Understanding Medicare coverage for ICDs

Overview

The following information represents the Medicare 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. For each indication, all specified criteria must be met.

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)
- 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

ICD as secondary prevention

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

ICD replacement

- Has severe NIDCM but no personal history of cardiac arrest or sustained VT
- 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
- Has severe IDCM but no personal history of sustained VT or cardiac arrest due to VF
- Has NYHA Class II or III
- Has LVEF ≤ 35%
- 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 required using an evidence-based decision tool on ICDs

Due to the end of battery life, elective replacement indicator (ERI), or device/lead malfunction

* Unless the patient meets a CMS-covered indication for pacing or has an existing ICD that requires replacement
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Required criteria for all ICD patients
In addition to the above, patients must meet the following criteria:

- Clinically stable
- LVEF measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography
- Patient must not have:
  - Significant, irreversible brain damage
  - Any other disease associated with survival < 1 year
  - SVT such as from atrial fibrillation with a poorly controlled ventricular rate

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Acronyms:
- CABG - Coronary artery bypass graft
- CMS - Centers for Medicare & Medicaid services
- IDCM - Ischemic dilated cardiomyopathy
- LVEF - Left ventricular ejection fraction
- MI - Myocardial infarction
- NCDR - National Cardiovascular Data Registry
- NIDCM - Non-ischemic dilated cardiomyopathy
- NYHA - New York Heart Association
- OMT - Optimal medical therapy
- PCI - Percutaneous coronary intervention
- SVT - Supraventricular tachycardia
- VF - Ventricular fibrillation
- VT - Ventricular tachycardia
References


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 ≤ 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF ≤ 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 ≤ 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction ≤ 30%, and NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤ 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.