changed in the new MRI NCD?

- A:** The previous NCD specified coverage explicitly for an MRI when performed in patients with an implanted pacemaker that had received FDA labeling for use in an MR environment. Under the new NCD language:
- For the purposes of the NCD, CIED is defined as a pacemaker, ICD, CRT-D, or CRT-P.
  - MRI in patients with a CIED that is FDA-approved for an MRI environment will be covered with no additional requirements.
  - MRI in patients with a CIED that is not FDA-approved for an MRI environment will also be covered, but only when the specified checklist criteria are met.
  - The previous coverage with evidence development (CED) requirement is removed.

### Q: Is an MRI covered for a patient with an implantable loop recorder (ILR) or implantable cardiac monitor (ICM)?

- A:** ILR and ICM devices are not specifically addressed in this policy. CMS coverage of an MRI in patients with one of these devices is determined by each Medicare Administrative Contractor (MAC).

### Q: What is CMS's definition of direct supervision?

- A:** Direct supervision means that the physician must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room where the procedure is performed.<sup>2</sup>

### 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: How is peri-procedural device evaluation and programming reported?

- A:** Peri-procedural device evaluation and programming codes (93286-93287) are reported for evaluation of an implantable device system to adjust the device to settings appropriate for the patient prior to and/or after a surgery, procedure, or test. These codes capture work that is beyond turning the device on or off. The applicable code(s) should be reported when devices may require changes and reprogramming. Peri-procedural evaluation services are billed once per service, up to two times if done both before and after the surgery, procedure, or test. Append modifier -76 (repeat service by same physician) or -77 (repeat service by another physician) to the second (post-service) code.

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

- A:** Not necessarily. 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](mailto:rs.healthcareeconomics@medtronic.com)

## References

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

<sup>1</sup>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 13, 2022.

<sup>2</sup>CMS Definition of Direct Supervision. Available at: [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/downloads/410\\_32.pdf](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/downloads/410_32.pdf). Accessed January 13, 2022

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