Medtronic

Coverage corner

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[1]. For each indication, all specified criteria must be met.

ICD as primary prevention

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

- 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

- 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

* Unless the patient meets a CMS-covered indication for pacing[2] or has an existing ICD that requires replacement

ICD as secondary prevention

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

ICD replacement

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

Disclaimer

Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules, and regulations. The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists, and/or legal counsel for interpretation of coding, coverage, and payment policies. This document provides assistance for FDA-approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA-cleared or approved labeling (e.g., instructions for use, operator's manual, or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service.

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

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

Contact us

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

References

[1]CMS National Coverage Determination for ICDs (20.4). Available: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=110. Accessed December 2, 2022.

[2]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 2, 2022.

[3]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.

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 II. 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.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000
medtronic.com

Medtronic