



Medical Coverage Policy

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Implantable Cardioverter Defibrillator (ICD)

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Related Coverage Resources

- [Biventricular Pacing/Cardiac Resynchronization Therapy \(CRT\)](#)
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Overview

This Coverage Policy addresses the use of implantable transvenous, subcutaneous cardioverter-defibrillator and leadless cardiac pacemaker devices to monitor heart rhythm and deliver an electrical shock when a life threatening ventricular arrhythmia is detected.

Coverage Policy

Secondary Prevention

A transvenous implantable cardioverter defibrillator (ICD) is considered medically necessary for ANY of the following indications:

- **Coronary artery disease (CAD): ventricular fibrillation (VF) or hemodynamically unstable ventricular tachycardia (VT) associated with acute (< 48 hours) myocardial infarction (MI) (newly diagnosed, no recent prior assessment of left ventricular ejection fraction (LVEF), and ANY of the following:**
 - Revascularization completed after cardiac arrest, and EITHER of the following:
 - Recurrent VF or polymorphic VT during/following acute (< 48 hours) MI

- VF or polymorphic VT during/following acute MI, nonsustained ventricular tachycardia (NSVT) 4 days post MI, Inducible VT/VF at electrophysiologic study (EPS) \geq 4 days after revascularization
 - No revascularization needed (i.e., no significant CAD), but recurrent VF or polymorphic VT during/following acute MI
 - Obstructive CAD with coronary anatomy not amenable to revascularization, with VF or polymorphic VT during/following acute MI
- **CAD: VF or hemodynamically unstable VT < 48 hours post-elective revascularization, with no evidence for acute coronary occlusion, restenosis, preceding infarct, or other clearly reversible cause**
- **CAD: VF or hemodynamically unstable VT (no recent MI [within the past 40 days] prior to VF/VT and/or no recent revascularization [3 Months] prior to VF/VT) and ANY of the following:**
 - No identifiable transient and completely reversible causes, and no need for revascularization identified by catheterization performed following VF/VT
 - Significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization
 - Significant CAD identified at catheterization performed following VF/VT, and revascularization performed after cardiac arrest
- **CAD: VF or hemodynamically unstable VT during exercise testing associated with significant CAD and ANY of the following:**
 - Significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization
 - Significant CAD identified at catheterization performed following VF/VT, and revascularization performed after cardiac arrest
- **No CAD, VF or Hemodynamically Unstable VT and ANY of the following:**
 - Dilated nonischemic cardiomyopathy
 - VT/VF associated with cocaine abuse, LVEF \leq 35%
 - Severe valvular disease, VT/VF < 48 hours after surgical repair or replacement of aortic or mitral valve, with no evidence of postoperative valvular dysfunction
 - VF/hemodynamically unstable VT associated with ANY of the following:
 - Myocardial sarcoidosis
 - Myocarditis or giant cell myocarditis
 - Takotsubo cardiomyopathy (stress-induced cardiomyopathy, apical ballooning syndrome) \geq 48 hours of onset of symptoms
- **Genetic conditions associated with sustained VT, VF (i.e., congenital long QT, short QT, catecholaminergic polymorphic VT, Brugada syndrome, arrhythmogenic right ventricular cardiomyopathy, hypertrophic cardiomyopathy)**
- **Absence of structural heart disease (LVEF > 50%) or known genetic causes of sustained VT/VF, and EITHER of the following:**
 - Idiopathic VF with normal ventricular function
 - Bradycardia dependent VT/VF
- **Unexplained syncope in the absence of structural heart disease in an individual with long QT syndrome, Brugada ECG pattern, catecholaminergic polymorphic VT**

- **Unexplained syncope in an individual with prior MI and no acute MI, with LVEF 36%-49% and ANY of the following:**
 - Nonobstructive CAD, revascularization is not indicated, and EPS failed to define a cause of syncope
 - Obstructive CAD not amenable to revascularization, and EPS failed to define a cause of syncope
 - EPS revealed inducible sustained VT/VF
- **Unexplained syncope in an individual with prior MI and no acute MI LVEF ≤ 35%**
- **Unexplained syncope in an individual with left ventricular hypertrophy/hypertensive heart disease, LVEF ≤ 49%**
- **Unexplained syncope in individual with nonischemic cardiomyopathy and ANY of the following:**
 - Nonischemic dilated cardiomyopathy, LVEF ≤ 49%
 - Left ventricular non-compaction
 - Hypertrophic cardiomyopathy
 - Cardiac amyloidosis
 - Tetralogy of Fallot with prior corrective surgery
- **Unexplained syncope in individual with arrhythmogenic right ventricular cardiomyopathy**
- **Sustained hemodynamically stable monomorphic VT associated with structural heart disease and ANY of the following:**
 - CAD and prior MI
 - Nonischemic dilated cardiomyopathy
 - Bundle branch re-entry successfully ablated in individual with nonischemic cardiomyopathy, LVEF ≤ 49%
 - Bundle branch re-entry successfully ablated in individual with nonischemic cardiomyopathy, LVEF ≤ 49%

Primary Prevention

A transvenous implantable cardioverter defibrillator (ICD) is considered medically necessary for ANY of the following indications:

- **Post-acute Myocardial Infarction (MI) (≤ 40 days) and revascularization, with LVEF ≤ 30% and BOTH of the following:**
 - Asymptomatic nonsustained ventricular tachycardia (NSVT) (>4 days post MI)
 - EPS with inducible sustained VT (EPS performed after revascularization, within 40 days after MI)
- **Post-acute MI (< 40 days), with obstructive CAD, not revascularized, with coronary anatomy not amenable to revascularization, and BOTH of the following:**
 - Asymptomatic NSVT (>4 days post MI)
 - EPS with inducible sustained VT (EPS performed within 40 days after MI)
- **Post acute MI (≤ 40 days) and revascularization, with LVEF 31%-40% and BOTH of the following:**
 - Asymptomatic NSVT (>4 days post MI)

- EPS with inducible sustained VT (EPS performed after revascularization, within 40 days after MI)
- **Post acute MI (≤ 40 days) with pre-existing chronic cardiomyopathy (≥ 3 Months) and ANY of the following:**
 - LVEF < 30% due to old infarction. New York Heart Association (NYHA) class I
 - LVEF < 35% due to old infarction. NYHA class II-III
 - LVEF < 35% due to nonischemic causes. NYHA class I-III
- **Post-MI (≤ 40 Days) and need for guideline-directed pacemaker therapy post-MI (e.g., sick sinus syndrome (SSS), complete heart block (CHB), or other indications for permanent pacemaker), with LVEF ≤ 40%**
- **Post-MI (>40 Days) with ischemic cardiomyopathy, no recent percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) and EITHER of the following:**
 - LVEF ≤ 35%
 - LVEF 36%-40%. asymptomatic NSVT with EPS showing inducible sustained VT/VF
- **Post-MI (>40 Days) with ischemic cardiomyopathy, with recent PCI or CABG (≤ 3 months, and ANY of the following:**
 - No known pre-existing cardiomyopathy, LVEF ≤ 35
 - Pre-existing documented cardiomyopathy. LVEF ≤ 35% on guideline-directed medical therapy > 3 months before PCI/CABG
 - LVEF ≤ 40%, with need for permanent pacemaker post-revascularization (e.g., SSS, CHB, or other guideline-directed indications for permanent pacemaker)
- **Ischemic cardiomyopathy without recent MI (revascularization not indicated), with LVEF ≤ 35%, on guideline-directed medical therapy**
- **Nonischemic cardiomyopathy, at least 3 months on guideline-directed medical therapy, with LVEF ≤ 35%, NYHA Class I-III**
- **Individual with ANY of the following conditions:**
 - Sarcoid heart disease,
 - myotonic dystrophy
 - Chagas disease
 - Amyloidosis with heart failure
 - Acute lymphocytic myocarditis, newly diagnosed (< 3 months)
 - Giant cell myocarditis
 - Peripartum cardiomyopathy, persists > 3 months postpartum, LVEF ≤ 35%
- **Individual with ANY of the following genetic conditions (excludes syncope and sustained VT, addressed above)**
 - Hypertrophic cardiomyopathy with 1 or more risk factors
 - Arrhythmogenic right ventricular dysplasia/cardiomyopathy with no symptoms due to arrhythmia
 - Congenital long QT Syndrome with 1 or more risk factors
 - Catecholaminergic polymorphic VT with nonsustained VT (without syncope)
 - Incidentally discovered Brugada by ECG (type I ECG pattern) in the absence of symptoms or family history of sudden cardiac death, with inducible VT or VF at EPS
 - Familial dilated nonischemic cardiomyopathy (RV/LV) associated with sudden cardiac death, and ANY of the following:

- Evidence of structural cardiac disease, but LVEF > 35%
- Normal ECG and echo, but carrying the implicated gene
- LV non-compaction with LVEF > 35%

A transvenous ICD is considered medically necessary in a child who is receiving optimal medical therapy and has survived cardiac arrest when evaluation fails to identify a reversible cause.

A transvenous ICD is considered medically necessary in a child with hypertrophic cardiomyopathy and unexplained syncope, massive left ventricular hypertrophy, or family history of sudden cardiac death.

A transvenous ICD is considered experimental, investigational or unproven for any other indication.

Replacement of a transvenous ICD pulse generator and/or leads is considered medically necessary.

A subcutaneous ICD (S-ICD) system (CPT codes 33270, 33271, 33272, 33273) is considered medically necessary when an individual has met the criteria for a transvenous ICD and has NONE of the following:

- symptomatic bradycardia
- incessant ventricular tachycardia (VT)
- spontaneous frequent recurring VT reliably terminated with anti-tachycardia pacing

A subcutaneous implantable cardioverter defibrillator system is considered experimental, investigational or unproven for any other indication.

A leadless cardiac pacemaker (CPT codes 33274, 33275) is considered experimental, investigational or unproven for any indication.

General Background

Transvenous Implantable Cardioverter Defibrillator (ICD)

There is a high incidence of sudden cardiac death (SCD) in patients with heart failure and diminished left ventricular ejection fraction (LVEF) and in patients who are recovering from acute myocardial infarction (MI). Although significant effort has been directed to the identification and treatment of high-risk patients, this group actually accounts for a small proportion of preventable SCD. Although the risk of SCD increases in proportion to the severity of cardiac disease in an individual patient, most events occur in patients with no known cardiac history and with few or no risk factors. There is no single test capable of accurately predicting SCD risk in various clinical settings and patient populations. Although available tests can provide valuable information, they are hampered by limited positive predictive value and are not sufficiently investigated in many categories of patients with structural heart disease (Zipes, et al., 2006; Kusmirek and Gold, 2007).

Ventricular fibrillation is the rhythm most frequently recorded at the time of sudden cardiac arrest. Although a number of studies have investigated the electrophysiologic (EP) mechanisms responsible for the onset of ventricular tachycardia and ventricular fibrillation, antiarrhythmic agents have not been shown to be effective in preventing SCD. Rather, it is the drugs that have no direct EP actions on cardiac muscle or specialized conducting tissue that have been demonstrated to be effective in preventing SCD. Such drugs include beta blockers, ACE inhibitors, angiotensin receptor-blocking agents, lipid-lowering agents, spironolactone, and fibrinolytic and anti-thrombotic agents (Zipes, et al., 2006).

SCD, a direct result of cardiac arrest, may be preventable if the arrest is responded to promptly. The implantable cardioverter defibrillator (ICD) is a surgically implanted device designed to constantly monitor an individual's heart rate, recognize VF or VT and deliver an electric shock to terminate these arrhythmias in order to reduce the risk of sudden death. The device is connected to leads positioned inside the heart or on its surface. These leads sense the cardiac rhythm, deliver electrical shocks, and sometimes pace the heart, as needed. The leads are tunneled to a pulse generator, which is implanted in a pouch beneath the skin of the chest or abdomen. Progressive improvements in design and miniaturization have allowed transvenous placement of ICDs to

become routine. An epicardial rather than transvenous approach may be required in children, and less commonly in adults. In this surgical procedure one end of the lead is attached to the heart and the other end of the lead is attached to the pulse generator and placed in a pocket created under the skin of the abdomen.

Procedural complication rates range from three to six percent, with up to one-half of these considered serious. Complications include bleeding infections, lead dislodgement, pneumothorax, cardiac perforation, and rarely death. Perioperative mortality with transvenous ICD implantation has ranged from 0.2 to 0.4 percent. Lead-related complications, in addition to infection and dislodgement, include fracture and insulation defects. Most lead dislodgements and infections occur in the first three months following implantation, while lead fractures continue to occur during follow-up. Reported lead failure rates vary from one to nine percent at two years, two to fifteen percent and five years and five to forty percent at eight to ten years. Deaths related to lead failure have been reported but are exceedingly rare. The overall complication rate has decreased over the period from 2006 to 2010, a period that correlates with the introduction of an ICD registry in the US. In an observational study of 367,153 ICD recipients between April 2006 and March 2010, in-hospital complications and mortality significantly decreased from 3.7% during year one to 2.8% during year four (Ganz, 2016).

Additional problems associated with ICDs include inappropriate shock discharge, defibrillator storm with appropriate recurrent ICD discharge for recurrent ventricular tachyarrhythmias, inappropriate discharge for multiple reasons, infections related to implantation and exacerbation of heart failure when a high percentage of the heartbeats are paced from the right ventricle apex and ventricular function is already compromised.

When an ICD nears the end of battery life it is replaced. A pulse generator will last for five or more years in most patients. One study suggested that devices implanted after 2002 have significantly longer battery lives (5.6 versus 4.9 years), and single chamber ICDs implanted since 2002 had the longest battery life (mean 6.7 years).

Two categories of trials have investigated the use of ICDs for prevention of SCD. ICDs have been evaluated for primary (i.e., prophylactic) prevention of SCD in patients who have not experienced a life-threatening ventricular arrhythmia (or a symptomatic equivalent). Secondary prevention trials have evaluated the use of ICDs in patients who have had an abortive cardiac arrest, a life-threatening VT, or unexplained syncope with high probability that a ventricular tachyarrhythmia was the cause (Priori, et al., 2015; Zipes, et al., 2006).

U.S. Food and Drug Administration (FDA)

Multiple ICD devices have been approved by the U. S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) process. Manufacturers of ICD devices include Biotronik (Lake Oswego, OR), Boston Scientific (Natick, MA), Sorin Group (Arvada, CO), Medtronic (Minneapolis, MN), and St. Jude Medical (St. Paul, MN),

Professional Societies/Organizations

American College of Cardiology Foundation (ACCF), Heart Rhythm Society (HRS), American Heart Association (AHA), American Society of Echocardiography (ASE), Heart Failure Society of America (HFSA), Society for Cardiovascular Angiography and Interventions (SCAI), Society of Cardiovascular Computed Tomography (SCCT), and Society for Cardiovascular Magnetic Resonance (SCMR) 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy describes the appropriate use of these devices for selected patient populations (Russo, et al., 2013). The authors state that the appropriate use criteria should be used in conjunction with the ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (Epstein et al., 2008) and the 2012 focused update of that guideline (Tracy, et al., 2012).

The appropriateness scores for each indication reflect the median score of the 17 technical panel members. The authors state that "The relationship of these criteria to existing guidelines was provided to the technical panel. In addition, extensive links to clinical trials and other literature regarding the role of ICD and CRT in each clinical scenario were provided to technical panel members. This document represents the current understanding of the clinical utility of ICD and CRT implantation in clinical practice as measured by physicians with a variety of backgrounds and areas of expertise. It is the goal that these criteria will help provide a guide to inform medical decisions and help clinicians and stakeholders understand areas of consensus as well as uncertainty, while identifying areas where there are gaps in knowledge that warrant additional investigation".

Recommendations are provided based on the following scoring method:

- Median score 7-9: Appropriate care: An appropriate option for management of patients in this population due to benefits generally outweighing risks; effective option for individual care plans, although not always necessary, depending on physician judgment and patient-specific preferences (i.e., procedure is generally acceptable and is generally reasonable for the indication).
- Median score 4-6: May be appropriate for care: At times an appropriate option for management of patients in this population due to variable evidence or agreement regarding the benefit/risk ratio, potential benefit based on practice experience in the absence of evidence, and/or variability in the population; effectiveness for individual care must be determined by a patient's physician in consultation with the patient based on additional clinical variables and judgment along with patient preferences (i.e., procedure may be acceptable and may be reasonable for the indication).
- Median score 1-3: Rarely appropriate care: Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e., procedure is not generally acceptable and is not generally reasonable for the indication).

Generally, criteria that have been deemed Appropriate or May Be Appropriate in these scenarios often meet Class I, IIa, or IIb criteria in guideline documents, are supported by a critical mass of existing data, or were deemed by the technical panel to meet sufficient clinical judgment to be reasonable and appropriate.

Indications rated as Appropriate or May be Appropriate are detailed below; indications rated as Rarely Appropriate are outlined in the appropriate use criteria document described above.

ICD implantation is rated as Appropriate (median score 7-9) for the following indications:

Secondary Prevention

Coronary artery disease (CAD): ventricular fibrillation (VF) or hemodynamically unstable ventricular tachycardia (VT) associated with acute (<48 hours) myocardial infarction (MI) (newly diagnosed, no prior assessment of left ventricular ejection fraction (LVEF))

- Total Revascularization Completed After Cardiac Arrest
VF or polymorphic VT during acute (<48 hours) MI, NSVT 4 days post MI, Inducible VT/VF at EPS ≥ 4 days after revascularization, LVEF 36-49% (7)
VF or polymorphic VT during acute (<48 hours) MI, LVEF ≤ 35% (8)
- Obstructive CAD with coronary anatomy not amenable to revascularization
VF or polymorphic VT during acute (<48 hours) MI, no electrophysiologic study (EPS) done (7)

CAD: VF or Hemodynamically Unstable VT <48 h (Acute) Post-Elective Revascularization

- No evidence for acute coronary occlusion, restenosis, preceding infarct, or other clearly reversible cause, LVEF ≤ 35% (7)

CAD: VF or Hemodynamically Unstable VT (No Recent MI [<40 Days] Prior to VF/VT and/or No Recent Revascularization [3 Months] Prior to VF/VT)

- No identifiable transient and completely reversible causes. No need for revascularization identified by cath performed following VF/VT (9)
- No revascularization performed (significant CAD present at cath performed following VF/VT, but coronary anatomy not amenable to revascularization (9)
- Significant CAD identified at cath performed following VF/VT. Complete revascularization performed after cardiac arrest. LVEF ≤ 49% (7)

- Significant CAD identified at cath performed following VF/VT. Incomplete revascularization performed after cardiac arrest LVEF \geq 50% (7)
- Significant CAD identified at cath performed following VF/VT. Incomplete revascularization performed after cardiac arrest. LVEF 36-49% (8)
- Significant CAD identified at cath performed following VF/VT. Incomplete revascularization performed after cardiac arrest. LVEF \leq 35% (9)

CAD: VF or Hemodynamically Unstable VT During Exercise Testing Associated With Significant CAD

- No revascularization performed (significant CAD present at cath performed following VF/VT, but coronary anatomy not amenable to revascularization) (9)
- Significant CAD identified at cath performed following VF/VT. Complete revascularization performed after cardiac arrest. LVEF \leq 35% (7)
- Significant CAD identified at cath performed following VF/VT. Incomplete revascularization performed after cardiac arrest LVEF \geq 36% (7)
- Significant CAD identified at cath performed following VF/VT. Incomplete revascularization performed after cardiac arrest LVEF \leq 35% (8)

No CAD, VF or Hemodynamically Unstable VT

- Dilated nonischemic cardiomyopathy (9)
- VF/Hemodynamically Unstable VT Associated With Other Structural Heart Disease
 - Myocardial Sarcoidosis (9)
 - Giant cell myocarditis (8)

Genetic Diseases with Sustained VT, VF

- Congenital long QT (9)
- Short QT (9)
- Catecholaminergic polymorphic VT (9)
- Brugada Syndrome (9)
- ARVC with successful ablation of all inducible monomorphic VTs (9)
- ARVC with unsuccessful attempt to ablate an inducible VT (9)
- ARVC without attempted ablation (9)
- Hypertrophic cardiomyopathy (9)

No Structural Heart Disease (LVEF >50%) or Known Genetic Causes of Sustained VT/VF

- Idiopathic VF With Normal Ventricular Function
 - No family history of sudden cardiac death (9)
 - First degree relative with sudden cardiac death (9)

Syncope in Patients Without Structural Heart Disease

- Unexplained Syncope in a Patient With Long QT Syndrome
 - While on treatment with beta blockers (9)
 - Not being treated with beta blockers (7)
- Unexplained Syncope in a Patient with Brugada ECG Pattern
 - No EPS performed (8)
 - EPS performed. No ventricular arrhythmia induced (8)
 - EPS performed Sustained VT/VF induced (9)
- Unexplained Syncope in a Patient with Catecholaminergic Polymorphic VT
 - While on treatment with beta blockers (8)
 - Not being treated with beta blockers (8)

Syncope in Patients With Coronary Artery Disease

- Unexplained Syncope With Prior MI and No Acute MI, LVEF 36%-49%
 - EPS revealed inducible sustained VT/VF (9)

Unexplained Syncope With Prior MI and no Acute MI. LVEF \leq 35%

- EPS not performed (9)
- Inducible VT/VF on EPS (9)
- Not inducible at EPS (8)

Syncope in Patients with Nonischemic Structural Heart Disease

- Unexplained Syncope in a Patient with Left Ventricular Hypertrophy, Without Criteria for Hypertrophic Cardiomyopathy
Left ventricular hypertrophy/hypertensive heart disease, LVEF \leq 35% (8)
- Unexplained Syncope in a Patient with Nonischemic Cardiomyopathy
Nonischemic dilated cardiomyopathy, LVEF \leq 35% (8)
Left ventricular non-compaction, LVEF 36%-49% (7)
Left ventricular non-compaction, \leq 35% (8)
Hypertrophic cardiomyopathy (8)
Tetralogy of Fallot with prior corrective surgery (7)
- Unexplained syncope in a Patient With Arrhythmogenic Right Ventricular Cardiomyopathy
No EPS performed (7)
No induction of VT/VF at EPS (7)
Inducible VT/VF at EPS. All inducible VTs successfully ablated. (7)
Inducible VT/VF at EPS. Ablation unsuccessful. (8)

Sustained Hemodynamically Stable Monomorphic VT Associated with Structural Heart Disease

- CAD and prior MI
LVEF \geq 36% (7)
LVEF \leq 35% (9)
- CAD and prior MI. All inducible VTs successfully ablated. LVEF \leq 35% (9)
- CAD and prior MI. Troponin elevation thought to be secondary to VT. All inducible VTs successfully ablated. LVEF 36%-49% (7)
- CAD and prior MI. Troponin elevation thought to be secondary to VT. All inducible VTs successfully ablated. LVEF \leq 35% (8)
- Nonischemic dilated cardiomyopathy. LVEF \geq 50% (7)
- Nonischemic dilated cardiomyopathy. LVEF 36%-49% (7)
- Nonischemic dilated cardiomyopathy LVEF \leq 35% (9)
- Nonischemic dilated cardiomyopathy. All inducible VTs successfully ablated. LVEF 36%-49% (7)
- Nonischemic dilated cardiomyopathy. All inducible VTs successfully ablated. LVEF \leq 35% (8)
- Bundle branch re-entry successfully ablated in a patient with nonischemic cardiomyopathy. LVEF 36%-49% (7)
- Bundle branch re-entry successfully ablated in a patient with nonischemic cardiomyopathy. LVEF \leq 35% (8)

Primary Prevention

Post-Acute Myocardial Infarction (MI) (< 40 days) LVEF \leq 30%

- Revascularized after Acute MI
Asymptomatic nonsustained ventricular tachycardia (NSVT) (>4 days post MI). EPS with inducible sustained VT (EPS performed after revascularization, within 30 days of MI) (7)
Asymptomatic NSVT (>4 days post MI). EPS with inducible sustained VT (EPS performed after revascularization, between 30 and 40 days after MI) (8)
- Not Revascularized. Obstructive CAD With Coronary Anatomy Not Amenable to Revascularization
Asymptomatic NSVT (>4 days post MI). EPS with inducible sustained VT (EPS performed within 30 days of MI) (7)
Asymptomatic NSVT (>4 days post MI) EPS with inducible sustained VT (EPS performed between 30 and 40 days after MI) (8)

Post Acute MI (\leq 40 days) LVEF 31%-40%

- Revascularized for acute MI
Asymptomatic NSVT (>4 days post MI). EPS with inducible sustained VT (EPS performed after revascularization, within 30 days of MI) (7)
Asymptomatic NSVT (>4 days post MI) EPS with inducible sustained VT (EPS performed after revascularization, between 30 and 40 days after MI) (7)

Post Acute MI (≤ 40 days) and Pre-Existing Chronic Cardiomyopathy (≥ 3 Months)

- LVEF < 30% due to old infarction. NYHA class I (8)
- LVEF < 35% due to old infarction. NYHA class II=III (9)
- LVEF < 35% due to nonischemic causes. NYHA class I-III (8)

Post-MI (≤ 40 Days) and Need for Guideline-Directed Pacemaker Therapy Post-MI (e.g., Sick Sinus Syndrome (SSS), Complete Heart Block (CHB), or Other Indications for Permanent Pacemaker)

- LVEF ≤ 35% (7)

Post-Myocardial Infarction (>40 Days) With Ischemic Cardiomyopathy

- No Recent Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Graft (CABG)
LVEF < 30%, New York Heart Association (NYHA) Class I (8)
LVEF < 30%, New York Heart Association (NYHA) Class II or III (9)
LVEF 31%-35%. NYHA Class I (7)
LVEF 31%-35%. NYHA Class II or III (9)
LVEF 36%-40%. Asymptomatic NSVT. EPS with inducible sustained VT/VF.(8)
- Recent PCI or CABG (≤ 3 months)
Pre-existing documented cardiomyopathy. LVEF ≤ 35% on guideline-directed medical therapy > 3 months before PCI/CABG (8)
LVEF ≤ 35%. Need for permanent pacemaker post-revascularization (e.g., SSS, CHB, or other guideline-directed indications for permanent pacemaker) (8)

Duration of Guideline-Directed Medical Therapy for Ischemic Cardiomyopathy Without Recent MI (Revascularization Not Indicated)

- LVEF ≤ 35%. On guideline-directed medical therapy for < 3 months, NSVT, EPS with inducible sustained VT (8)
- LVEF ≤ 35%. On guideline-directed medical therapy ≥ 3 months (9)

Nonischemic Cardiomyopathy

- At Least 3 Months on Guideline-Directed Medical Therapy
LVEF < 30%, NYHA Class I (7)
LVEF < 30%, NYHA Class II or III (9)
LVEF 31%-35%, NYHA Class I (7)
LVEF 31-35%, NYHA Class II or III (9)

Specific Etiologies

- Sarcoid heart disease, myotonic dystrophy, or Chagas disease, with LVEF ≤ 35%. (8)
- Giant cell myocarditis, LVEF ≤ 35%. (8)
- Giant cell myocarditis, LVEF > 35%. (7)
- Peripartum cardiomyopathy, persists > 3 months postpartum (8)

Genetic Conditions (Excludes Syncope and Sustained VT, addressed above)

- Hypertrophic cardiomyopathy with 1 or more risk factors (7)
- Arrhythmogenic right ventricular dysplasia/cardiomyopathy with no symptoms due to arrhythmia (7)
- Congenital long QT Syndrome with 1 or more risk factors, receiving guideline-directed medical therapy (7)
- Catecholaminergic polymorphic VT with nonsustained VT (without syncope)
Not receiving beta-blockers, flecainide, or propafenone (7)
Receiving beta-blockers (7)

- Not tolerating or breakthrough nonsustained ventricular arrhythmias on beta-blockers (8)
- Incidentally discovered Brugada by ECG (type I ECG pattern) in the absence of symptoms or family history of sudden cardiac death, with inducible VT or VF at EPS (7)
- Familial dilated nonischemic cardiomyopathy (RV/LV) associated with sudden cardiac death
Evidence of structural cardiac disease, but LVEF > 35% (7)
LV non-compaction with LVEF > 35% (7)

ICD implantation is rated as May Be Appropriate (median score 4-6) for the following indications:

Secondary Prevention

Coronary artery disease (CAD): ventricular fibrillation (VF) or hemodynamically unstable ventricular tachycardia (VT) associated with acute (<48 hours) myocardial infarction (MI) (newly diagnosed, no prior assessment of left ventricular ejection fraction (LVEF):

- Total Revascularization Completed After Cardiac Arrest
Single episode VF or polymorphic VT during acute (< 48 hours) MI (4)
Recurrent VF or polymorphic VT during acute (< 48 hours) MI (5)
VF or polymorphic VT during acute (<48 hours) MI, NSVT 4 days post MI, Inducible VT/VF at EPS ≥ 4 days after revascularization (5)
- No Revascularization Indicated (No Significant CAD)
Single episode VF or polymorphic VT during acute (< 48 hours) MI, LVEF ≤ 35% (4)
Recurrent VF or polymorphic VT during acute (< 48 hours) MI LVEF ≤ 35% (5)
- Obstructive CAD with coronary anatomy not amenable to revascularization
VF or polymorphic VT during acute (< 48 hours) MI, no EPS done. EF ≥ 36% (5)

CAD: VF or Hemodynamically Unstable VT <48 Hours (Acute) Post-Elective Revascularization

- No evidence for acute coronary occlusion, restenosis, preceding infarct, or other clearly reversible cause, LVEF ≥ 36% (6)

CAD: VF or Hemodynamically Unstable VT (No Recent MI [<40 Days] Prior to VF/VT and/or No Recent Revascularization [3 Months] Prior to VF/VT)

- Significant CAD identified at cath performed following VF/VT. Complete revascularization performed after cardiac arrest. LVEF ≤ 50% (5)

CAD: VF or Hemodynamically Unstable VT During Exercise Testing Associated With Significant CAD

- Significant CAD identified at cath performed following VF/VT. Complete revascularization performed after cardiac arrest. LVEF ≥ 50% (5)
- Significant CAD identified at cath performed following VF/VT. Complete revascularization performed after cardiac arrest. LVEF 36%-49% (6)

No CAD, VF or Hemodynamically Unstable VT

- VT/VF associated with cocaine abuse, LVEF 36%-49% (4)
- VT/VF associated with cocaine abuse, LVEF ≤ 35% (5)
- Severe valvular disease, VT/VF < 48 hours after surgical repair or replacement of aortic or mitral valve
No evidence of postoperative valvular dysfunction, LVEF ≥ 50% (5)
No evidence of postoperative valvular dysfunction, LVEF 36%-49% (6)
No evidence of postoperative valvular dysfunction, LVEF ≤ 35% (6)
- VF/Hemodynamically Unstable VT Associated With Other Structural Heart Disease
Myocarditis; not giant cell myocarditis (5)
Takotsubo cardiomyopathy (stress-induced cardiomyopathy, apical ballooning syndrome), ≥ 48 hours of onset of symptoms

No Structural Heart Disease (LVEF >50%) or Known Genetic Causes of Sustained VT/VF

- Bradycardia-dependent VT/VF (5)

Syncope in Patients With Coronary Artery Disease

- Unexplained Syncope With Prior MI and No Acute MI, LVEF 36%-49%
EPS failed to define a cause of syncope, nonobstructive CAD; revascularization not indicated (5)
EPS failed to define a cause of syncope, nonobstructive CAD; not amenable to revascularization (6)

Syncope in Patients with Nonischemic Structural Heart Disease

- Unexplained Syncope in a Patient with Left Ventricular Hypertrophy, Without Criteria for Hypertrophic Cardiomyopathy
Left ventricular hypertrophy/hypertensive heart disease. LVEF 36%-49% (5)
- Unexplained Syncope in a Patient with Nonischemic Cardiomyopathy
Nonischemic dilated cardiomyopathy, LVEF \geq 50% (4)
Nonischemic dilated cardiomyopathy, LVEF 36-49% (6)
Left ventricular non-compaction. LVEF \geq 50% (6)
Cardiac amyloidosis (6)

Sustained Hemodynamically Stable Monomorphic VT Associated with Structural Heart Disease

- CAD and prior MI. All inducible VTs successfully ablated. LVEF \geq 36% (6)
- CAD and prior MI. Troponin elevation thought to be secondary to VT. All inducible VTs successfully ablated. LVEF \geq 50% (5)
- Nonischemic dilated cardiomyopathy. All inducible VTs successfully ablated. LVEF \geq 50% (5)
- Bundle branch re-entry successfully ablated in a patient with nonischemic cardiomyopathy. LVEF \geq 50% (4)

Primary Prevention

Post-Acute Myocardial Infarction (MI) (< 40 days) LVEF \leq 30%

- Revascularized after acute MI
Asymptomatic NSVT (> 4 days post MI), EPS without inducible VT (EPS performed after revascularization, between 30 and 40 days after MI) (4)
- Not revascularized. Obstructive CAD with coronary anatomy not amenable to revascularization
Asymptomatic NSVT (> 4 days post MI), No EPS performed (4)
Asymptomatic NSVT (> 4 days post MI), EPS without inducible VT (EPS performed within 30 days of MI) (4)
Asymptomatic NSVT (> 4 days post MI), EPS without inducible VT (EPS performed between 30 and 40 days after MI. (4)

Post-MI (\leq 40 Days) and Need for Guideline-Directed Pacemaker Therapy Post-MI (e.g., Sick Sinus Syndrome (SSS), Complete Heart Block (CHB), or Other Indications for Permanent Pacemaker)

- LVEF 36%-40% (6)

Post-Myocardial Infarction (>40 Days) With Ischemic Cardiomyopathy

- No Recent PCI or CABG
LVEF 36%-40%, asymptomatic NSVT, no EPS (5)
LVEF 36%-40%, asymptomatic NSVT, EPS without inducible VT/VF (5)
- Recent PCI or CABG
No known pre-existing cardiomyopathy, LVEF \leq 35% (6)
LVEF 36%-40%, need for permanent pacemaker post-revascularization (e.g., SSS, CHB, or other guideline-directed indications for permanent pacemaker (6)

Duration of Guideline-Directed Medical Therapy for Ischemic Cardiomyopathy Without Recent MI (Revascularization Not Indicated)

- LVEF \leq 35%, on guideline-directed medical therapy for < 3 months (5)

- Treatment since diagnosis < 3 months, newly diagnosed cardiomyopathy with narrow QRS, LVEF < 30% (4)
- At least 3 months on guideline-directed medical therapy, LVEF 36%-40% (4)

Specific Etiologies

- Sarcoid heart disease or Chagas disease, with LVEF > 35% (6)
- Myotonic dystrophy, amyloidosis with heart failure, with LVEF > 35% (5)
- Peripartum cardiomyopathy, persists > 3 months post-partum (4)

Genetic Conditions (Excludes Syncope and Sustained VT, addressed above)

- Congenital long QT syndrome with 1 or more risk factors, not receiving guideline-directed medical therapy (6)
- Familial dilated / nonischemic cardiomyopathy (RV/LV) associated with sudden cardiac death, normal ECG and echo but carrying the implicated gene (6)

American College of Cardiology (ACC) / American Heart Association (AHA) /Heart Rhythm Society (HRS) Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (Epstein et al.) were published in 2008 to update the 2002 ACC/AHA/NASPE guideline on implantation of cardiac pacemakers and antiarrhythmic devices. Guideline recommendations are classified as Class I, Class IIa, Class IIb, and Class III. The classification system is described as follows:

- Class I: Benefit >>>Risk; Procedure/Treatment should be performed/administered
- Class IIa: Benefit >> Risk; Additional studies with focused objectives needed. It is reasonable to perform procedure/administer treatment
- Class IIb: Benefit ≥ Risk; Additional studies with broad objectives needed; additional registry data would be helpful. Procedure/treatment may be considered.
- Class III: Risk ≥ Benefit; Procedure/treatment should not be performed/administered, since it is not helpful and may be harmful.

The weight of evidence supporting each recommendation is classified as follows:

- Level A: Multiple populations evaluated. Data derived from multiple randomized clinical trials or meta-analyses.
- Level B: Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies.
- Level C: Very limited populations evaluated. Only consensus opinion of experts, case studies, or standard of care.

The following recommendations for ICD placement are included in the 2008 guideline:

Class I

- ICD therapy is indicated in patients who are survivors of cardiac arrest due to VF or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes. (*Level of Evidence: A*)
- ICD therapy is indicated in patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable. (*Level of Evidence: B*)
- ICD therapy is indicated in patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study. (*Level of Evidence: B*)
- ICD therapy is indicated in patients with LVEF less than 35% due to prior MI who are at least 40 days post-MI and are in NYHA functional Class II or III. (*Level of Evidence: A*)
- ICD therapy is indicated in patients with nonischemic DCM who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III. (*Level of Evidence: B*)
- No ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than 30%, and are in NYHA functional Class I. (*Level of Evidence: A*)

- ICD therapy is indicated in patients with nonsustained VT due to prior MI, LVEF less than 40%, and inducible VF or sustained VT at electrophysiological study. *(Level of Evidence: B)*

Class IIa

- ICD implantation is reasonable for patients with unexplained syncope, significant LV dysfunction, and nonischemic DCM. *(Level of Evidence: C)*
- ICD implantation is reasonable for patients with sustained VT and normal or near-normal ventricular function. *(Level of Evidence: C)*
- ICD implantation is reasonable for patients with HCM who have one or more major risk factors for SCD. *(Level of Evidence: C)*
- ICD implantation is reasonable for the prevention of SCD in patients with ARVD/C who have 1 or more risk factors for SCD. *(Level of Evidence: C)*
- ICD implantation is reasonable to reduce SCD in patients with long-QT syndrome who are experiencing syncope and/or VT while receiving beta blockers. *(Level of Evidence: B)*
- ICD implantation is reasonable for non-hospitalized patients awaiting transplantation. *(Level of Evidence: C)*
- ICD implantation is reasonable for patients with Brugada syndrome who have had syncope. *(Level of Evidence: C)*
- ICD implantation is reasonable for patients with Brugada syndrome who have documented VT that has not resulted in cardiac arrest. *(Level of Evidence: C)*
- ICD implantation is reasonable for patients with catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers. *(Level of Evidence: C)*
- ICD implantation is reasonable for patients with cardiac sarcoidosis, giant cell myocarditis, or Chagas disease. *(Level of Evidence: C)*

Class IIb

- ICD therapy may be considered in patients with nonischemic heart disease who have an LVEF of less than or equal to 35% and who are in NYHA functional Class I. *(Level of Evidence: C)*
- ICD therapy may be considered for patients with long-QT syndrome and risk factors for SCD. *(Level of Evidence: B)* (16,349–354)
- ICD therapy may be considered in patients with syncope and advanced structural heart disease in whom thorough invasive and noninvasive investigations have failed to define a cause. *(Level of Evidence: C)*
- ICD therapy may be considered in patients with a familial cardiomyopathy associated with sudden death. *(Level of Evidence: C)*
- ICD therapy may be considered in patients with LV noncompaction. *(Level of Evidence: C)*

Class III

- ICD therapy is not indicated for patients who do not have a reasonable expectation of survival with an acceptable functional status for at least 1 year, even if they meet ICD implantation criteria specified in the Class I, IIa, and IIb recommendations above. *(Level of Evidence: C)*
- ICD therapy is not indicated for patients with incessant VT or VF. *(Level of Evidence: C)*
- ICD therapy is not indicated in patients with significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up. *(Level of Evidence: C)*
- ICD therapy is not indicated for NYHA Class IV patients with drug-refractory congestive heart failure who are not candidates for cardiac transplantation or CRT-D. *(Level of Evidence: C)*
- ICD therapy is not indicated for syncope of undetermined cause in a patient without inducible ventricular tachyarrhythmias and without structural heart disease. *(Level of Evidence: C)*
- ICD therapy is not indicated when VF or VT is amenable to surgical or catheter ablation (e.g., atrial arrhythmias associated with the Wolff-Parkinson-White syndrome, RV or LV outflow tract VT, idiopathic VT, or fascicular VT in the absence of structural heart disease). *(Level of Evidence: C)*
- ICD therapy is not indicated for patients with ventricular tachyarrhythmias due to a completely reversible disorder in the absence of structural heart disease (e.g., electrolyte imbalance, drugs, or trauma). *(Level of Evidence: B)*

The 2008 ACC/AHA/HRS guideline provides the following recommendations for ICD placement in children, adolescents, and patients with congenital heart disease:

Class I

- ICD implantation is indicated in the survivor of cardiac arrest after evaluation to define the cause of the event and to exclude any reversible causes. (*Level of Evidence: B*)
- ICD implantation is indicated for patients with symptomatic sustained VT in association with congenital heart disease who have undergone hemodynamic and electrophysiological evaluation. Catheter ablation or surgical repair may offer possible alternatives in carefully selected patients. (*Level of Evidence: C*)

Class IIa

- ICD implantation is reasonable for patients with congenital heart disease with recurrent syncope of undetermined origin in presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study. (*Level of Evidence: B*)

Class IIb

- ICD implantation may be considered for patients with recurrent syncope associated with complex congenital heart disease and advanced systemic ventricular dysfunction when thorough invasive and noninvasive investigations have failed to define a cause. (*Level of Evidence: C*)

Class III

- All Class III recommendations listed above apply to pediatric patients and patients with congenital heart disease, and ICD implantation is not indicated in these patient populations. (*Level of Evidence: C*)

A 2012 ACCF/AHA/HRS Focused Update of the 2008 Guidelines for Device-Based Therapy (Tracy et al.) contains no change in recommendations for ICD therapy. The guideline states that although some new information may be available, recommendations remain current. The authors refer the reader to the ACCF/AHA Guideline for discussion of ICDs in hypertrophic cardiomyopathy (discussed below).

Additional recommendations for patient selection for ICDs in those with hypertrophic cardiomyopathy are included in American College of Cardiology Foundation (ACCF) / American Heart Association (AHA) Guidelines for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy (Gersh et al., 2011). The guidelines use the classification system and evidence weighting used in the guideline on device-based therapy described above, with the exception of the description of Class III. The 2011 guideline defines this category as Class III: no benefit, or Class III: harm.

The guideline includes the following recommendations for selection of patients for ICD placement:

Class I

- The decision to place an ICD in patients with HCM should include application of individual clinical judgment, as well as a thorough discussion of the strength of evidence, benefits, and risks to allow the informed patient's active participation in decision making (*Level of Evidence: C*)
- ICD placement is recommended for patients with HCM with prior documented cardiac arrest, ventricular fibrillation, or hemodynamically significant ventricular tachycardia (VT) (*Level of evidence: B*)

Class IIa,

- It is reasonable to recommend an ICD for patients with HCM with:
 - Sudden death presumably caused by HCM in one or more first-degree relatives
 - A maximum LV wall thickness greater than or equal to 30 mm
 - One or more recent unexplained syncopal episodes (*Level of Evidence: C*)
- An ICD can be useful in select patients with nonsustained VT (particularly those <30 years of age) in the presence of other SCD risk factors or modifiers. (*Level of Evidence: C*)

- An ICD can be useful in select patients with HCM with an abnormal blood pressure response with exercise in the presence of other SCD risk factors or modifiers *(Level of Evidence: C)*
- It is reasonable to recommend an ICD for high-risk children with HCM, based on unexplained syncope, massive LV hypertrophy, or family history of SCD, after taking into account the relatively high complication rate of long-term ICD implantation. *(Level of Evidence: C)*

Class IIb

- The usefulness of an ICD is uncertain in patients with HCM with isolated bursts of nonsustained VT when in the absence of any other SCD risk factors or modifiers. *(Level of Evidence: C)*
- The usefulness of an ICD is uncertain in patients with HCM with an abnormal blood pressure response with exercise when in the absence of any other SCD risk factors or modifiers, particularly in the presence of significant outflow obstruction. *(Level of Evidence: C)*

Class III: Harm

- ICD placement as a routine strategy in patients with HCM without an indication of increased risk is potentially harmful. *(Level of Evidence: C)*
- ICD placement as a strategy to permit patients with HCM to participate in competitive athletics is potentially harmful. *(Level of Evidence: C)*
- ICD placement in patients who have an identified HCM genotype in the absence of clinical manifestations of HCM is potentially harmful. *(Level of Evidence: C)*

The guideline also includes the following recommendation for ICD placement in a section addressing left ventricular systolic dysfunction:

Class IIb

- ICD therapy may be considered in adult patients with advanced (as defined by NYHA functional class III or IV heart failure) nonobstructive HCM, on maximal medical therapy, and EF less than or equal to 50%, who do not otherwise have an indication for an ICD. *(Level of Evidence: C)*

As stated above, the guideline includes a recommendation for ICD use in high-risk children with HCM, based on unexplained syncope, massive LV hypertrophy, or family history of SCD, after taking into account the relatively high complication rate of long-term ICD implantation. Although not defined in the guideline, massive LV hypertrophy is generally considered to be a maximal wall thickness approximately three times greater than normal. The authors note that the rate of inappropriate shocks and lead fractures appears to be higher in children than in adults, primarily because their activity level and body growth places continued strain on the leads, which are the weakest link in the system. This is of particular concern, considering the long period of time young patients will have prophylactically implanted devices. Other treatment options that may be considered for children with HCM include pharmacological management and surgical septal myectomy.

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative: The Heart Rhythm Society recommends the following:

- Don't implant pacemakers for asymptomatic sinus bradycardia in the absence of other indications for pacing (Epstein, et al., 2008).
- Don't implant an implantable cardioverter-defibrillator (ICD) for the primary prevention of sudden cardiac death in patients with New York Heart Association (NYHA) Functional Class IV who are not candidates for either cardiac transplantation, a left ventricular assist device as destination therapy or cardiac resynchronization therapy (CRT) (Epstein, et al., 2008).
- Don't implant an ICD for the primary prevention of sudden cardiac death in patients unlikely to survive at least one year due to non-cardiac comorbidity (Epstein, et al., 2008).

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCDs): Implantable Automatic Defibrillators (20.4). Last revised February 15, 2018. This Coverage Policy is broader in scope than the NCD. Refer to the CMS NCD table of contents link in the reference section.
- Local Coverage Determinations (LCDs): No LCDs found.

Use Outside the U.S.

National Institute for Clinical Excellence (NICE) Guidance (United Kingdom)

A NICE Technology Appraisal Guidance on the Implantable Cardioverter Defibrillators and Cardiac Resynchronization Therapy for Arrhythmias and Heart Failure, updated in 2014, states that ICDs are recommended as options for:

- treating people with previous serious ventricular arrhythmia, that is, people who, without a treatable cause:
 - have survived a cardiac arrest caused by either ventricular tachycardia (VT) or ventricular fibrillation or
 - have spontaneous sustained VT causing syncope or significant haemodynamic compromise or have sustained VT without syncope or cardiac arrest, and also have an associated reduction in left ventricular ejection fraction (LVEF) of 35% or less but their symptoms are no worse than class III of the New York Heart Association (NYHA) functional classification of heart failure.
- treating people who:
 - have a familial cardiac condition with a high risk of sudden death, such as long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome or arrhythmogenic right ventricular dysplasia or
 - have undergone surgical repair of congenital heart disease.

Subcutaneous ICD

The subcutaneous ICD (S-ICD) has been proposed as an alternative to transvenous ICDs for selected patients. To implant the device, an incision is made in the left chest along the rib cage to create a pouch beneath the skin. A subcutaneous electrode is connected to the pulse generator, and the system is adjusted using an external programmer prior to closing the incisions. Since no electrodes are placed in or on the heart, investigators expect fewer perioperative and long-term vascular complications, problems with obtaining venous access, and lead complications. Avoiding the intravascular space has inherent limitations; however. The S-ICD cannot provide antitachycardia pacing, advanced diagnostics, or radiofrequency interrogation with remote monitoring. The S-ICD therefore would not be considered for patients with symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing. Evidence published to date evaluating the S-ICD is limited.

The median longevity of the first generation S-ICD system is reported as 5.0 years. The majority of devices were replaced because of battery depletion (Theuns, et al., 2015).

In the EFFORTLESS Registry, discussed below Lambiase et al. (2014), the rate of complications requiring reintervention within 360 days was 6.4%. Complication rates among various publications on the S-ICD range from 1.3 to 19%. Inappropriate shocks are one of the most common and concerning complications, with most studies reporting an incidence of 4-16%. The most common cause is over sensing of T-waves. Inappropriate shocks are more likely to occur in younger, physically active patients. Pocket infections have been reported in 1-10% of implantations, and complicated infections requiring device explantation have been reported in 1-4% of patients. Lead dislodgement or migration has been reported in 3-11% of patients, and is thought to result from vigorous physical activity without adequate fixation of the parasternal lead. Suture sleeves are currently used to anchor the parasternal lead in order to eliminate lead dislodgement and migration. Less common complications that may require reintervention include skin erosion, premature battery depletion, or explantation due to the need for antitachycardia/bradycardia pacing or a new indication for resynchronization therapy.

U.S. Food and Drug Administration (FDA)

The Subcutaneous Implantable Cardioverter Defibrillator (S-ICD™) System (Cameron Health, Inc., San Clemente, CA) received FDA approval through the PMA process on September 28, 2012. Cameron Health was

subsequently acquired by Boston Scientific. The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

FDA approval was based on review of data from a 321-patient non-randomized study conducted at 33 investigational sites, in which 304 patients were successfully implanted with the S-ICD System (Weiss, et al., 2013). The primary safety endpoint was defined as the 180 day S-ICD system Type I complication-free rate. Type I complications were defined as clinical events caused by the device that required invasive intervention. The primary effectiveness endpoint was defined as the acute ventricular fibrillation conversion effectiveness rate of induced episodes. The panel concluded that the primary safety and efficacy endpoints were both met. The data provided reasonable assurance through response to induced and spontaneous episodes that the device functioned as intended, and the incidence of inappropriate shocks was comparable to that of transvenous ICDs.

According to the FDA approval letter, a post-approval trial is required, consisting of continued follow-up of patients who participated in the S-ICD IDE and prospective enrollment of patients with newly implanted devices. Approximately 1616 patients from approximately 50 investigational centers in the US are to be followed annually through 60 months post-implant, with at least 1025 evaluable at 60 months. The primary safety endpoint is the Type 1 complication-free rate at 60 months, and the primary effectiveness endpoint is the first-shock effectiveness in converting spontaneous discrete episodes of ventricular tachycardia/ventricular fibrillation through 60 months, which will be compared to a performance criterion of 94.0%. The S-ICD System post approval study can be found at ClinicalTrials.gov Identifier: NCT01736618.

On March 13, 2015 the EMBLEM™ S-ICD System (Boston Scientific Corp., St. Paul, MN) received FDA approval through the PMA process. FDA approval was based on the original PMA for the S-ICD (P110042/S043). The Emblem MRI S-ICD and the Emblem S-ICD subcutaneous electrode, insertion tool, and software application and programmer were approved (P110042/S058) on August 8, 2016

Literature Review

In a multicenter prospective study, Gold et al. (2017) reported results from the S-ICD Post-Approval Study. The objective of this registry is to evaluate the short- and long-term safety and efficacy of the S-ICD system. Patients deemed appropriate for implantation of an S-ICD system were eligible for enrollment. Patients were excluded if they had a remaining life expectancy of one year or were ineligible for the S-ICD owing to bradycardia or a history of pace-terminable ventricular tachycardia. The primary and secondary safety end points were S-ICD system complication-free rate and electrode-related complication-free rate at 60 months. A total of 1637 patients underwent S-ICD implantation. The cohort included 68.6% (1123/1637) male patients, and 13.4% (220/1636) were receiving dialysis for endstage renal disease. The mean age was 52 6 15 years, with a mean left ventricular ejection fraction of 32.0%. Induced ventricular tachycardia/ventricular tachycardia was successfully converted in 98.7% (1394/1412) of patients. The 30-day complication-free rate was 96.2%. Predictors of complications included diabetes, younger age, and higher body mass index. Only perioperative outcomes are available at this time. A five-year follow-up of this cohort is planned.

Boersma et al. (2017) reported on the full EFFORTLESS cohort, which is the largest S-ICD database in the world with the longest follow-up. This observational nonrandomized standard of care registry included nearly 1000 patients at 42 clinical centers in 10 countries. Average follow-up was 3.1 years with 82 completing the study protocol 5-year visit. The primary goal of the EFFORTLESS registry is to demonstrate the safety of the S-ICD by evaluating complications and inappropriate shock rate. Patients eligible for implantation of an S-ICD system or with an S-ICD currently implanted at enrollment were eligible for inclusion. Exclusion criteria involved patients with spontaneous, incessant, or frequently recurring ventricular tachycardia (VT) amenable to ATP; patients with an indication for cardiac resynchronization therapy or symptomatic bradycardia, and patients with unipolar pacemakers or implanted systems that revert to unipolar pacing. Average age was 48 years, 28% were women, mean ejection fraction was 43 and 65% had a primary prevention indication. The S-ICD system and procedure complication rate was 4.1% at 30 days and 8.4% at 360 days. Few device extractions occurred due to need for antitachycardia (n=5), or biventricular (n=4) or bradycardia pacing (n=1). Inappropriate shocks occurred in 8.1% at 1 year and 11.7% after 3.1 years. At implant, 99.5% of patients had a successful conversion of induced ventricular tachycardia or ventricular fibrillation. The 1- and 5-year rates of appropriate shock were 5.8%

and 13.5%, respectively. Conversion success for discrete spontaneous episodes was 97.4%. Infections requiring device removal occurred in 24 (2.4%) patients over the 3.1-year average follow-up. Infections requiring device removal were most common in the first year.

A retrospective analysis of 5760 patients from the National Cardiovascular Data Registry ICD Registry was performed to compare in-hospital outcomes among patients with a subcutaneous implantable cardioverter defibrillator (S-ICD) with those of patients with a single-chamber (SC)-ICD and dual-chamber (DC)-ICD (Friedman, et al., 2016). For the comparative analysis the population was restricted to individuals who were admitted for ICD implantation and were eligible for an S-ICD, single-chamber (SC)-ICD, or dual-chamber (DC)-ICD. The study excluded individuals with a previous ICD as well as those with bradycardia or resynchronization indication for permanent pacing or patients undergoing implantation during an acute hospitalization. The main outcomes measures were analysis of trends in S-ICD adoption as a function of total ICD implants and comparison of in-hospital outcomes (death, complications, and defibrillation threshold [DFT] testing) among S-ICD and transvenous (TV)-ICD recipients. A total of 3717 received S-ICDs. A total of 27.8% of the patients were female; the mean age was 67.03 years. Compared with SC-ICD and DC-ICD recipients, those with S-ICDs were more often younger, female, black, undergoing dialysis, and had experienced prior cardiac arrest. Among 2791 patients with S-ICD who underwent DFT testing, 2588 (92.7%), 2629 (94.2%), 2635 (94.4%), and 2784 (99.7%) were successfully defibrillated. The in-hospital complication rates associated with S-ICDs (0.9%) were comparable to those of SC-ICDs (0.6%) and DC-ICD rates (1.5%). Mean length of stay after S-ICD implantation was comparable to that after SC-ICD implantation and less than after DC-ICD implantation.

Lambiase et al. (2014) reported clinical, system, and patient related outcome data from S-ICD patients implanted since the commercial release of the S-ICD (n=472). The EFFORTLESS S-ICD Registry is an observational non-randomized standard of care evaluation conducted outside the US, where the S-ICD has been available since 2009. Of 471 patients, 241 were enrolled prospectively. The mean follow-up duration was 558 days (range 13-1342). The inclusion criteria included patients receiving a S-ICD. Specific contraindications included class I indications for permanent pacing, pace-terminable VT, and previously implanted functional unipolar pacing system. Seventy-two percent of patients were male, the mean age was 49 ± 18 years (range 9-88 years), with a mean ejection fraction of 42%. A total of 317 spontaneous episodes were recorded in 86 patients during the follow-up period; 169 of these (53%) received therapy (93 for VT/VF). One patient died of recurrent VF and severe bradycardia. First shock conversion efficacy was 88%, with 100% overall successful clinical conversion after a maximum of 5 shocks. A total of 73 inappropriate shocks were recorded in 32 patients over an average follow-up of 18 months (360-day inappropriate shock rate of 7%). The majority were due to oversensing of cardiac signals. Procedure-related complication requiring intervention occurred in 29 (6.4%) patients. The most frequent complication was system infection (2.4%), with serious infection requiring implant removal in 10 patients), suboptimal electrode position/electrode movement (1.1%) and erosion or extrusion of the implanted electrode or pulse generator (0.9%).

A prospective case series (S-ICD® System Clinical Investigation [IDE] study) conducted by Weiss et al. (2013) evaluated the safety and effectiveness of a subcutaneous ICD (Cameron Health/Boston [n=330] Scientific) for treatment of life-threatening ventricular arrhythmias. Patients were enrolled if they were aged ≥18 years and had a guideline indication for ICD implantation. Patients with a life expectancy of less than one year were not enrolled. Patients with documented spontaneous and frequently recurring VT reliably terminated with antitachycardia pacing were excluded unless the patient was not a candidate for a transvenous ICD system. Patients with existing epicardial patches or subcutaneous electrodes in the left thoracic space were also excluded. Patients with unipolar pacemakers or pacing devices that revert to unipolar pacing could not participate in the study. Patients with an estimated glomerular filtration rate ≤29 mL/min per 1.73m² were excluded. The primary safety endpoint was 180 day complication-free rate compared with a prespecified performance goal of 79%. The primary effectiveness end-point was the induced VF conversion rate compared with a prespecified performance goal of 88%, with success defined as two consecutive ventricular fibrillation (VF) conversions of four attempts. Of 330 enrolled patients, implantation was attempted in 321 and was successful in 314. The 180 day system complication-free rate was 99%, and sensitivity analysis of the acute VF conversion rate was > 90%. There were 38 episodes of ventricular tachycardia/ventricular fibrillation recorded in 20 patients; all were successfully converted. Inappropriate shocks were received by 41 (13.1%) patients.

Burke et al. (2015) reported the 2-year pooled results of the IDE study and EFFORTLESS S-ICD Registry. The study included 882 subjects who underwent implantation of the S-ICD and were followed for 651 ± 345 days with a mean 22-month follow-up. Patients with recurrent VT reliably terminated with antitachycardia pacing and patients in need of pacing were excluded. Patients with end stage renal disease were excluded from the IDE trials. Spontaneous ventricular tachyarrhythmia (VT)/ventricular fibrillation (VF) events ($n=111$) were treated in 59 subjects; 100 (90.1%) events were terminated with 1 shock, and 109 events (98.2%) were terminated within the 5 available shocks. The estimated 3-year inappropriate shock rate was 13.1%. Estimated 3-year, all-cause mortality was 4.7% (95% confidence Interval [CI]: 0.9% to 8.5%), with 26 deaths (2.9%). Device-related complications occurred in 11.1% at 3 years. There were no electrode failures, and no S-ICD-related endocarditis or bacteremia occurred. Three devices (0.3%) were replaced for right ventricular pacing. The 6-month complication rate decreased by quartile of enrollment (Q1: 8.9%; Q4: 5.5%), and there was a trend toward a reduction in inappropriate shocks (Q1: 6.9%; Q4: 4.5%). The authors concluded that the S-ICD system demonstrated high efficacy for VT/VF. Complications and inappropriate shock rates were reduced consistently with strategic programming and as operator experience increased. The outcomes data from these trials, reported thus far, is reported as sufficient to demonstrate the safety and efficacy of the S-ICD devices for a limited subset of individuals who do not have a pacing requirement.

Olde Nordkamp et al. (2012) conducted a retrospective study to evaluate the efficacy and safety of the S-ICD in the first 118 patients implanted with the device at four high-volume ICD implantation centers in the Netherlands. Patients with a Class I or IIa indication for ICD therapy (according to the AHA/ACC/ESC 2006 guidelines for prevention of sudden cardiac death) were eligible for the device. The S-ICD was implanted without fluoroscopy using only anatomical landmarks. All patients were evaluated within two months after implantation and at six month intervals thereafter. Individual follow-up visits occurred if indicated (e.g., following shock therapy or complications). At 18 months of follow-up, 8 patients experienced 45 successful, appropriate shocks (98% first shock conversion efficacy). Fifteen patients (13%) received inappropriate shocks, primarily due to T-wave oversensing. This issue was largely solved by a software upgrade and changing S-ICD settings. Sixteen patients (14%) experienced complications; the most frequent complications were infection (7, 5.9%) and lead dislodgement (3, 2.5%). Inappropriate shocks and complications were more common in the first 15 implantations per center, reflecting an apparent learning curve. The authors concluded that the S-ICD is a viable alternative to conventional ICD systems in selected patients. Randomized controlled trials with the S-ICD and transvenous ICD will further define the role of the S-ICD as an adjunctive or primary therapy in patients at risk for sudden cardiac death.

Köbe et al. (2013) conducted a multicenter case control series to compare patients who received an S-ICD ($n=69$) with patients who received a conventional single-chamber ICD ($n=69$). The control group was randomly selected from an ICD database, matched by sex and age. The inclusion criteria were patients with a primary or secondary prevention indication for an ICD. The exclusion criteria were not mentioned. The comparison focused on conversion rates of induced ventricular fibrillation (VF) at the time of implantation, perioperative adverse events, and short-term follow-up. Termination of induced ventricular fibrillation was successful in 89.5% of the S-ICD patients compared to 90.8% in the control group ($p=.815$). Procedural complication rates were low and similar in both groups. The mean follow-up was 217 ± 138 days. Three patients with S-ICD were appropriately treated for ventricular arrhythmias during the follow-up period, while 9 patients in the control group experienced appropriate episodes. There were three inappropriate episodes (5.2%) in the S-ICD group due to T-wave oversensing, while atrial fibrillation with rapid conduction was the most common reason for inappropriate therapy in the control group ($p=.745$). A limitation of the study is the relatively low rate of appropriate episodes in the S-ICD group during the mean follow-up of 10.4 months.

In a discussion of the S-ICD, Weinstock et al. (UpToDate 2017) notes that the S-ICD system obviates some of the mechanical complications associated with transvenous lead implantation, and the solid core design and lack of exposure to the repeated mechanical stresses of myocardial contraction may improve lead durability when compared to transvenous leads. The S-ICD system does have its own potential complications, including inappropriate shocks, pocket infection and lead dislodgement or migration. The authors note that limited data directly comparing the efficacy of the S-ICD with traditional ICDs, and that patient selection criteria are continuing to evolve. There are no guidelines for the selection of an S-ICD over a transvenous-ICD (TV-ICD). The authors consider several clinical factors in choosing a device for a patient with an indication for an ICD for primary or secondary prevention. The authors suggest that if there is no indication for transvenous pacing, cardiac

resynchronization therapy, or antiachycardia pacing. An S-ICD may be considered in a patient less than age 45, or a patient with an indwelling central venous catheter, high risk for systemic infection, complex congenital heart disease or challenging vascular access, multiple prior transvenous endocardial leads, or a TV-ICD complication.

In a review of the literature, Aziz et al. (2014) states that the exclusive use of a subcutaneous lead for sensing and defibrillation represents the greatest advantage of this novel technology, since the S-ICD eliminates the drawbacks associated with endovascular electrodes. The lack of demand bradycardia or anti-tachycardia pacing, however, limits its utility in patients with conduction system disease or pace-terminable VT. There are concerns with this first-generation device regarding the increased risk of pocket infections, battery longevity, and inappropriate shocks compared with the newest T-ICD systems. The authors also noted that no study to date directly compared the T-ICD and the S-ICD in patients indicated for ICD therapy as primary prevention of sudden cardiac death. The clinical experience suggests that use of the S-ICD may be considered in relatively younger patients (i.e. age less than 40 years), those at increased risk for bacteremia, patients with indwelling intravascular hardware at risk for endovascular infection, or in patients with compromised venous access.

The safety and efficacy of implantable transvenous ICDs (T-ICD) in diverse patient populations has been demonstrated during three decades of use in over one million patients. The S-ICD has not been shown to be safe and effective in a diverse patient population, nor has it been shown to be non-inferior to the T-ICD. Although the primary safety and efficacy endpoints were met in the investigational device exemption (IDE) study on which FDA approval of the S-ICD was based, the study did not test the ability of the S-ICD to terminate spontaneous ventricular fibrillation. The IDE efficacy endpoint was based on detection and termination of induced VF, and did not demonstrate the efficacy of the S-ICD in ambulatory patients. Although the S-ICD is a promising technology, additional well-designed trials are needed to determine the long-term safety and efficacy of S-ICDs and to define patient selection criteria. An S-ICD may be indicated, however, for selected patients at increased risk for bacteremia, patients with indwelling intravascular hardware at risk for endovascular infection, or in patients with compromised venous access.

As noted above, the 2012 FDA approval required a post-approval registry study, which began in March, 2013, and is expected to be completed in October 2020. The PRAETORIAN trial, a multicenter, randomized trial, is designed to (1) To compare the subcutaneous ICD to the transvenous ICD for major adverse events (i.e. inappropriate shocks, acute and chronic implant related complications and lead- or device related complications), and (2) To determine to which degree the lack of ATP function leads to more appropriate shocks in patients with a subcutaneous ICD. The trial began in February 2011, with an estimated completion date of June 2018 and enrollment of 850 patients.

Technology Assessments

A 2017 Hayes Technology Brief on subcutaneous implantable cardioverter defibrillator (S-ICD) for prevention of sudden cardiac death included six clinical studies (n=64-1920) that evaluated the efficacy, safety, or quality of life (QOL) associated with S-ICD compared with transvenous (TV)-ICD for the prevention of SCD due to ventricular tachyarrhythmias in adults, with follow-up from approximately 1 day to 5 years. Overall, a low-quality body of evidence suggests that S-ICD administers appropriate treatment less frequently than TV-ICD. There is no apparent difference in failure to treat ventricular tachyarrhythmia episodes culminating in SCD or mortality. Evidence suggests that lead related complications occur significantly less frequently with S-ICD than TV-ICD; however, overall complications, notably inappropriate administration of shocks (IAS) and failure of shocks to resolve ventricular tachyarrhythmia episodes, appear similar (Hayes, 2017; annual review 2018, 2019).

Professional Societies/Organizations

The 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Al-Khatib et al.) provides the following recommendations for a subcutaneous implantable cardioverter-defibrillator:

Class 1

- In patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended (Bardy, et al., 2010;

Weiss, et al., 2013; Lambiase, et al., 2014; Burke, et al., 2015; El-Chami, et al., 2015). (Level of Evidence: B-NR).

The recommendation supportive text in the guideline states that difficulties in achieving venous access can prolong the implantation procedure and occasionally result in failed ICD implantation. These difficulties are likely to be encountered in patients with limited venous access such as patients with ESRD. The risk of infection appears to be lower with subcutaneous implantable cardioverter-defibrillators than with transvenous ICDs. Therefore, a subcutaneous implantable cardioverter-defibrillator may be preferred in patients who are at high risk of infection, such as those with a prior device infection, ESRD, diabetes mellitus, or who are chronically immunosuppressed.

Class IIa

- In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated (Bardy, et al., 2010; Weiss, et al., 2013; Lambiase, et al., 2014; Burke, et al., 2015). (Level of Evidence: B-NR).

The recommendation supportive text in the guideline states that nonrandomized studies show that the subcutaneous implantable cardioverter-defibrillator reliably detects and converts VF during defibrillation threshold testing and successfully terminates spontaneous sustained VT that occurs during follow-up. An ongoing trial will compare the effect of the subcutaneous implantable cardioverter-defibrillator with that of the transvenous ICD on the outcomes of inappropriate shocks, complications, shock efficacy, and mortality (Olde Nordkamp, et al., 2012).

Class III: Harm

- In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted (Bardy, et al., 2010; Weiss, et al., 2013; Lambiase, et al., 2014; Burke, et al., 2015; de Bie, et al., 2013; Olde Nordkamp, et al., 2012; Köbe, et al., 2013). (Level of Evidence: B-NR).

The recommendation supportive text in the guideline states that the subcutaneous implantable cardioverter-defibrillator is incapable of bradycardia pacing, biventricular pacing, or antitachycardia pacing. Patients who need any of these types of pacing from an ICD should not be offered a subcutaneous implantable cardioverter-defibrillator. Some clinical scenarios may come up in which a transvenous pacemaker for bradycardia pacing in a patient with a subcutaneous implantable cardioverter-defibrillator- which is needed; this can be performed as long as the pacing is not unipolar. Leadless pacing devices for patients who require bradycardia pacing will be evaluated with the subcutaneous implantable cardioverter-defibrillator in the near future.

Class (Strength) of Recommendation:

Class I (Strong) Benefit >>>>Risk

Class IIa (Moderate) Benefit>>Risk

Class IIb (Weak) Benefit > Risk

Class III No Benefit (Moderate) Benefit=Risk

Class III Harm (Strong) Benefit>Risk

Level (Quality) of Evidence:

Level A if the data were derived from high-quality evidence from more than one randomized clinical trial, meta-analyses of high-quality randomized clinical trials, or one or more randomized clinical trials corroborated by high-quality registry.

Level B-R when data were derived from moderate quality evidence from one or more randomized clinical trials, or meta-analyses of moderate-quality randomized clinical trials.

Level B-NR was used to denote moderate-quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies. This designation was also used to denote moderate-quality evidence from meta-analyses of such studies.

Level C-LD when the primary source of the recommendation was randomized or nonrandomized observational or registry studies with limitations of design or execution, meta-analyses of such studies, or physiological or mechanistic studies of human subjects.

Level C-EO was defined as expert opinion based on the clinical experience of the writing group.

American College of Cardiology Foundation (ACCF), Heart Rhythm Society (HRS), American Heart Association (AHA), American Society of Echocardiography (ASE), Heart Failure Society of America (HFSA), Society for Cardiovascular Angiography and Interventions (SCAI), Society of Cardiovascular Computed Tomography (SCCT), and Society for Cardiovascular Magnetic Resonance (SCMR) 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy states that the subcutaneous ICD system is not addressed in this document as further study is necessary to determine whether benefits might outweigh risks in patients who currently appear to derive little benefit from ICD therapy due to comorbidities and competing mortality risks.

A 2012 ACCF/AHA/HRS Focused Update of the 2008 Guidelines for Device-Based Therapy (Tracy et al.) contains no recommendations for S-ICD therapy.

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCDs): No NCD found.
- Local Coverage Determinations (LCDs): No LCDs found.

Use Outside the U.S.

The Canadian Cardiovascular Society/Canadian Heart Rhythm Society 2016 Implantable Cardioverter-Defibrillator Guidelines recommend an S-ICD be considered in patients with limited vascular access or pocket sites in whom an ICD is recommended (Strong Recommendation; Low-Quality Evidence) (Bennett, et al., 2016).

The European Society of Cardiology (ESC) Guidelines for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death, Priori et al. (2015), provides the following recommendations for a subcutaneous implantable cardioverter-defibrillator:

Class IIa

- Subcutaneous defibrillators should be considered as an alternative to transvenous defibrillators in patients with an indication for an ICD when pacing therapy for bradycardia support, cardiac resynchronization or antitachycardia pacing is not needed (Weiss, et al., 2013; Lambiase, et al., 2014) (Level of evidence: C).

Class IIb

- The subcutaneous ICD may be considered as a useful alternative to the transvenous ICD system when venous access is difficult, after the removal of a transvenous ICD for infections or in young patients with a long-term need for ICD therapy (Level of evidence: C).

Class IIa recommendation indicates that weight of evidence/opinion is in favor of usefulness/efficacy

Class IIb recommendation indicates that usefulness/efficacy is less well established by evidence/opinion.

Level of evidence C indicates a consensus of opinion of the experts and/or small studies, retrospective studies, or registries.

Updated NICE guidance issued in December 2017, states that current evidence on the safety and efficacy of subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

Permanent Leadless Pacemaker

Traditional single-chamber cardiac pacemakers are implanted through a small incision and fitted into a pocket created under the skin of the upper chest near the collarbone with the pacemaker leads placed via transvenous access to the heart chambers and attached to the generator. The leads transmit information from the heart to the generator, and electrical impulses from the generator to heart muscle. Leadless pacemaker systems utilize a

self-contained system which includes both the pulse generator and the electrode within a single unit that is placed into the right ventricle via a transvenous approach.

U.S. Food and Drug Administration (FDA)

In 2016, the FDA granted premarket approval application (PMA) for the Micra™ Transcatheter Pacemaker System (TPS) (Medtronic, Mounds View, MN). This device is indicated for use in patients who have experienced one or more of the following conditions:

- symptomatic paroxysmal or permanent high-grade AV block in the presence of AF
- symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy
- symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.

The Micra device is contraindicated for patients who have implanted devices that would interfere with the pacemaker, who are severely obese, or who have an intolerance to materials in the device or the blood thinner heparin. It is also contraindicated for patients with veins that are unable to accommodate the 7.8 millimeter introducer sheath or pacemaker implant.

The Nanostim leadless pacemaker (St. Jude Medica, Sylmar, CA) is currently being developed but has not yet received FDA approval.

Literature Review

In a prospective registry, El-Chami et al. (2018) compared the outcomes of the Micra transcatheter pacing system (TPS) to a historical transvenous pacing cohort implanted with dual-chamber pacemakers. The authors report updated performance of the Micra TPS from a worldwide post approval registry (PAR) and compare it with The Micra Investigational Device Exemption (IDE) study as well as a transvenous historical control. The safety objective of the analysis was system- or procedure-related major complications through 12 months postimplantation. A comparison of the major complication rate with that of the 726 patients from the IDE and with a reference data set of 2667 patients with transvenous pacemakers. The Micra device was successfully implanted in 1801 of 1817 patients (99.1%). The mean follow-up period was 6.8 months. Through 12 months, the major complication rate was 2.7%. The risk of major complications for Micra PAR patients was 63% lower than that for patients with transvenous pacemakers through 12 months postimplantation. The major complication rate trended lower in the PAR than in the IDE study, driven by the lower pericardial effusion rate in the PAR. There were three cases of infection associated with the procedure, but none required device removal and there were no battery or telemetry issues. Pacing thresholds were low and stable through 12 months postimplantation. A reported limitation of this study is lack of a randomized controlled study which would allow a direct comparison and would clearly define the benefits and drawbacks of leadless pacing compared to traditional transvenous pacemakers.

Roberts et al. (2017) reported acute performance of the Micra transcatheter pacemaker from a worldwide Post-Approval Registry. The registry is an ongoing prospective single-arm observational study designed to assess the safety and effectiveness of Micra in the post-approval setting. The safety end point was system or procedure-related major complications at 30 days post implant. Major complication rates were compared with that of the 726 patients from the investigational study (Reynolds, et al., 2016). Electrical performance was also characterized. The device was successfully implanted in 792 of 795 registry patients (99.6%) by 149 implanters at 96 centers in 20 countries. Through 30 days post implant, a total of 13 major complications occurred in 12 patients, for a major complication rate of 1.51% (95%). Major complications included cardiac effusion/perforation (1, 0.13%), device dislodgement (1, 0.13%), and sepsis (1, 0.13%). After adjusting for baseline differences, the rate of major complications in the registry trended lower than the investigational trial. Early pacing capture thresholds were low and stable. The data does not include all patients implanted with Micra TPS worldwide. This report is an interim analysis with limited follow-up, including patients who had not yet been followed for 30 days, and it reflects the geographies of enrolled patients who were primarily from Europe. However, enrollment of patients in the United States is continuing, and patients in the registry will be followed for a minimum of nine

years. Few patients had follow-up electrical data available, and thus battery projections are preliminary and based on only 54 patients.

In a multicenter prospective international study, the Micra Transcatheter Pacing Study, Duray et al. (2017) reported on long-term safety of Micra at 12 months and electrical performance through 24 months. Enrolled patients met class I or II guideline recommendations for de novo ventricular pacing. The long-term safety objective was freedom from a system- or procedure-related major complication at 12 months. A predefined historical control group of 2667 patients with transvenous pacemakers was used to compare major complication rates. The long-term safety objective was achieved with a freedom from major complication rate of 96.0% at 12 months. The risk of major complications for patients with Micra (n=726) was 48% lower than that for patients with transvenous systems through 12 months postimplant. Across subgroups of age, sex, and comorbidities, Micra reduced the risk of major complications compared to transvenous systems. Electrical performance was excellent through 24 months, with a projected battery longevity of 12.1 years.

In a prospective, nonrandomized multicenter post-approval study, the Micra Post-Approval Registry, Duray et al. (2017) reported on the safety and efficacy of the Micra transcatheter pacing system (TPS). The safety end point was system or procedure-related major complications at 30 days post implant. The major complication rate was compared with 726 patients from the investigational study. Electrical performance was also characterized. The device was successfully implanted in 792 of 795 registry patients (99.6%) by 149 implanters at 96 centers in 20 countries. Through 30 days post implant, a total of 13 major complications occurred in 12 patients, for a major complication rate of 1.51%. Major complications included cardiac effusion/perforation (1, 0.13%), device dislodgement (1, 0.13%), and sepsis (1, 0.13%). After adjusting for baseline differences, the rate of major complications in the registry trended lower than the investigational trial. Early pacing capture thresholds were low and stable.

In a prospective observational study (n=30), Martinez-Sande et al. (2017) reported on the safety and electrical of the Micra leadless pacemaker. Outcome measures were major complication (defined as death, serious deterioration of patient's condition, event resulting in vital risk requiring intervention, hospitalization ≥ 48 hrs). Successful implantation was accomplished in all patients referred for leadless implantation. The mean age was 79.4 years; 20 (66.6%) were men and 28 had permanent atrial fibrillation (93.3%); one had atrial tachycardia and one had sinus rhythm. Concomitant atrioventricular node ablation was performed immediately after implantation in five patients (16.6%), and implantation was performed after transcatheter aortic valve implantation in two. With the exception of 1 moderate pericardial effusion without tamponade, there were no severe complications. The mean follow-up was 5.3 months and four patients had more than one year of follow-up. Sensing and pacing parameters were stable both at implantation and during the short- to mid-term follow-up.

Reynolds et al. (2016) reported on interim analysis of an on-going prospective, nonrandomized, single-study-group, multisite, clinical study to evaluate the safety and efficacy of the Micra Transcatheter Pacemaker System (Medtronic). Transcatheter pacemaker was implanted in 725 patients with guideline-based indications for ventricular pacing, with 719 (99.2%) successfully implanted and followed for six months. The primary safety end point was freedom from system-related or procedure-related major complications. The primary efficacy end point was the percentage of patients with low and stable pacing capture thresholds at 6 months (≤ 2.0 V at a pulse width of 0.24 msec and an increase of ≤ 1.5 V from the time of implantation). The safety and efficacy end points were evaluated against performance goals (based on historical data) of 83% and 80%, respectively. A post hoc analysis in which the rates of major complications was compared with a control cohort of 2667 patients with transvenous pacemakers from six previously published studies. The Kaplan–Meier estimate of the rate of the primary safety end point was 96.0% (95% confidence interval [CI], 93.9 to 97.3; $p < 0.001$ for the comparison with the safety performance goal of 83%); there were 28 major complications in 25 of 725 patients, and no dislodgements. The rate of the primary efficacy for 297 patients end point was 98.3% (95% CI, 96.1 to 99.5; $p < 0.001$ for the comparison with the efficacy performance goal of 80%) among 292 of 297 patients with paired 6-month data. Patients with transcatheter pacemakers had fewer major complications than did the control patients (hazard ratio, 0.49; 95% CI, 0.33 to 0.75; $p = 0.001$). The study was limited by the lack of randomization, the comparator was historical data and this was an interim analysis of less than half the participants at six months.

Technology Assessments

A 2017 Hayes technology brief on the Micra transcatheter pacing system (TPS) (Medtronic Inc.) for single chamber pacemaker indications reports that the body of evidence was of very low quality, largely due to the observational studies, small number of studies, absence of contemporaneous comparisons with transvenous pacemakers, relatively limited follow-up and lack of direct patient-centered efficacy outcomes. There remains substantial uncertainty regarding the safety and efficacy of the Micra transcatheter pacing system for treatment of adult patients indicated for single-chamber pacemaker. Similar conclusions regarding the quality of evidence were reported in a 2019 Hayes Health Technology Assessment on the Micra TPS.

Professional Societies/Organizations

Clinical guidelines that recommend use of a single-chamber leadless cardiac pacemaker are lacking.

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCDs): Leadless Pacemakers (20.8.4). Last revised January 18, 2017. The CMS NCD is broader in scope. Refer to the CMS NCD table of contents link in the reference section.
- Local Coverage Determinations (LCDs): No LCD found.

Use Outside of the US

National Institute for Clinical Excellence (NICE) Guidance (United Kingdom)

An August 2018 NICE Interventional procedures guidance on leadless cardiac pacemaker implantation for bradyarrhythmias states that “evidence on the safety of leadless cardiac pacemaker implantation for bradyarrhythmias shows that there are serious but well-recognized complications. The evidence on efficacy is inadequate in quantity and quality. Clinicians wishing to do leadless cardiac pacemaker implantation for bradyarrhythmias in people who cannot have conventional cardiac pacemaker implantation should ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy compared with conventional pacemaker implantation, and provide them with clear written information. Further research in people who could have conventional cardiac pacemaker implantation should report the patient selection criteria and compare leadless pacemakers with conventional pacemakers. Follow-up should be for at least 5 years and outcomes should include adverse events, symptom relief, quality of life and device durability in the long-term”.

The Micra TPS was granted CE Marking in April 2015. The Nanostim device received CE Marking in 2013.

The 2015 Canadian Agency for Drugs and Technologies in Health (CADTH) Emerging Health Technologies on leadless pacemakers for the treatment of cardiac arrhythmias states that further evaluation of leadless pacemakers for long-term pacing performance and complication rates compared with traditional pacemakers is required. If long-term efficacy and safety can be demonstrated, leadless pacemakers may provide an additional treatment option for select patients with cardiac arrhythmias.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Transvenous Implantable Cardioverter Defibrillator (ICD)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
33202	Insertion of epicardial electrode(s); open incision (eg, thoracotomy, median sternotomy, subxiphoid approach)
33203	Insertion of epicardial electrode(s); endoscopic approach (eg, thoracoscopy, pericardioscopy)
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator

33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion and/or replacement of existing generator)
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only, with existing multiple leads
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead
33241	Removal of implantable defibrillator pulse generator only
33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy
33244	Removal of single or dual chamber implantable defibrillator electrodes(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
33263	Removal implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system

HCPCS Codes	Description
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
G0448	Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
33271	Insertion of subcutaneous implantable defibrillator electrode
33272	Removal of subcutaneous implantable defibrillator electrode
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode
33999†	Unlisted procedure, cardiac surgery
93260	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system
93261	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection

	per patient encounter; implantable subcutaneous lead defibrillator system
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

†**Note:** Considered medically necessary when used to report implantation of subcutaneous implantable cardioverter defibrillator (S-ICD).

Permanent Leadless Pacemaker

Considered Experimental/Investigational/Unproven:

CPT® Codes	Description
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed

***Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.**

References

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