

# UNDERSTANDING CMS COVERAGE FOR ICDs



## OVERVIEW

The following information represents the CMS covered indications for the use of Implantable Cardioverter Defibrillators (ICDs) based on the National Coverage Determination (NCD) for ICDs (20.4) effective February 15, 2018<sup>1</sup>. For each indication, all specified criteria must be met.

### ICD AS SECONDARY PREVENTION

Has had prior sustained VT or cardiac arrest due to VF, not due to transient or reversible cause

### ICD AS PRIMARY PREVENTION\*

- Has documented familial or genetic disorders with a high risk of sustained VT or VF (e.g. long QT syndrome; hypertrophic cardiomyopathy)

OR

- § Has prior MI
- § Has LVEF ≤ 30
- § Does not have NYHA Class IV
- § Has not had CABG/PCI in last 3 months\*\*
- § Has not had MI in last 40 days\*\*
- § Is not a candidate for coronary revascularization

OR

- § Has severe IDCM/NIDCM
- § Has NYHA Class II or III
- § Has LVEF ≤ 35%
- § Has been on OMT ≥ 3 months
- § Has not had CABG/PCI in last 3 months\*\*
- § Has not had MI in last 40 days\*\*
- § Is not a candidate for coronary revascularization

\*Formal shared decision making is required using an evidence-based decision tool on ICDs

\*\*Unless the patient meets a CMS-covered indication for pacing<sup>2</sup> or has an existing ICD that requires replacement

## REQUIRED CRITERIA FOR ALL ICD PATIENTS

In addition to the above, patients must meet the following criteria:

- Clinically stable
- LVEF measured by at least one of the following: Echocardiography, Radionuclide (nuclear medicine) Imaging, Cardiac Magnetic Resonance Imaging (MRI), Catheter Angiography
- Patient must not have:
  - Significantly irreversible brain damage
  - Life expectancy < 1 year
  - Uncontrolled SVT such as from atrial fibrillation

## ACRONYMS

- CABG** - Coronary Artery Bypass Graft
- CMS** - Centers for Medicare and Medicaid Services
- ICD** - Implantable Cardioverter Defibrillator
- (N)IDCM** - (Non) Ischemic Dilated Cardiomyopathy
- LVEF** - Left Ventricular Ejection Fraction
- MI** - Myocardial Infarction
- NYHA** - New York Heart Association
- OMT** - Optimal Medical Therapy
- PCI** - Percutaneous Coronary Intervention
- SVT** - Supraventricular Tachycardia
- VF** - Ventricular Fibrillation
- VT** - Ventricular Tachycardia

## FREQUENTLY ASKED QUESTIONS

### Q: Is the coverage for ICDs limited or expanded as compared to the previous NCD?

**A:** The new coverage determination has not substantially changed which patients would be covered under the previous NCD. CMS has added a couple of new exceptions to the waiting periods post MI/CABG (for patients who have a pacemaker indication and for those needing a device replacement), so patients receiving an ICD under these conditions will now be covered before the waiting period expires.

### Q: Are CRT-D devices covered as part of the ICD National Coverage Determination?

**A:** According to the CMS decision memo<sup>2</sup> finalizing changes to this NCD, "The scope of this review is limited to ICDs. While we reference cardiac resynchronization therapy defibrillator (CRT-D) devices in this document since these devices have defibrillator functions, CRT devices are outside the scope of this decision. CRT devices are currently covered at local contractor discretion and not currently subject to an NCD." Check with your local Medicare Administrative Contractor about specific coverage requirements for CRT-D devices.

### Q: With the removal of the NCD R ICD Registry requirement, can I immediately cease data collection for ICD recipients?

**A:** Check with your hospital administrator first. While the new NCD eliminates the requirement for data collection as a condition for coverage, hospital participation in the NCD R ICD Registry continues in a voluntary capacity. If your hospital has elected to continue participating in the registry, you may have continuing reason to collect data.

### Q: How can I meet the shared decision making requirement?

**A:** For primary prevention patients, CMS specifies that a formal shared decision making encounter must occur between the patient and a physician or qualified non-physician practitioner (physician assistant, nurse practitioner, or clinical nurse specialist) using an evidence-based decision tool on ICDs prior to initial ICD implantation. This encounter can happen during a separate visit.

The NCD references a sample shared decision making tool that can be found at <https://patientdecisionaid.org/icd/>. A second sample tool can be found at <https://www.cardiosmart.org/healthwise/abk4/103/abk4103>. In addition, guidelines published in 2017 by AHA/ACC/HRS provide recommendations for the elements of shared decisionmaking.<sup>3</sup>

### Q: Do private payers have the same ICD indications for coverage as Medicare?

**A:** Not necessarily. Consult the specific payer coverage policy to determine requirements for coverage.

#### Disclaimer

These interpretations are for educational purposes and do not replace seeking coverage advice from CMS and/or your own staff. The ultimate responsibility for appropriate use of therapy lies with the provider of services. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare (or other third party payers).

Be sure to reference your local CMS Medicare Administrative Contractor Local Coverage Determination (LCD) for state or region-specific coverage requirements.

#### Contact

For additional information, contact Reimbursement Customer Support by email at [rs.healthcareconomics@medtronic.com](mailto:rs.healthcareconomics@medtronic.com) or call us at 1-866-877-4102 (8 a.m. to 5 p.m. CT, Monday-Friday)

#### References

<sup>1</sup> CMS National Coverage Determination for ICDs (20.4). Available: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=110>. Accessed December 11, 2020.

<sup>2</sup> CMS Decision Memo for Implantable Cardioverter Defibrillators (CAG-00157R4). Available: <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=288>. Accessed December 11, 2020

<sup>3</sup> Al-Khatib SM, Stevenson WG, Ackerman MJ et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm. 2017 Oct 30; pii: S1547-5271(17)31249-3.

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