

Medical Policy



Title: Implantable Cardioverter Defibrillators

See also: *Wearable Cardioverter Defibrillators*

Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With a high risk of sudden cardiac death due to ischemic cardiomyopathy in adulthood 	Interventions of interest are: <ul style="list-style-type: none"> Transvenous implantable cardioverter defibrillator placement 	Comparators of interest are: <ul style="list-style-type: none"> Medical management without implantable cardioverter defibrillator placement 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Morbid events Quality of life Treatment-related mortality Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With a high risk of sudden cardiac death due to nonischemic cardiomyopathy in adulthood 	Interventions of interest are: <ul style="list-style-type: none"> Transvenous implantable cardioverter defibrillator placement 	Comparators of interest are: <ul style="list-style-type: none"> Medical management without implantable cardioverter defibrillator placement 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Morbid events Quality of life Treatment-related mortality Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With a high risk of sudden cardiac death due to hypertrophic cardiomyopathy in adulthood 	Interventions of interest are: <ul style="list-style-type: none"> • Transvenous implantable cardioverter defibrillator placement 	Comparators of interest are: <ul style="list-style-type: none"> • Medical management without implantable cardioverter defibrillator placement 	Relevant outcomes include: <ul style="list-style-type: none"> • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> • With a high risk of sudden cardiac death due to an inherited cardiac ion channelopathy 	Interventions of interest are: <ul style="list-style-type: none"> • Transvenous implantable cardioverter defibrillator placement 	Comparators of interest are: <ul style="list-style-type: none"> • Medical management without implantable cardioverter defibrillator placement 	Relevant outcomes include: <ul style="list-style-type: none"> • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> • With life-threatening ventricular tachyarrhythmia or fibrillation or who have been resuscitated from sudden cardiac arrest 	Interventions of interest are: <ul style="list-style-type: none"> • Transvenous implantable cardioverter defibrillator placement 	Comparators of interest are: <ul style="list-style-type: none"> • Medical management without implantable cardioverter defibrillator placement 	Relevant outcomes include: <ul style="list-style-type: none"> • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> • Who need an implantable cardioverter defibrillator and have a contraindication to transvenous ICD 	Interventions of interest are: <ul style="list-style-type: none"> • Subcutaneous implantable cardioverter defibrillator placement 	Comparators of interest are: <ul style="list-style-type: none"> • Medical management without implantable cardioverter defibrillator placement 	Relevant outcomes include: <ul style="list-style-type: none"> • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> • Who need an implantable cardioverter defibrillator and have no contraindication to transvenous ICD 	Interventions of interest are: <ul style="list-style-type: none"> • Subcutaneous implantable cardioverter defibrillator placement 	Comparators of interest are: <ul style="list-style-type: none"> • Transvenous implantable cardioverter defibrillator placement 	Relevant outcomes include: <ul style="list-style-type: none"> • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity

DESCRIPTION

An implantable cardioverter defibrillator (ICD) is a device designed to monitor a patient's heart rate, recognize ventricular fibrillation or ventricular tachycardia, and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. A subcutaneous implantable cardioverter defibrillator (S-ICD), which lacks transvenous leads, is intended to reduce lead-related complications.

OBJECTIVE

The objective of this policy is to determine whether implantable cardioverter defibrillators improve the net health outcome for individuals with high risk of cardiac death.

BACKGROUND

Ventricular Arrhythmia and Sudden Cardiac Death

The risk of ventricular arrhythmia and sudden cardiac death (SCD) may be significantly increased in various cardiac conditions such as individuals with ischemic cardiomyopathy, particularly when associated with reduced left ventricular ejection fraction (LVEF) and prior myocardial infarction; nonischemic dilated cardiomyopathy with reduced LVEF;

hypertrophic cardiomyopathy and additional risk factors; congenital heart disease, particularly with recurrent syncope; and cardiac ion channelopathies.

Treatment

Implantable cardioverter defibrillators (ICDs) monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of SCD. Indications for ICD placement can be broadly subdivided into (1) secondary prevention, ie, use in patients who have experienced a potentially life-threatening episode of VT (near SCD); and (2) primary prevention, ie, use in patients who are considered at high risk for SCD but who have not yet experienced life-threatening VT or VF.

The standard ICD placement surgery involves placement of a generator in the subcutaneous tissue of the chest wall. Transvenous leads are attached to the generator and threaded intravenously into the endocardium. The leads sense and transmit information on cardiac rhythm to the generator, which analyzes the rhythm information and produces an electrical shock when a malignant arrhythmia is recognized.

A subcutaneous implantable cardioverter defibrillator (S-ICD) has been developed. It does not use transvenous leads and thus avoids the need for venous access and complications associated with the insertion of venous leads. Rather, the S-ICD uses a subcutaneous electrode implanted adjacent to the left sternum. The electrodes sense the cardiac rhythm and deliver countershocks through the subcutaneous tissue of the chest wall.

Several automatic ICDs have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. FDA-labeled indications generally include patients who have experienced life-threatening VT associated with cardiac arrest or VT associated with hemodynamic compromise and resistance to pharmacologic treatment. In addition, devices typically have approval in the secondary prevention setting for patients with a previous myocardial infarction and reduced ejection fraction.

REGULATORY STATUS

Transvenous Implantable Cardioverter Defibrillators

A large number of implantable cardioverter defibrillators (ICDs) have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process (FDA product code: LWS). A 2014 review of FDA approvals of cardiac implantable devices reported that, between 1979 and 2012, FDA approved 19 ICDs (7 pulse generators, 3 leads, 9 combined systems) through new PMA applications.¹ Many originally approved ICDs have undergone multiple supplemental applications. A summary of some currently available ICDs is provided in Table 1.

Subcutaneous ICDs

In September 2012, FDA approved the Subcutaneous Implantable Defibrillator (S-ICD[®]) System, through the PMA process 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 (see Table 1).

In March 2015, the Emblem S-ICD™ (Boston Scientific), which is smaller and longer-lasting than the original S-ICD, was cleared for marketing through a PMA supplement process.

Table 1: Implantable Cardioverter Defibrillator With FDA Approval

Device	Manufacturer	Original PMA Approval Date
Transvenous		
Ellipse™/Fortify Assura™ Family (originally: Cadence Tiered Therapy Defibrillation System)	St. Jude Medical (St. Paul, MN)	Jul 1993
Current® Plus ICD (originally: Cadence Tiered Therapy Defibrillation System)	St. Jude Medical (St. Paul, MN)	Jul 1993
Dynagen™, Inogen™, Origen™, and Teligen® Family (originally: Ventak, Vitality, Cofient family)	Boston Scientific (Marlborough, MA)	Jan 1998
Evera™ Family (originally: Virtuosos/Entrust/Maximo/ Intrinsic/Marquis family)	Medtronic (Minneapolis, MN)	Dec 1998
Subcutaneous		
Subcutaneous Implantable Defibrillator System (S-ICD™)	Cameron Health (San Clemente, CA); acquired by Boston Scientific	Sep 2012

FDA: Food and Drug Administration; PMA: premarket application.

NOTE: ICDs may be combined with other pacing devices, such as pacemakers for atrial fibrillation, or biventricular pacemakers designed to treat heart failure. This policy addresses ICDs alone, when used solely to treat patients at risk for ventricular arrhythmias.

POLICY

I. Adults

A. The use of the automatic implantable cardioverter defibrillator (ICD) may be considered **medically necessary** in adults who meet the following criteria:

1. Primary Prevention
 - a) Ischemic cardiomyopathy with New York Heart Association (NYHA) functional class II or class III symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 35% or less; or
 - b) Ischemic cardiomyopathy with NYHA functional class I symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 30% or less; or
 - c) Nonischemic dilated cardiomyopathy and left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; or

- d) Hypertrophic cardiomyopathy (HCM) or arrhythmogenic right ventricular cardiomyopathy with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with cardiomyopathy.
 - e) Diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death (see Policy Guidelines):
 - i. Congenital long QT syndrome; or
 - ii. Catecholaminergic polymorphic ventricular tachycardia; or
 - iii. Brugada syndrome; or
 - iv. Short QT syndrome.
2. Secondary Prevention
- a) Patients with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes (eg, acute ischemia) have been excluded.
- B. The use of the ICD is considered **experimental / investigational** in primary prevention patients who:
- 1. Have had an acute myocardial infarction (ie, less than 40 days before ICD treatment); **OR**
 - 2. Have New York Heart Association (NYHA) Class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy ICD device); **OR**
 - 3. Have had a cardiac revascularization procedure in the past 3 months (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) or are candidates for a cardiac revascularization procedure; **OR**
 - 4. Have noncardiac disease that would be associated with life expectancy less than 1 year
- C. The use of the ICD for secondary prevention is considered **experimental / investigational** for patients who do not meet the criteria for secondary prevention.

II. Pediatrics

A. The use of the ICD may be considered **medically necessary** in children who meet any of the following criteria:

1. Survivors of cardiac arrest, after reversible causes have been excluded;
OR
2. Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; **OR**
3. Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias; **OR**
4. Hypertrophic cardiomyopathy (HCM) or arrhythmogenic right ventricular cardiomyopathy with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; massive left ventricular hypertrophy based on age-specific norms; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with cardiomyopathy; **OR**
5. Diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death (see Policy Guidelines):
 - a) Congenital long QT syndrome; or
 - b) Brugada syndrome; or
 - c) Short QT syndrome; or
 - d) Catecholaminergic polymorphic ventricular tachycardia.

B. The use of the ICD is considered **experimental / investigational** for all other indications in pediatric patients.

III. Subcutaneous ICDs

A. The use of a subcutaneous ICD may be considered **medically necessary** for adults or children who have an indication for ICD implantation for primary or secondary prevention for any of the above reasons and meet all of the following criteria:

1. Have a contraindication to a transvenous ICD due to 1 or more of the following:
 - a) lack of adequate vascular access; or

- b) compelling reason to preserve existing vascular access (ie, need for chronic dialysis; younger patient with anticipated long-term need for ICD therapy); or
 - c) history of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy.
2. Have no indication for antibradycardia pacing; **AND**
 3. Do not have ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing.
- B. The use of a subcutaneous ICD is considered **experimental / investigational** for individuals who do not meet the criteria outlined above.

Policy Guidelines

1. This policy addresses the use of implantable cardioverter defibrillator (ICD) devices as stand-alone interventions, not as combination devices to treat heart failure (ie, cardiac resynchronization devices) or in combination with pacemakers. Unless specified, the policy statements and rationale are referring to transvenous ICDs.
2. Indications for pediatric ICD use are based on American College of Cardiology / American Heart Association/Heart Rhythm Society (ACC/AHA/HRS) guidelines published in 2008 (updated in 2012), which acknowledged the lack of primary research in this field on pediatric patients (see Rationale section). These are derived from nonrandomized studies, extrapolation from adult clinical trials, and expert consensus.
3. Criteria for ICD Implantation in Patients with Cardiac Ion Channelopathies
 - a) Individuals with cardiac ion channelopathies may have a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes, in which case they should be considered for ICD implantation for secondary prevention, even if they do not meet criteria for primary prevention.
 - b) Criteria for ICD implantation in patients with cardiac ion channelopathies are derived from results of clinical input, a 2013 consensus statement from the HRS, European Heart Rhythm Association (EHRA), and the Asia-Pacific Heart Rhythm Society on the diagnosis and management of patients with inherited primary arrhythmia syndromes (Priori et al, 2013), 2012 guidelines from the ACC, AHA, and HRS on device-based therapy of cardiac rhythm abnormalities (Epstein et al, 2013), and a report from the HRS/EHRA's Second Consensus Conference on Brugada syndrome (Antzelevitch et al, 2005).
 - c) Indications for consideration for ICD implantation for each cardiac ion channelopathy are as follows:
 - 1) Long QT syndrome (LQTS):
 - Patients with a diagnosis of LQTS who are survivors of cardiac arrest.
 - Patients with a diagnosis of LQTS who experience recurrent syncope events while on beta-blocker therapy.
 - 2) Brugada syndrome (BrS):

- Patients with a diagnosis of BrS who are survivors of cardiac arrest.
 - Patients with a diagnosis of BrS who have documented spontaneous sustained ventricular tachycardia (VT) with or without syncope.
 - Patients with a spontaneous diagnostic type 1 ECG who have a history of syncope, seizure, or nocturnal agonal respiration judged to be likely caused by ventricular arrhythmias (after noncardiac causes have been ruled out).
 - Patients with a diagnosis of BrS who develop ventricular fibrillation (VF) during programmed electrical stimulation.
- 3) Catecholaminergic polymorphic ventricular tachycardia (CPVT):
- Patients with a diagnosis of CPVT who are survivors of cardiac arrest.
 - Patients with a diagnosis of CPVT who experience recurrent syncope or polymorphic/bidirectional ventricular tachycardia (VT) despite optimal medical management, and/or left cardiac sympathetic denervation.
- 4) Short QT syndrome (SQTS):
- Patients with a diagnosis of SQTS who are survivors of cardiac arrest.
 - Patients with a diagnosis of SQTS who are symptomatic and have documented spontaneous VT with or without syncope.
 - Patients with a diagnosis of SQTS or are asymptomatic or symptomatic and have a family history of sudden cardiac death.

NOTE: For congenital LQTS, patients may have one or more clinical or historical findings other than those outlined above that may, alone or in combination, put them at higher risk for sudden cardiac death. These may include patients with a family history of sudden cardiac death due to LQTS, infants with a diagnosis of LQTS with functional 2:1 atrioventricular block, patients with a diagnosis of LQTS in conjunction with a diagnosis of Jervell and Lange-Nielsen syndrome or Timothy syndrome, and patients with a diagnosis of LQTS with profound QT prolongation (>550 ms). These factors should be evaluated on an individualized basis by a clinician with expertise in LQTS in considering the need for an ICD implantation.

RATIONALE

This policy has been updated periodically with literature review. The most recent update with literature review covers the period through March 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, two domains are examined: the relevance and the quality and credibility. To be

relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Transvenous Implantable Cardioverter Defibrillators

Primary Prevention in Adults

Transvenous implantable cardioverter defibrillators (TV-ICDs) have been evaluated for primary prevention in a number of populations considered at high risk of sudden cardiac death (SCD), including those with ischemic cardiomyopathy, nonischemic dilated cardiomyopathy (NIDCM), and hypertrophic cardiomyopathy (HCM). There is a large body of evidence, including a number of randomized clinical trials (RCTs) and systematic reviews of these trials addressing the role of ICDs for primary prevention and identifying specific populations who may benefit.

Ischemic Cardiomyopathy and Nonischemic Dilated Cardiomyopathy

Randomized Controlled Trials: At least 13 RCTs of ICDs for primary prevention have been conducted. Five were in populations with ischemic cardiomyopathy with prior myocardial infarction (MI; usually ≥ 3 weeks post-MI):

- Multicenter Automatic Defibrillator Implantation Trial (MADIT);
- MADIT II;
- Coronary Artery Bypass Graft (CABG) Patch trial;
- Multicenter Unsustained Tachycardia Trial (MUSTT); and
- Sudden Cardiac Death in Heart Failure (SCD HeFT) trial.

Three trials were conducted in patients implanted with ICD in the first few weeks following MI (recent MI):

- Defibrillator in Acute Myocardial Infarction Trial (DINAMIT);
- Immediate Risk Stratification Improves Survival (IRIS) trial; and
- BETA-blocker STRategy plus ICD (BEST-ICD) trial.

Six trials were conducted in populations with nonischemic dilated cardiomyopathy (NIDCM):

- Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial;
- Amiodarone Versus Implantable Cardioverter-Defibrillator (AMIOVIRT) trial;
- Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial;
- SCD HeFT trial;
- Cardiomyopathy Trial (CAT); and
- Danish Study to Assess the Efficacy of ICDs in Patients with Non-Ischemic Systolic Heart Failure on Mortality (DANISH).

The characteristics and mortality results for these 3 groups of trials are shown in Table 2.

Most of the trials for both ischemic and nonischemic cardiomyopathy reported results consistent with a mortality benefit for ICD in patients with left ventricular systolic dysfunction or with heart

failure and reduced ejection fraction, although not all trials were powered for the mortality outcome and some findings were not statistically significant. However, the DINAMIT, IRIS, and BEST-ICD trials did not support a mortality benefit for ICD in the early weeks following MI and CABG-Patch showed no benefit in patients having recently undergone coronary revascularization. Another notable exception is the 2016 DANISH trial, which enrolled primarily outpatients with nonischemic cardiomyopathy (NICM) in stable condition who were almost all receiving β -blocker or angiotensin-converting enzyme inhibitors, with the majority also receiving mineralocorticoid-receptor antagonists. While overall mortality did not differ significantly between the ICD and medical therapy groups in DANISH, SCD was significantly reduced in the ICD group (4% vs 8%; hazard ratio [HR], 0.50; 95% confidence interval [CI], 0.31 to 0.82).

Table 2. RCTs of Implantable Cardiac Defibrillators for Primary Prevention

Trial	Participants	Treatment Groups		Mean Follow-Up	Mortality Results	
		Group	n		Hazard Ratio	95% CI
ICM with prior MI						
MADIT (1996) ²	<ul style="list-style-type: none"> LVEF \leq35% Asymptomatic non-SVT MI \geq3 wk prior Inducible VT NYHA class I-III 	<ul style="list-style-type: none"> ICD Standard therapy 	95 101	27 mo (trial stopped early by DSMB)	0.46	0.26 to 0.82
MADIT II (2002) ³	<ul style="list-style-type: none"> LVEF \leq30% No history of VT MI \geq1 mo prior NYHA class I-III 	<ul style="list-style-type: none"> ICD Standard therapy 	742 490	20 mo (trial stopped early by DSMB)	0.69	0.51 to 0.93
CABG Patch (1997) ⁴	<ul style="list-style-type: none"> Scheduled for CABG LVEF \leq35% No sustained VT or VF Age >80 y Signal-averaged ECG abnormalities 82% had prior MI, time since MI not reported 	<ul style="list-style-type: none"> ICD during CABG No ICD 	446 454	32 mo	1.07	0.81 to 1.42
MUSTT (1999) ⁵	<ul style="list-style-type: none"> LVEF \leq40% Asymptomatic non-SVT Inducible VT MI \geq4 d prior (median, \approx3 y prior) No sustained VT or VF 	<ul style="list-style-type: none"> EPS-guided therapy (AAD with or without ICD) (202 got ICD) Standard therapy 	351 353	39 mo	5-y outcomes^b: EPS-guided vs standard therapy • 0.80 ICD vs AAD alone • 0.42	
SCD HeFT (2005) ⁶	<ul style="list-style-type: none"> LVEF \leq35% NYHA class II-III No asymptomatic SVT 52% received ICM Treated with ACE inhibitors and β-blockers 	<ul style="list-style-type: none"> Ischemic patients: ICD Amiodarone Placebo 	431 426 453	45 mo	ICD vs placebo Ischemic • 0.79 ^a Overall • 0.77 ^a	
ICM with recent MI						
DINAMIT (2004) ⁷	<ul style="list-style-type: none"> LVEF \leq35% NYHA class I-III No asymptomatic SVT MI in preceding 6-40 d (mean, 18 d) 	<ul style="list-style-type: none"> ICD Standard therapy 	332 342	30 mo	1.08	0.76 to 1.55

Trial	Participants	Treatment Groups	Mean Follow-Up	Mortality Results	
IRIS (2009) ⁸	<ul style="list-style-type: none"> Reduced HR variability or elevated resting HR MI in preceding 5-31 d At least 1 of the following: <ul style="list-style-type: none"> LVEF \leq40% and resting HR \geq90 or non-SVT 	<ul style="list-style-type: none"> ICD Standard therapy 	445 453	37 mo	1.04 0.81 to 1.35
BEST-ICD (2005) ⁹	<ul style="list-style-type: none"> LVEF \leq35% NYHA class I-III No asymptomatic SVT MI in preceding 5-30 d At least 1 other risk factor 	<ul style="list-style-type: none"> EPS-guided therapy (24 got ICD) Standard therapy 	79 59	540 d	1-year mortality^d <ul style="list-style-type: none"> EPS-guided therapy: 14% Conventional therapy: 18% 2-y mortality^d <ul style="list-style-type: none"> EPS-guided therapy: 20% Conventional therapy: 29.5%
Nonischemic cardiomyopathy					
DEFINITE (2004) ¹⁰	<ul style="list-style-type: none"> LVEF \leq35% NYHA class II-IV 	<ul style="list-style-type: none"> ICD and medical therapy Medical therapy alone 	229 229	29 mo	<ul style="list-style-type: none"> 0.65 (0.40 to 1.06)
SCD HeFT (2005) ⁶	<ul style="list-style-type: none"> LVEF \leq35% NYHA class II-III No asymptomatic SVT 48% with non-ICM Treated with ACE inhibitor and β-blocker 	Nonischemic patients: <ul style="list-style-type: none"> ICD Amiodarone Placebo 	398 419 394	45 mo	ICD vs placebo Nonischemic <ul style="list-style-type: none"> 0.73^a Overall <ul style="list-style-type: none"> 0.77^a 0.50 to 1.07 0.62 to 0.96
COMPANION (2004) ¹¹	<ul style="list-style-type: none"> LVEF \leq35% NYHA class III-IV DCM 	Nonischemic patients: <ul style="list-style-type: none"> CRT-D Medical therapy CRT 	270 127 285	16 mo	CRT-D vs medical therapy Nonischemic <ul style="list-style-type: none"> 0.50 Overall <ul style="list-style-type: none"> 0.64 0.29 to 0.88 0.48 to 0.86
AMIOVIRT (2003) ¹²	<ul style="list-style-type: none"> LVEF \leq35% NYHA class I-III DCM Asymptomatic non-SVT 	<ul style="list-style-type: none"> ICD Amiodarone 	51 52	2 y	1-y survival^d <ul style="list-style-type: none"> ICD: 96% Amiodarone: 90% 2-y survival^d <ul style="list-style-type: none"> ICD: 88% Amiodarone: 87%
CAT (2002) ¹³	<ul style="list-style-type: none"> LVEF \leq30% NYHA class II-III No symptomatic VT, VF, or bradycardia Recent-onset DCM 	<ul style="list-style-type: none"> ICD Control 	50 54	23 mo (trials stopped early due to low event rates)	<ul style="list-style-type: none"> ICD: 4 deaths (8%)^d Control: 2 deaths (3.7%)
DANISH (2016) ¹⁴	<ul style="list-style-type: none"> LVEF \leq35% NYHA class II-IV 58% received CRT 	<ul style="list-style-type: none"> ICD and medical therapy 	556 560	5.6 y ^c	0.87 0.68 to 1.12

Trial	Participants	Treatment Groups	Mean Follow-Up	Mortality Results
	<ul style="list-style-type: none"> • Almost all patients on ACE-inhibitors or β-blockers; \approx60% treated with mineralocorticoid-receptor antagonist 	<ul style="list-style-type: none"> • Medical therapy 		

AAD: antiarrhythmic drugs; ACE: angiotensin-converting enzyme; CABG: coronary artery bypass grafting; CI: confidence interval; CRT: cardiac resynchronization therapy; CRT-D: cardiac resynchronization therapy implantable cardioverter defibrillator; DCM: dilated cardiomyopathy; DSMB: Data Safety Monitoring Board; ECG: electrocardiogram; EPS: electrophysiologic study; HR: heart rate; ICD: implantable cardioverter defibrillator; ICM: ischemic cardiomyopathy; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; RBBB: right bundle-branch block; RCT: randomized controlled trial; SUDS: sudden unexplained death syndrome; SVT: sustained ventricular tachycardia; VF: ventricular fibrillation; VT: ventricular tachycardia.

^a 97.5% confidence interval.

^b Relative risk.

^c Median.

^d Hazard ratio not given, no significant differences.

Systematic Reviews: Woods et al (2015) published an individual patient data network meta-analysis of primary prevention RCTs of implantable cardiac devices, including studies of patients with heart failure and reduced ejection fraction and excluding studies of patients with recent MI or coronary revascularization.¹⁵ The COMPANION, DEFINITE, MADIT, MADIT II, SCD HeFT, AMIOVIRT, and CAT trials were included, representing 6134 patients for the direct ICD comparisons and 12,638 patients overall. Patients included in the ICD arms had a mean age of 63.5, mean QRS interval of 140.5 ms, and mean ejection fraction of 23%. Twenty-one percent of patients were women. The overall estimated effect of ICD on mortality compared to medical therapy was 0.71 (95% CI, 0.63 to 0.80).

Four systematic reviews and meta-analyses of ICD trials in NICM were published in 2017 and incorporated the 2016 DANISH trial results.¹⁶⁻¹⁹ Two of the 2017 reviews included the CAT, AMIOVIRT, DEFINITE, SCD-HeFT, COMPANION, and DANISH trials; the other 2 reviews included all but the COMPANION trial. All 4 reviews concluded that there was a statistically significant overall reduction in mortality for ICD versus medical therapy, ranging from 20% to 23%, even with the inclusion of the null DANISH results.

Risk for death varies by age, sex, and clinical characteristics such as LVEF and time since revascularization and comorbid conditions such as diabetes and kidney disease. Meta-analyses have examined whether there is a beneficial effect on mortality of ICD in these subgroups. The Agency for Healthcare Research and Quality sponsored a review of evidence for ICD across important clinical subgroups published in 2014.²⁰ Reviewers included 10 studies that provided subgroup analyses. Subgroup data were available from at least 4 studies for sex, age (<65 years vs \geq 65 years), and QRS interval (<120 ms vs \geq 120 ms) and were combined to calculate a relative odds ratio (ROR) using random-effects meta-analyses. There was no statistically significant difference in the mortality benefit by sex (ROR=0.95; 95% CI, 0.75 to 1.27), age (ROR=0.93; 95% CI, 0.73 to 1.20), or QRS interval (ROR=1.13; 95% CI, 0.82 to 1.54). Other comparisons of subgroups were not meta-analyzed because too few studies compared them; however, no consistent differences between subgroups were found across studies for diabetes. The Woods 2015 IPD network meta-analysis (described previously) also examined ICD and medical therapy in various subgroups, and similarly concluded that ICD reduced mortality in patients with heart failure and reduced ejection for QRS interval less than 120 ms, 120 to 149 ms, and 150 ms or higher, age less than 60 and 60 and older, and for men.¹⁵ However, the effect on mortality in women was not statistically significant (HR=0.93; 95% CI, 0.73 to 1.18).

Registry Studies: Fontenla et al (2016) reported results from the Spanish UMBRELLA Registry, a multicenter, observational, prospective nationwide registry of 1514 patients implanted with Medtronic ICDs equipped with remote monitoring (NCT01561144) who were enrolled between August 2012 and October 2013.²¹ Mean age was 64 years; 82% of the patients were men; and 65% received an ICD for primary prevention. Fifty-one percent of the patients had ischemic heart disease, 30% had NICM, 7% had HCM, 3% had Brugada syndrome (BrS), and 1.4% had long QT syndrome (LQTS). Mean follow-up was 26 months. The cumulative incidence of sustained ventricular arrhythmias was 15% (95% CI, 13% to 16%) at 1 year, 23% (95% CI, 21% to 25%) at 2 years, and 31% (95% CI, 28% to 34%) at 3 years. Thirteen percent of the episodes of sustained ventricular arrhythmias self-terminated and did not require shocks. One hundred seventy-five (12%) patients had 482 appropriate shocks and 76 (5%) patients had 190 inappropriate shocks.

High-Risk HCM

Schinkel et al (2012) reported results of a systematic review and meta-analysis of 27 observational studies including 16 cohorts and 2190 patients reporting outcomes after ICD therapy for HCM.²² Most patients (83%) received an ICD for primary prevention of SCD. Mean age was 42, 38% of patients were women, and patients had a mean of 1.8 risk factors for SCD. With a mean follow-up of 3.7 years, 14% of patients had an appropriate ICD intervention with an annualized rate of 3.3%. Twenty percent of patients had an inappropriate ICD intervention, for an annualized rate of 4.8%. The annualized cardiac mortality rate was 0.6%, noncardiac mortality rate was 0.4%, and heart transplantation rate was 0.5%.

In 2015, Magnusson et al reported outcomes for 321 patients with HCM treated with an ICD and enrolled in a Swedish registry.²³ Over a mean follow-up of 5.4 years, appropriate ICD discharges in response to ventricular tachycardia (VT) or ventricular fibrillation (VF) occurred in 77 (24%) patients, corresponding to an annual rate of appropriate discharges of 5.3%. At least 1 inappropriate shock occurred in 46 (14.3%) patients, corresponding to an annualized event rate of 3.0%. Ninety-two (28.7%) patients required at least 1 surgical intervention for an ICD-related complication, with a total of 150 ICD-related reinterventions. Most reinterventions (n=105 [70%]) were related to lead dysfunction.

Inherited Cardiac Ion Channelopathy

ICDs have been used for primary and secondary prevention in patients with a number of hereditary disorders, also called cardiac ion channelopathies, that predispose to ventricular arrhythmias and SCD, including LQTS, BrS, short QT syndrome (SQTS), and catecholaminergic polymorphic ventricular tachycardia (CPVT). Some of these conditions are extremely rare. Use of ICDs has been described in small cohorts of patients with LQTS, BrS, and CPVT.

Long QT Syndrome: In 2010, Horner et al reported on outcomes for 51 patients with genetically confirmed LQTS treated with an ICD from 2000 to 2010 who were included in a single-center retrospective analysis of 459 patients with genetically confirmed LQTS.²⁴ Of patients treated with ICDs, 43 (84%) received the device as primary prevention. Twelve (24%) patients received appropriate VF or torsades de pointes-terminated ICD shocks. Factors associated with appropriate shocks included secondary prevention indications (p=0.008), QT corrected (QTc) duration greater than 500 ms (p<0.001), non-LQT3 genotype (p=0.02), documented syncope (p=0.05), documented torsades de pointes (p=0.003), and a negative sudden family death

history ($p < 0.001$). Inappropriate shocks were delivered in 15 (29%) patients. Patients with the LQT3 genotype only received inappropriate shocks.

Brugada Syndrome: Hernandez-Ojeda et al (2017) reported on results from a single-center registry of 104 patients with BrS who were treated with ICDs.²⁵ Ten (9.6%) patients received an ICD for secondary prevention and in 94 (90.4%) patients received an ICD for primary prevention. During an average 9.3-year follow-up, 21 (20.2%) patients received a total of 81 appropriate shocks. In multivariate analysis, type 1 electrocardiogram with syncope and secondary prevention indication were significant predictors of appropriate therapy. Nine (8.7%) patients received 37 inappropriate shocks. Twenty-one (20.2%) patients had other ICD-related complications.

Conte et al (2015) described outcomes for a cohort of 176 patients with spontaneous or drug-induced Brugada type 1 electrocardiographic (ECG) findings who received an ICD at a single institution and were followed for at least 6 months.²⁶ Before ICD implantation, 14.2% of subjects had a history of aborted SCD due to sustained spontaneous ventricular arrhythmias, 59.7% had at least 1 episode of syncope, and 25.1% were asymptomatic. Over a mean follow-up of 83.8 months, 30 (17%) patients had spontaneous sustained ventricular arrhythmias detected. Sustained ventricular arrhythmias were terminated by ICD shocks or antitachycardia pacing in 28 (15.9%) patients and 2 (1.1%) patients, respectively. However, 33 (18.7%) patients experienced inappropriate shocks.

Dores et al (2015) reported on results of a Portuguese registry that included 55 patients with BrS, 36 of whom were treated with ICDs for primary or secondary prevention.²⁷ Before ICD placement, 52.8% of subjects were asymptomatic, 30.6% had a history of syncope with suspected arrhythmic cause, and 16.7% had a history of aborted SCD. Over a mean follow-up of 74 months, 7 patients experienced appropriate shocks, corresponding to an incidence rate of 19.4% and an annual event rate of 2.8%. In multivariable analysis, predictors of appropriate shocks were a history of aborted SCD (HR=7.87; 95% CI, 1.27 to 49.6; $p=0.027$) and nonsustained VT during follow-up (HR=6.73; 95% CI, 1.27 to 35.7; $p=0.025$).

Catecholaminergic Polymorphic Ventricular Tachycardia: Roses-Noguer et al (2014) reported on results of a small retrospective study of 13 patients with CPVT who received an ICD.²⁸ The indication for ICD therapy was syncope despite maximal β -blocker therapy in 6 (46%) patients and aborted SCD in 7 (54%) patients. Over a median follow-up of 4.0 years, 10 (77%) patients received a median of 4 shocks. For 96 shocks, 87 ECGs were available for review; of those, 63 (72%) were appropriate and 24 (28%) inappropriate. Among appropriate shocks, 20 (32%) restored sinus rhythm.

Section Summary: Primary Prevention in Adults (Ischemic Cardiomyopathy, NICM, HCM, and Cardiac Ion Channelopathy)

Ischemic Cardiomyopathy and NIDCM: A large body of RCTs has addressed the effectiveness of TV-ICD implantation for primary prevention in patients at high risk of SCD due to ischemic cardiomyopathy and NICM. Evidence from several RCTs has demonstrated improvements in outcomes with ICD treatment for patients with symptomatic heart failure due to ischemic or NICM with a LVEF of 35% or less. The notable exceptions are that data from several RCTs, including the BEST-ICD, DINAMIT and IRIS trials and subanalyses from earlier RCTs, have shown that outcomes with ICD therapy do not appear to improve for patients treated with an ICD within 40 days of recent MI and the CABG Patch trial did not find a benefit for patients undergoing coronary revascularization.

Hypertrophic Cardiomyopathy: Less evidence is available for use of ICDs for primary prevention in patients with HCM. In a meta-analysis of cohort studies, the annual rates of appropriate ICD discharge was 3.3% and the mortality rate was 1%. Given the long-term high risk of SCD in patients with HCM, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence for the use of SCDs in patients with HCM.

Inherited Cardiac Ion Channelopathy: The evidence related to the use of ICDs in patients with inherited cardiac ion channelopathy includes primarily single-center cohort studies or registries of patients with LQTS, BrS, and CPVT that have reported on appropriate shock rates. Patient populations typically include a mix of those requiring ICD placement for primary or secondary prevention. The limited available data for ICDs for LQTS and CPVT have reported high rates of appropriate shocks. For BrS, more data are available and have suggested that rates appropriate shocks are similarly high. Studies comparing outcomes between patients treated and untreated with ICDs are not available. However, given the relatively small patient populations and the high risk of cardiac arrhythmias, clinical trials are unlikely. Given the long-term high risk of SCD in patients with inherited cardiac ion channelopathy, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence for the use of SCDs in patients with inherited cardiac ion channelopathy.

Secondary Prevention in Adults

At least 5 trials comparing ICD plus medical therapy to medical therapy alone have been conducted in the secondary prevention setting: the Antiarrhythmics Versus Implantable Defibrillators (AVID) trial²⁹ (N=1016), Cardiac Arrest Survival in Hamburg (CASH) trial³⁰ (N=288), Canadian Implantable Defibrillator Study (CIDS)³¹ (N=659), Defibrillator Versus beta-Blockers for Unexplained Death in Thailand (DEBUT)³² trial (N=66; pilot, n=20; main study, n=46), and Wever et al (1995)³³ (N=60). The trials are shown in Table 3. Mean length of follow-up varied from 18 to 57 months across trials. Lee et al (2003) combined the AVID, CASH, CIDS, and Wever trials in a meta-analysis of secondary prevention trials.³⁴ The mortality analysis included 2023 participants and 518 events. In combined estimates, the ICD group had a significant reduction in both mortality (HR=0.75; 95% CI, 0.64 to 0.87) and SCD (HR=0.50; 95% CI, 0.34 to 0.62) compared with to the group receiving medical therapy alone. To support NICE guidance on use of ICDs, a meta-analysis of AVID, CASH, CIDS, and the pilot DEBUT participants were combined in a meta-analysis.³⁵ The results were similar, indicating a reduction in mortality for ICDs compared with medical therapy alone (relative risk [RR], 0.75; 95% CI, 0.61 to 0.93). Two other meta-analyses that included AVID, CIDS, and CASH reached similar conclusions.^{36,37}

Table 3. RCTs of ICDs for Secondary Prevention

Trials	Participants	Treatment Groups		Mortality Results	
		Group	N	RR	95% CI
AVID (1997) ²⁹	Patients resuscitated from near-fatal VT/VF, SVT with syncope, or SVT with LVEF ≤40% and symptoms	• ICD	507	0.66	0.51 to 0.85
		• AAD	509		
CASH (2000) ³⁰	Patients resuscitated from cardiac arrest due to sustained ventricular arrhythmia	• ICD	99	0.82	0.60 to 1.11
		• Amiodarone	92		
		• Metoprolol	97		
CIDS (2000) ³¹	Patients with VF, out-of-hospital cardiac arrest requiring defibrillation, VT with syncope, VT with rate ≥150/min causing presyncope or angina in patient with LVEF	• ICD	328	0.85	0.67 to 1.10
		• Amiodarone	331		

Trials	Participants	Treatment Groups	Mortality Results
	≤35% or syncope with inducible VT inducible		
Wever et al (1995) ³³	Patients with previous MI and resuscitated cardiac arrest due to VT or VF and inducible VT	<ul style="list-style-type: none"> • ICD • AAD 	29 31 0.39 0.14 to 1.08
DEBUT (2003) ³²	Patients were either SUDS survivors or probable SUDS with ECG abnormalities showing a RBBB-like pattern with ST elevation in the right precordial leads and inducible VT/VF	Pilot <ul style="list-style-type: none"> • ICD • β-blockade therapy Main trial <ul style="list-style-type: none"> • ICD • β-blockade therapy 	10 10 37 29 • RR not calculable (DSMB stopped trial early due to efficacy of ICD) • 7 deaths in β-blockade vs 0 in ICD

AA: antiarrhythmic drugs; CI: confidence interval; DSMB: data safety monitoring board; ECG: electrocardiogram; ICD: implantable cardioverter defibrillator; LVEF: left ventricular ejection fraction; MI: myocardial infarction; RBBB: right bundle-branch block; RR: relative risk; SUDS: sudden unexplained death syndrome; SVT: sustained ventricular tachycardia; VF: ventricular fibrillation; VT: ventricular tachycardia.

An analysis by Chan and Hayward (2005) using the National Veterans Administration database previously confirmed that this mortality benefit is generalizable to the clinical setting.³⁸ A cohort of 6996 patients in the National Veterans Administration database from Austin, Texas, from 1995 to 1999, who had new-onset ventricular arrhythmia and preexisting ischemic heart disease and congestive heart failure were included. Of those, 1442 patients had received an ICD. Mortality was determined through the National Death Index at 3 years from the hospital discharge date. The cohort was stratified by quintiles of a multivariable propensity score created using many demographic and clinical confounders. The propensity score adjusted mortality reduction for ICD compared to no ICD was a relative risk of 0.72 (95% CI, 0.69 to 0.79) for all-cause mortality and a relative risk of 0.70 (95% CI, 0.63 to 0.78) for cardiovascular mortality.

Section Summary: Secondary Prevention in Adults

Systematic reviews of RCTs in patients who have experienced symptomatic life-threatening sustained VT or VF or have been successfully resuscitated from sudden cardiac arrest have shown a 25% reduction in mortality for ICD compared to medical therapy. Analysis of data from a large administrative database confirms that this mortality benefit is generalizable to the clinical setting.

TV-ICDs in Pediatric Populations

There is limited direct evidence on the efficacy of ICDs in the pediatric population. Most published studies have retrospectively analyzed small case series. A review of some representative series is provided next.

The largest published series (2008) combined pediatric patients and patients with congenital heart disease from 4 clinical centers.⁴¹ Median age was 16 years, although some adults included were as old as 54 years. A total of 443 patients were included. The most common diagnoses were tetralogy of Fallot and HCM. ICD placement was performed for primary prevention in 52% of patients and for secondary prevention in 48%. Over a 2-year follow-up, appropriate shocks occurred in 26% of patients and inappropriate shocks occurred in 21%.

Silka et al (1993) compiled a database of 125 pediatric patients treated with an ICD through query of the manufacturers of commercially available devices.⁴⁰ Indications for ICD placement were survivors of cardiac arrest (95 [76%] patients), drug-refractory VT (13 [10%] patients), and syncope with heart disease and inducible VT (13 [10%] patients). During a mean follow-up of 31

months, 73 (59%) patients received at least 1 appropriate shock and 25 (20%) received at least 1 inappropriate shock. Actuarial rates of SCD-free survival were 97% at 1 year, 95% at 2 years, and 90% at 5 years.

Alexander et al (2004) reported on 90 ICD procedures in 76 young patients with a mean age of 16 years (range, 1-30 years).⁴¹ Indications for placement were 27 (36%) patients with cardiac arrest or sustained VT, 40 (53%) with syncope, 17 (22%) with palpitations, 40 (53%) with spontaneous ventricular arrhythmias, and 36 (47%) with inducible VT. Numerous patients had more than 1 indication for ICD in this study. Over a median follow-up of 2 years, 28% of patients received an appropriate shock and 25% received an inappropriate shock. Lewandowski et al (2010) reported on long-term follow-up for 63 patients, between the ages 6 and 21 years, who were treated with an ICD device.⁴⁴ At 10-year follow-up, 13 (21%) patients had surgical infections. Fourteen (22%) patients experienced at least 1 appropriate shock and 17 (27%) had at least 1 inappropriate shock. Serious psychological sequelae developed in 27 (43%) patients.

Section Summary: TV-ICDs in Pediatric Populations

The available evidence for the use of ICDs in pediatric patients is limited and consists primarily of small case series that include mixed populations with mixed indications for device placement. Overall, these studies have reported both relatively high rates of appropriate and inappropriate shocks. Pediatric patients may also be eligible ICD placement if they have inherited cardiac ion channelopathy (see ICDs in Patients With inherited cardiac ion channelopathy section).

Adverse Events Associated With TV-ICDs

Systematic Reviews: Mixed Adverse Events

Perrson et al (2014) conducted a systematic review of adverse events following ICD placement.⁴³ They included data from 35 cohort studies, reported in 53 articles. In-hospital serious adverse event rates ranged from 1.2% to 1.4%, most frequently pneumothorax (0.4%-0.5%) and cardiac arrest (0.3%). Posthospitalization complication rates varied: device-related complications occurred in 0.1% to 6.4%; lead-related complications in 0.1% to 3.9% of patients; infection in 0.2% to 3.7%; thrombosis in 0.2% to 2.9%; and inappropriate shock in 3% to 21%.

In another systematic review of adverse events following ICD placement, Ezzat et al (2015) compared event rates reported in clinical trials of ICDs with those reported in the U.S. National Cardiovascular Data Registry.⁴⁴ Reviewers included 18 RCTs (total N=6796 patients). In pooled analysis, the overall AE rate was 9.1% (95% CI, 6.4% to 12.6%). Rates of access-related complications, lead-related complications, generator-related complications, and infection were 2.1% (91% CI, 1.3% to 3.3%), 5.8% (95% CI, 3.3% to 9.8%), 2.7% (95% CI, 1.3% to 5.7%), and 1.5% (95% CI, 0.8% to 2.6%), respectively. Complication rates in the RCTs were higher than those in the U.S. registry, which reports only in-hospital complications (9.1% in the RCTs vs 3.08% in the U.S. registry, $p<0.01$). The overall complication rate was similar to that reported by Kirkfelt et al (2014), in a population-based cohort study including all Danish patients who underwent a cardiac implantable electronic device procedure from 2010 to 2011 (562 [9.5%] 5918 patients with at least 1 complication).⁴⁵

In 2011, van Rees et al (2011) reported results of a systematic review of RCTs assessing implant-related complications of ICDs and cardiac resynchronization therapy (CRT) devices.⁴⁶ Reviewers included 18 trials and 3 subgroup analyses. Twelve trials assessed ICDs, 4 of which used both thoracotomy and nonthoracotomy ICDs (n=951) and 8 of which used nonthoracotomy ICDs (n=3828). For nonthoracotomy ICD placement, the rates for in-hospital and 30-day mortality

were 0.2% and 0.6%, respectively, and pneumothorax was reported in 0.9% of cases. For thoracotomy ICD placement, the average in-hospital mortality rate was 2.7%. For nonthoracotomy ICD placement, the overall lead-dislodgement rate was 1.8%.

In 2016, Olde Nordkamp et al reported on a systematic review and meta-analysis of studies reporting on ICD complications in individuals with inherited arrhythmia syndromes.⁴⁷ Reviewers included 63 cohort studies with a total of 4916 patients (710 [10%] with arrhythmogenic right VT; 1037 [21%] with BrS; 28 [0.6%] with CPVT; 2466 [50%] with HCM; 162 [3.3%] with lamin A/C gene variants; 462 [9.4%] with LQTS; 51 [1.0%] with SQTS). Overall, inappropriate shocks occurred in 20% of patients over a mean follow-up of 51 months, corresponding to an annual inappropriate shock rate of 4.7% (95% CI, 4.2% to 5.3%). Over a mean follow-up of 55 months, ICD-related complications occurred in 22%, most commonly lead malfunction (10.3% of patients). The pooled rate of ICD-related complications was 4.4% per year (95% CI, 3.6% to 5.2%).

Systematic Review: Specific Complications

Lead Failure

The failure of leads in specific ICD devices led the U.S. Food and Drug Administration (FDA) to require St. Jude Medical to conduct 3-year postmarket surveillance studies to address concerns related to premature insulation failure and important questions related to follow-up of affected patients.⁴⁸ A 2010 evaluation found that 57 deaths and 48 serious cardiovascular injuries associated with device-assisted ICD or pacemaker lead extraction were reported to the FDA's Manufacturers and User Defined Experience (MAUDE) database.⁴⁹

In 2015, Providencia et al reported on a meta-analysis of 17 observational studies evaluating performance of 49,871 leads (5538 Durata, 10,605 Endotak Reliance, 16119 Sprint Quattro, 11,709 Sprint Fidelis, 5900 Riata).⁵⁰ Overall, the incidence of lead failure was 0.93 per 100 lead-years (95% CI, 0.88 to 0.98). In analysis of studies restricted to head-to-head comparisons of leads, there were no significant differences in the lead failure rates among nonrecalled leads (Endotak Reliance, Durata, Sprint Quattro).

Birnie et al (2012) reported clinical predictors of failure for 3169 Sprint Fidelis leads implanted from 2003 to 2007 at 11 centers participating in the Canadian Heart Rhythm Society Device Committee study.⁵¹ A total of 251 lead failures occurred, corresponding to a 5-year lead failure rate of 16.8%. Factors associated with higher failure rates included female sex (HR=1.51; 95% CI, 1.14 to 2.04; p=0.005), axillary vein access (HR=1.94; 95% CI, 1.23 to 3.04), and subclavian vein access (HR=1.63; 95% CI, 1.08 to 2.46). In a 2011 study from 3 centers reporting on predictors of Fidelis lead failures, compared with Quattro lead failures, Hauser et al reported a failure rate for the Fidelis lead of 2.81% per year (vs 0.42% per year for Quattro leads; p<0.001).⁵²

In an earlier study from 12 Canadian centers, Gould et al (2008) reported on outcomes from ICD replacements due to ICD advisories from 2004 to 2005, which included 451 replacements (of 2635 advisory ICD devices).⁵³ Over 355 days of follow-up, 41 (9.1%) complications occurred, including 27 (5.9%) requiring surgical reintervention and 2 deaths.

In a large prospective multicenter study, Poole et al (2010) reported on complications rates associated with generator replacements and/or upgrade procedures of pacemaker or ICD devices, which included 1031 patients without a planned transvenous lead replacement (cohort

1) and 713 with a planned transvenous lead replacement (cohort 2).⁵⁴ A total of 9.8% and 21.9% of cohort 1 and 19.2% and 25.7% of cohort 2 had a single-chamber ICD and a dual-chamber ICD, respectively, at baseline. Overall periprocedural complication rates for those with a planned transvenous lead replacement were cardiac perforation in 0.7%, pneumothorax or hemothorax in 0.8%, cardiac arrest in 0.3%, and, most commonly, need to reoperate because of lead dislodgement or malfunction in 7.9%. Although rates were not specifically reported for ICD replacements, complication rates were higher for ICDs and CRT devices than pacemakers.

Ricci et al (2012) evaluated the incidence of lead failure in a cohort of 414 patients given an ICD with Sprint Fidelis leads.⁵⁵ Patients were followed for a median of 35 months. Lead failures occurred in 9.7% (40/414) of patients, for an annual rate of 3.2% per patient-year. Most lead failures (87.5%) were due to lead fracture. Median time until recognition of lead failure, or until an adverse event, was 2.2 days. A total of 22 (5.3%) patients received an inappropriate shock due to lead failure.

Cheng et al (2010) examined the rate of lead dislodgements in patients enrolled in a national cardiovascular registry.⁵⁶ Of 226,764 patients treated with an ICD between April 2006 and September 2008, lead dislodgement occurred in 2628 (1.2%). Factors associated with lead dislodgement were New York Heart Association class IV heart failure, AF or atrial flutter, a combined ICD and CRT device, and having the procedure performed by a nonelectrophysiologist. Lead dislodgement was associated with an increased risk for other cardiac adverse events and death.

In another single-center study, Faulkner et al (2010) reported on the time-dependent hazard of failure of Sprint Fidelis leads.⁵⁷ Over an average follow-up of 2.3 years, 38 (8.9%) of 426 leads failed. There was a 3-year lead survival rate of 90.8% (95% CI, 87.4% to 94.3%), with a hazard of fracture increasing exponentially over time by a power of 2.13 (95% CI, 1.98 to 2.27; $p < 0.001$).

Infection Rates

Several publications have reported on infection rates in patients receiving an ICD. Smit et al (2010) published a retrospective, descriptive analysis of the types and distribution of infections associated with ICDs over a 10-year period in Denmark.⁵⁸ Of 91 total infections identified, 39 (42.8%) were localized pocket infections, 26 (28.6%) were endocarditis, 17 (18.7%) were ICD-associated bacteremic infections, and 9 (9.9%) were acute postsurgical infections. Nery et al (2010) reported the rate of ICD-associated infections among consecutive patients treated with an ICD at a tertiary referral center.⁵⁹ Twenty-four of 2417 patients had infections, for a rate of 1.0%. Twenty-two (91.7%) of the 24 patients with infections required device replacement. Factors associated with infection were device replacement (vs de novo implantation) and use of a complex device (eg, combined ICD plus CRT or dual-/triple-chamber devices). Sohail et al (2011) performed a case-control study evaluating the risk factors for an ICD-related infection in 68 patients and 136 matched controls.⁶⁰ On multivariate analysis, the presence of epicardial leads (odds ratio [OR], 9.7; $p = 0.03$) and postoperative complications at the insertion site (OR=27.2, $p < 0.001$) were significant risk factors for early infection. For late-onset infections, hospitalization for more than 3 days (OR=33.1, $p < 0.001$ for 2 days vs 1 day) and chronic obstructive pulmonary disease (OR=9.8, $p = 0.02$) were significant risk factors.

Chua et al (2000) described the diagnosis and management of infections in a retrospective case series that included 123 patients, 36 of whom were treated for ICD infections.⁶¹ Most ($n = 117$

[95%]) patients required removal of the device and all lead material. Of those who had all hardware removed, 1 patient experienced a relapse, while 3 of the 6 patients who did not undergo hardware removal experienced a relapse.

Borleffs et al (2010) also reported on complications after ICD replacement for pocket-related complications, including infection or hematoma, in a single-center study.⁶² Of 3161 ICDs included, 145 surgical reinterventions were required for 122 ICDs in 114 patients. Ninety-five (66%) reinterventions were due to infection and the remaining 50 (34%) were due to other causes. Compared with first-implanted ICDs, the occurrence of surgical reintervention in replacements was 2.5 (95% CI, 1.6 to 3.7) times higher for infection and 1.7 (95% CI, 0.9 to 3.0) times higher for non-infection-related causes.

Inappropriate Shocks

Inappropriate shocks may occur with ICDs due to faulty sensing or sensing of atrial arrhythmias with rapid ventricular conduction; these shocks may lead to reduced QOL and risk of ventricular arrhythmias. In the MADIT II trial (described above), 1 or more inappropriate shocks occurred in 11.5% of ICD subjects and were associated with a greater likelihood of mortality (HR=2.29; 95% CI, 1.11 to 4.71; p=0.02).⁶³

Tan et al (2014) conducted a systematic review to identify outcomes and AEs associated with ICDs with built-in therapy-reduction programming.⁶⁴ Six randomized trials and 2 nonrandomized cohort studies (total N=7687 patients) were included (3598 with conventional ICDs, 4089 therapy-reduction programming). A total of 267 (4.9%) patients received inappropriate ICD shocks, 99 (3.4%) in the therapy reduction group and 168 (6.9%) in the conventional programming group (RR=50%; 95% CI, 37% to 61%; p<0.001). Therapy-reduction programming was associated with a significantly lower risk of death than conventional programming (RR=30%; 95% CI, 16% to 41%; p<0.001).

Sterns et al (2016) reported on results of an RCT comparing a strategy using a prolonged VF detection time to reduce inappropriate shocks with a standard strategy among secondary prevention patients.⁶⁵ This study reported on a prespecified subgroup analysis of the PainFree SST trial, which compared standard and prolonged detection in patients receiving an ICD for secondary prevention. Patients treated for secondary prevention indications were randomized to a prolonged VF detection period ("Number of Intervals to Detect" VF 30/40; n=352) or a standard detection period ("Number of Intervals to Detect" VF 18/24; n=353). At 1 year, arrhythmic syncope-free rates were 96.9% in the 30/40 (intervention) group and 97.7% in the 18/24 (control) group (rate difference, -1.1%; 90% lower confidence limit, -3.5%; above the prespecified noninferiority margin of -5%; p=0.003 for noninferiority).

Auricchio et al (2015) assessed data from the PainFree SST trial, specifically newer ICD programming strategies for reducing inappropriate shocks.⁶⁶ A total of 2790 patients with an indication for ICD placement who were given a device programmed with a SmartShock Technology designed to differentiate between ventricular arrhythmias and other rhythms. The inappropriate shock incidence for dual-/triple-chamber ICDs was 1.5% at 1 year (95% CI, 1.0% to 2.1%), 2.8% at 2 years (95% CI, 2.1% to 3.8%), and 3.9% at 3 years (95% CI, 2.8% to 5.4%).

Other Complications

Lee et al (2010) evaluated rates of early complications among patients enrolled in a prospective, multicenter population-based registry of all newly implanted ICDs in Ontario, from February 2007 through May 2009.⁶⁷ Of 3340 patients receiving an ICD, major complications (lead dislodgement requiring intervention, myocardial perforation, tamponade, pneumothorax, infection, skin erosion, hematoma requiring intervention) within 45 days of implantation occurred in 4.1% of new implants. Major complications were more common in women, in patients who received a combined ICD-CRT device, and in patients with a left ventricular end-systolic size of larger than 45 mm. Direct implant-related complications were associated with a major increase in early death (HR=24.9; $p<0.01$).

Furniss et al (2015) prospectively evaluated changes in high-sensitivity troponin T (hs-TnT) levels and ECG results that occur during ICD placement alone, ICD placement with testing, and ICD testing alone.⁶⁸ The 13 subjects undergoing ICD placement alone had a median increase in hs-TnT level of 95% ($p=0.005$) while the 13 undergoing implantation and testing had a median increase of 161% ($p=0.005$). Those undergoing testing alone demonstrated no significant change in hs-TnT levels.

Subcutaneous Implantable Cardioverter Defibrillators

The subcutaneous implantable cardioverter defibrillator (S-ICD) is intended for patients who have standard indications for an ICD, but who do not require pacing for bradycardia or antitachycardia overdrive pacing for VT. The S-ICD has been proposed to benefit patients with limited vascular access (including patients undergoing renal dialysis or children), or those who have had complications requiring TV-ICDs explantation. No RCTs were identified comparing the performance of an S-ICD with that of TV-ICDs. The first multicenter, randomized trial (PRAETORIAN, NCT01296022) to directly compare S-ICDs with TV-ICDs is underway.

S-ICD Efficacy

Several observational studies have compared S-ICD to TV-ICD.

Observational Studies

The observational studies are briefly described in Table 4. All studies were performed in the United States and/or Europe.

Table 4. Summary of Observational Studies of S-ICD to TV-ICD

Author	Study Type	N	Follow-Up	Results			
				Outcomes	TV-ICD	S-ICD	DC TV-ICD
Mithani et al (2018) ⁶⁹	Matching based on dialysis status, sex, age	182 (91 matched pairs)	180 d	<ul style="list-style-type: none"> Inappropriate shocks Infection requiring explant Death from all causes Total with adverse event or death 	2.2% 1.1% 2.2% 7.7%	1.1% 3.3% 2.2% 5.5%	
Honarbaksh (2017) ⁷⁰	Propensity matched case-control	138 (69 matched pairs)	32 mo ^a	<ul style="list-style-type: none"> Total device-related complications Infections Inappropriate shocks Failure to cardiovert VA 	29% 5.8% 8.7% 1.4%	9% 1.4% 4.3% 1.4%	
Kobe (2017) ⁷¹	Sex- and age-	120 (60 pairs); 84	942 d vs 622 d	<ul style="list-style-type: none"> Posttraumatic stress disorder Major depression 	14.3% 9.5%	14.3% 4.8%	

Author	Study Type	N	Follow-Up	Results			
Pedersen (2016) ⁷²	matched case-control	pairs analyzed	6 mo	• SF-12 Physical well-being score	40	47	
	Retrospective analysis of propensity-matched cohort	334 (167 matched pairs)		• SF-12 Mental well-being score	52	52	
				• SF-12 Physical well-being score	43	44	
				• SF-12 Mental well-being score	45	45	
Brouwer (2016) ⁷³	Retrospective analysis of propensity-matched cohort	280 (140 matched pairs)	5 y	• Overall complications	18%	14%	
Friedman (2016) ⁷⁴	Retrospective analysis of propensity-matched cohort from NCDR for ICD	5760 (1920 matched, groups)	NR	• Lead complications	11.5%	0.8%	
				• Non-lead complications	2.2%	9.9%	
				• Infections	3.6%	4.1%	
				• Appropriate ICD intervention (HR=2.4; 95% CI, NR; p=0.01)	31%	17%	
				• Inappropriate ICD intervention (HR=1.3; 95% CI, NR; p=0.42)	30%	21%	
				• Survival	95%	96%	
				• Any in-hospital complication	0.6%	0.9%	1.5%
Kobe (2013) ⁷⁵	Sex- and age-matched case-control	138 (69 matched pairs)	217 d ^a	• Deaths	0.1%	0.2%	0.05%
				• Infections	0%	0.05%	0.1%
				• Lead dislodgements	0.2%	0.1%	0.6%
				• Pneumothorax	0.2%	0%	0.3%
				• Pericardial effusion	1	0	
• Successful termination of induced VF	91%	90%					
• Appropriate shocks	9	3					
• Inappropriate shocks	3	5					

CI: confidence interval; DC: dual chamber; HR: hazard ratio; ICD: implantable cardioverter defibrillator; NCDR: National Cardiovascular Data Registry; NR: not reported; SF-12: 12-Item Short-Form Health Survey; S-ICD: subcutaneous implantable cardioverter defibrillator; TV-ICD: transvenous implantable cardioverter defibrillator; VA: ventricular arrhythmia; VF: ventricular fibrillation.

^aMean.

^bMedian.

Noncomparative Studies

The EFFORTLESS S-ICD Registry is a multicenter European registry reporting outcomes for patients treated with S-ICD. Several publications from EFFORTLESS, the pivotal trial submitted to FDA for the investigational device exemption, and other noncomparative studies are described in Table 5.

Table 5. Summary of Noncomparative Studies of Subcutaneous ICD

Study; Trial	Countries	N	Mean FU	Results	
				Outcomes	Values
Lambiase et al (2014) ⁷⁶ ;	10 European countries	985	3.1 y	Complication-rates by 360 d	8.4%
Olde Nordkamp et al (2015) ⁷⁷ ;				Inappropriate shocks by 360 d	8.1%
Boersma et al (2017) ⁷⁸				Complication rates through follow-up	11.7%
EFFORTLESS S-ICD Registry				Inappropriate shocks through follow-up	11.7%
				Appropriate shocks through follow-up	13.5%
Weiss et al (2013) ⁷⁹	U.S., U.K., New Zealand, Netherlands	330	11 mo	Implanted successfully:	95%
IDE study				Complication-free at 180 d	99%
				Inappropriate shocks	13%
				Episodes of discrete spontaneous VT or VF, all successfully converted	38
Burke et al (2015) ⁸⁰ ;	Multiple European	882	651 d	Complications within 3 y	11%
Boersma et al (2016) ⁸¹ ;					1.7%

Study; Trial	Countries	N	Mean FU	Results	
Lambiase et al (2016) ⁸² EFFORTLESS and IDE studies	countries, U.S., New Zealand			Infections requiring device removal or revision Annual mortality rate 2-y cumulative mortality Incidence of therapy for VT or VF: 1 year 2 years 3 years Incidence of inappropriate shock at 3 y	1.6% 3.2% 5.3% 7.9% 10.5% 13.1%
Bardy et al (2010) ⁸³ ; Theuns et al (2015) ⁸⁴	Europe, New Zealand	55	5.8 y	Devices replaced Devices explanted Replaced with TV-ICD Shocks recorded in 16 (29%) patients	26 (47%) 5 (9%) 4 (7%) 119
Olde-Nordkamp et al (2012) ⁸⁵	Netherlands	118	18 mo	All device-related complications Infections Dislodgements of device/leads Skin erosion Battery failure Replaced with TV-ICD Appropriate shocks experienced in 8 patients Total inappropriate shocks delivered to 15 (13%) patients Deaths (cancer, progressive heart failure)	14% 5.9% 3.3% 1.7% 1.7% 1 (0.8%) 45 33 2

ESRD: end-stage renal disease; FU: follow-up; HCM: hypertrophic cardiomyopathy; ICD: implantable cardioverter defibrillator; NZ: New Zealand; S-ICD: subcutaneous implantable cardioverter defibrillator; TV-ICD: transvenous implantable cardioverter defibrillator; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia. ^aMedian.

Inappropriate Shocks

Although Kobe et al⁷² reported no differences between inappropriate shock rates in patients treated TV-ICD or S-ICD, noncomparative studies have reported relatively high rates of inappropriate shocks with S-ICD.⁷¹ Inappropriate shocks from S-ICDs often result from T-wave oversensing. Because the sensing algorithm and the discrimination algorithm for arrhythmia detection are fixed in the S-ICD, management to reduce inappropriate shocks for an S-ICD differs from that for a TV-ICD. Kooiman et al (2014) reported inappropriate shock rates among 69 patients treated at a single center with an S-ICD between February 2009 and July 2012 who were not enrolled in 1 of 2 other concurrent trials.⁸⁶ Over a total follow-up of 1316 months (median per patient, 21 months), the annual incidence of inappropriate shocks was 10.8%. In 8 patients, inappropriate shocks were related to T-wave oversensing. After patients underwent adjustment of the sensing vector, no further inappropriate shocks occurred in 87.5% of patients with T-wave oversensing.

Section Summary: Subcutaneous Implantable Cardioverter Defibrillators

Contraindications to TV-ICD: Nonrandomized studies have suggested that S-ICDs are as effective as TV-ICDs at terminating laboratory-induced ventricular arrhythmias. Data from 2 large patient registries have suggested that S-ICDs are effective at terminating ventricular arrhythmias when they occur. Given the need for cardioverter defibrillation for SCD risk in this population, with the assumption that appropriate shocks are life-saving, these rates suggest S-ICDs, in patients with contraindication to TV-ICD, are likely an improvement over medical management alone.

No Contraindications to TV-ICD: No RCTs directly comparing TV-ICDs with S-ICDs were identified and therefore evidence is not sufficient to show that outcomes for S-ICDs are noninferior to those for TV-ICD for patients who could otherwise receive TV-ICD.

SUMMARY OF EVIDENCE

Transvenous ICDs

For individuals who have a high risk of SCD due to ischemic or to nonischemic cardiomyopathy in adulthood who receive TV-ICD placement for primary prevention, the evidence includes multiple well-designed and well-conducted RCTs as well as systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Multiple, well-done RCTs have shown a benefit in overall mortality for patients with ischemic cardiomyopathy and reduced ejection fraction. RCTs assessing early ICD use following recent myocardial infarction did not support a benefit for immediate vs delayed implantation for at least 40 days. For nonischemic cardiomyopathy, there is less clinical trial data, but pooled estimates of available evidence from RCTs enrolling patients with nonischemic cardiomyopathy and from subgroup analyses of RCTs with mixed populations have supported a survival benefit for this group. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a high risk of SCD due to HCM in adulthood who receive TV-ICD placement for primary prevention, the evidence includes several large registry studies. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. In these studies, the annual rate of appropriate ICD discharge ranged from 3.6% to 5.3%. Given the long-term high risk of SCD in patients with HCM, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence to support the use of ICDs in patients with HCM. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a high risk of SCD due to an inherited cardiac ion channelopathy who receive TV-ICD placement for primary prevention, the evidence includes small cohort studies of patients with these conditions treated with ICDs. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. The limited evidence for patients with long QT syndrome, catecholaminergic polymorphic ventricular tachycardia, and Brugada syndrome has reported high rates of appropriate shocks. No studies were identified on the use of ICDs for patients with short QT syndrome. Studies comparing outcomes between patients treated and untreated with ICDs are not available. However, given the relatively small patient populations with these channelopathies and the high risk of cardiac arrhythmias, clinical trials are unlikely. Given the long-term high risk of SCD in patients with inherited cardiac ion channelopathy, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence to support the use of TV-ICDs in patients with inherited cardiac ion channelopathy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have had symptomatic life-threatening sustained VT or VF or who have been resuscitated from sudden cardiac arrest (secondary prevention) who receive TV-ICD placement, the evidence includes multiple well-designed and well-conducted RCTs as well as systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs have demonstrated a 25% reduction in mortality for ICD compared with medical therapy. Analysis of data from a large administrative database has confirmed that this mortality benefit is generalizable to the clinical setting. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Subcutaneous ICDs

For individuals who need an ICD and have a contraindication to a TV-ICD but no indications for antibradycardia pacing and no antitachycardia pacing–responsive arrhythmias who receive S-ICD placement, the evidence includes nonrandomized studies and case series. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Nonrandomized controlled studies have reported success rates in terminating laboratory-induced VF that are similar to TV-ICD. Case series have reported high rates of detection and successful conversion of VF, and inappropriate shock rates in the range reported for TV-ICD. Given the need for ICD placement in this population at risk for SCD, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence to support the use of S-ICDs in patients with contraindication to TV-ICD. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have need for an ICD and have no contraindication to TV-ICD but no indications for antibradycardia pacing and no antitachycardia pacing–responsive arrhythmias who receive S-ICD placement, the evidence includes nonrandomized studies and case series. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Nonrandomized controlled studies have reported success rates in terminating laboratory-induced VF that are similar to TV-ICD. However, there is scant evidence on comparative clinical outcomes of both types of ICD over longer periods. Case series have reported high rates of detection and successful conversion of ventricular tachycardia, and inappropriate shock rates in the range reported for TV-ICD. This evidence does not support conclusions on whether there are small differences in efficacy between the 2 types of devices, which may be clinically important due to the nature to the disorder being treated. Also, adverse event rates are uncertain, with variable rates reported. At least 1 RCT is currently underway comparing S-ICD with TV-ICD. The evidence is insufficient to determine the effects of the technology on health outcomes.

CLINICAL INPUT RECEIVED FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input

In response to requests, input was received from 1 physician specialty society (4 responses) and 5 academic medical centers, for a total of 9 responses, while this policy was under review in 2015 with a focus on the use of ICDs as primary prevention for cardiac ion channelopathies and on the use of the S-ICD. Reviewers generally indicated that an ICD should be considered medically necessary for primary prevention of ventricular arrhythmias in both adults and children with a diagnosis of long QT syndrome (LQTS), Brugada syndrome (BrS), short QT syndrome (SQTS), and catecholaminergic polymorphic ventricular tachycardia (CPVT). Reviewers generally indicated that the S-ICD should be considered medically necessary, particularly for patients with indications for an ICD but who have difficult vascular access or have had TV-ICD lead explantation due to complications.

2011 Input

In response to requests, input was received from no physician specialty societies and 6 academic medical centers while this policy was under review in 2011. For most policy indications, including pediatric indications, there was agreement from those providing input. On the question of timing of ICD implantation, input was mixed, with some commenting about the potential role of early implantation in selected patients. Reviewers indicated that a waiting period of 9 months for patients with NICM was not supported by the available evidence or consistent with the prevailing practice patterns in academic medical centers. Specialty society input emphasized the difficulty of prescribing strict timeframes given the uncertainty of establishing the onset of cardiomyopathy and the inability to risk stratify patients based on time since onset of cardiomyopathy.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American College of Cardiology, et al

Heart Failure

The American Heart Association (AHA,) American College of Cardiology (ACC), and Heart Rhythm Society (HRS) (2017) published joint guidelines on the management of heart failure, which updated their 2012 guidelines.^{87,88} These guidelines made the following recommendations on the use of implantable cardioverter defibrillator (ICD) devices (see Tables 6-11). The recommendations for the use of an ICD apply only if meaningful survival is expected to be greater than 1 year.

Table 6. Guidelines on Device-Based Therapy of Cardiac Rhythm Abnormalities

Recommendation	COR	LOE
"In patients with ischemic heart disease, who either survive SCA due to VT/VF or experience hemodynamically unstable VT (LOE: B-R) or stable VT (LOE: B-NR) not due to reversible causes...."	I	B-R B-NR
"A transvenous ICD provides intermediate value in the secondary prevention of SCD particularly when the patient's risk of death due to a VA is deemed high and the risk of nonarrhythmic death (either cardiac or noncardiac) is deemed low based on the patient's burden of comorbidities and functional status."		B-R
"In patients with ischemic heart disease and unexplained syncope who have inducible sustained monomorphic VT on electrophysiological study...."	I	B-NR
"In patients resuscitated from SCA due to coronary artery spasm in whom medical therapy is ineffective or not tolerated...."	IIa	B-NR
"In patients resuscitated from SCA due to coronary artery spasm, an ICD in addition to medical therapy may be reasonable...."	IIb	B-NR
"In patients with arrhythmogenic right ventricular cardiomyopathy and an additional marker of increased risk of SCD (resuscitated SCA, sustained VT, significant ventricular dysfunction with RVEF or LVEF ≤35%)...."	I	B-NR
"In patients with arrhythmogenic right ventricular cardiomyopathy and syncope presumed due to VA...."	IIa	B-NR

COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; RVEF: right ventricular ejection fraction; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.

Table 7. Guidelines on Use of ICDs as a Primary Prevention of Ischemic Heart Disease

Recommendation	COR	LOE
"In patients with LVEF of 35% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days postrevascularization, and with NYHA class II or III HF despite GDMT...."	I	A
"In patients with LVEF of 30% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days postrevascularization, and with NYHA class I HF despite GDMT...."	I	A
"A transvenous ICD provides high value in the primary prevention of SCD particularly when the patient's risk of death due to a VA is deemed high and the risk of nonarrhythmic death (either cardiac or noncardiac) is deemed low based on the patient's burden of comorbidities and functional status...."		B-R

Recommendation	COR	LOE
"In patients with NSVT due to prior MI, LVEF of 40% or less and inducible sustained VT or VF at electrophysiological study...."	I	B-R
"In nonhospitalized patients with NYHA class IV symptoms who are candidates for cardiac transplantation or an LVAD...."	IIa	B-NR
"An ICD is not indicated for NYHA class IV patients with medication-refractory HF who are not also candidates for cardiac transplantation, an LVAD, or a CRT defibrillator that incorporates both pacing and defibrillation capabilities."	III ^a	C-EO

CRT: cardiac resynchronization therapy; COR: class of recommendation; ICD: implantable cardioverter defibrillator; GDMT: guideline-directed management and therapy; HF: heart failure; LOE: level of evidence; LVAD: left ventricular assist device; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NSVT: nonsustained ventricular tachycardia; NYHA: New York Heart Association; SCD: sudden cardiac death; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.

^a No benefit.

Table 8. Guidelines on Use of ICDs for Nonischemic Cardiomyopathy

Recommendation	COR	LOE
"In patients with NICM who either survive SCA due to VT/VF or experience hemodynamically unstable VT (LOE: B-R) (1-4) or stable VT (LOE: B-NR) (5) not due to reversible causes...."	I	B-R B-NR
"In patients with NICM who experience syncope presumed to be due to VA and who do not meet indications for a primary prevention ICD, an ICD or an electrophysiological study for risk stratification for SCD can be beneficial...."	IIa	B-NR
"In patients with NICM, HF with NYHA class II-III symptoms and an LVEF of 35% or less, despite GDMT...."	IIa	B-R
"In patients with NICM, HF with NYHA class I symptoms and an LVEF of 35% or less, despite GDMT...."	IIb	B-R
"In patients with medication-refractory NYHA class IV HF who are not also candidates for cardiac transplantation, an LVAD, or a CRT defibrillator that incorporates both pacing and defibrillation capabilities, an ICD should not be implanted."	III ^a	C-EO

COR: class of recommendation; CRT: cardiac resynchronization therapy; GDMT: guideline-directed management and therapy; HF: heart failure; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVAD: left ventricular assist device; LVEF: left ventricular ejection fraction; NICM: nonischemic cardiomyopathy; NYHA: New York Heart Association; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.

^a No benefit.

Table 9. Guidelines on Use of ICDs for HCM

Recommendation	COR	LOE
"In patients with HCM who have survived an SCA due to VT or VF, or have spontaneous sustained VT causing syncope or hemodynamic compromise...."	I	B-NR
"In patients with HCM and 1 or more of the following risk factors...."	IIa	
a. Maximum LV wall thickness ≥ 30 mm (LOE: B-NR).		B-NR
b. SCD in 1 or more first-degree relatives presumably caused by HCM (LOE: C-LD).		C-LD
c. 1 or more episodes of unexplained syncope within the preceding 6 months (LOE: C-LD)"		C-LD
"In patients with HCM who have spontaneous NSVT (LOE: C-LD) or an abnormal blood pressure response with exercise (LOE: B-NR), who also have additional SCD risk modifiers or high risk features..."	IIa	B-NR C-LD
"In patients with HCM who have NSVT (LOE: B-NR) or an abnormal blood pressure response with exercise (LOE: B-NR) but do not have any other SCD risk modifiers, an ICD may be considered, but its benefit is uncertain."	IIb	B-NR B-NR
"In patients with an identified HCM genotype in the absence of SCD risk factors, an ICD should not be implanted"	III ^a	B-NR

COR: class of recommendation; HCM: hypertrophic cardiomyopathy; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LV: left ventricular; NSVT: nonsustained ventricular tachycardia; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VF: ventricular fibrillation; VT: ventricular tachycardia.

^a No benefit.

Table 10. Guidelines on Use of ICDs for Other Conditions

Recommendation	COR	LOE
"In patients with HFREF who are awaiting heart transplant and who otherwise would not qualify for an ICD (e.g., NYHA class IV and/or use of inotropes) with a plan to discharge home, an ICD is reasonable"	IIa	B-NR
"In patients with an LVAD and sustained VA, an ICD can be beneficial."	IIa	C-LD
"In patients with a heart transplant and severe allograft vasculopathy with LV dysfunction...."	IIb	B-NR
"In patients with neuromuscular disorders, primary and secondary prevention ICDs are recommended for the same indications as for patients with NICM...."	I	B-NR
In patients with a cardiac channelopathy (see Guideline Tables 7.9 and 7.9.1)	I	B-NR
In patients with catecholaminergic polymorphic ventricular tachycardia and recurrent sustained VT or syncope (see Guideline Table 7.9.1.2)	I	B-NR
"In patients with Brugada syndrome with spontaneous type 1 Brugada electrocardiographic pattern and cardiac arrest, sustained VA or a recent history of syncope presumed due to VA...."	I	B-NR
"In patients with early repolarization pattern on ECG and cardiac arrest or sustained VA...."	I	B-NR
"In patients resuscitated from SCA due to idiopathic polymorphic VT or VF...."	I	B-NR
"For older patients and those with significant comorbidities, who meet indications for a primary prevention ICD, an ICD is reasonable."	IIa	B-NR
"In patients with adult congenital heart disease with SCA due to VT or VF in the absence of reversible causes...."	I	B-NR
"In patients with repaired moderate or severe complexity adult congenital heart disease with unexplained syncope and at least moderate ventricular dysfunction or marked hypertrophy, either ICD implantation or an electrophysiological study with ICD implantation for inducible sustained VA is reasonable...."	IIa	B-NR

COR: class of recommendation; ECG: electrocardiogram; HFREF: heart failure with reduced ejection fraction; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LV: left ventricle; LVAD: left ventricular assist device; LVEF: left ventricular ejection fraction; NICM: nonischemic cardiomyopathy; NYHA: New York Heart Association; SCA: sudden cardiac arrest; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.

Table 11. Guidelines on Use of Subcutaneous ICDs

Recommendation	COR	LOE
"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."	I	B-NR
"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."	IIa	B-NR
"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."	III ^a	B-NR

CRT: cardiac resynchronization therapy; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; VT: ventricular tachycardia.

^a Harm.

The 2013 update made the following recommendations on ICD therapy for children (see Table 12).⁸⁷

Table 12. Guidelines on ICD Therapy for Children

Recommendation	COR	LOE
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.	I	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.	I	C
ICD implantation is reasonable for patients with congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study.	IIa	B
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.	IIb	C

Recommendation	COR	LOE
All class III recommendations found in Section 3, "Indications for Implantable Cardioverter-Defibrillator Therapy," apply to pediatric patients and patients with congenital heart disease, and ICD implantation is not indicated in these patient populations.	III ^a	C

COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; VT: ventricular tachycardia.
^a Not recommended.

ICD Therapy in Patients Not Well Represented in Clinical Trials

The HRS, ACC, and AHA (2014) published an expert consensus statement on the use of ICD therapy for patients not included or poorly represented in ICD clinical trials.⁸⁹ The statement presented a number of consensus-based guidelines on the use of ICDs in select patient populations.

American Heart Association

AHA (2010) issued a scientific statement, endorsed by HRS, on cardiovascular implantable electronic device infections and their management.⁹⁰ This statement made the following recommendations on the removal of device-related infections (see Table 13).

Table 13. Guidelines on the Management of CIED Infections

Recommendation	COR	LOE
Complete device and lead removal is recommended for all patients with definite CIED infection, as evidenced by valvular and/or lead endocarditis or sepsis.	I	A
Complete device and lead removal is recommended for all patients with CIED pocket infection as evidenced by abscess formation, device erosion, skin adherence, or chronic draining sinus without clinically evident involvement of the transvenous portion of the lead system.	I	B
Complete device and lead removal is recommended for all patients with valvular endocarditis without definite involvement of the lead(s) and/or device.	I	B
Complete device and lead removal is recommended for patients with occult staphylococcal bacteremia.	I	B

CIED: cardiovascular implantable electronic device; COR: class of recommendation; LOE: level of evidence.

European Society of Cardiology

The European Society of Cardiology (2015) and endorsed by the Association for European Paediatric and Congenital Cardiology, issued guidelines on the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death.⁹¹ These guidelines make the following statements on use of device-based therapy for ventricular arrhythmia and prevention of sudden cardiac death (see Table 14).

Table 14. Guidelines on the Management of Ventricular Arrhythmia and Sudden Cardiac Death

Recommendation	COR	LOE
"ICD implantation is recommended in patients with documented VF or haemodynamically not tolerated VT in the absence of reversible causes or within 48 h after myocardial infarction who are receiving chronic optimal medical therapy and have a reasonable expectation of survival with a good functional status >1 year."	I	A
"ICD implantation should be considered in patients with recurrent sustained VT (not within 48 h after myocardial infarction) who are receiving chronic optimal medical therapy, have a normal LVEF and have a reasonable expectation of survival with good functional status for > 1 year."	IIa	C
"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."	IIa	C
"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."	IIb	C

COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; VF: ventricular fibrillation; VT: ventricular tachycardia.

Heart Rhythm Society et al

HRS, the European Heart Rhythm Association, and the Asia-Pacific Heart Rhythm Society (2013) issued a consensus statement on the diagnosis and management of patients with inherited primary arrhythmia syndromes, which included recommendations on ICD use in patients with long QT syndrome, Brugada syndrome, catecholaminergic polymorphic ventricular tachycardia, and short QT syndrome (see Table 15).⁹²

Table 15. Guidelines on the Diagnosis and Management of Inherited Primary Arrhythmia Syndromes

Recommendation	COR
Long QT syndrome	
ICD implantation is recommended for patients with a diagnosis of LQTS who are survivors of a cardiac arrest	I
ICD implantation can be useful in patients with a diagnosis of LQTS who experience recurrent syncope events while on beta-blocker therapy	IIa
Except under special circumstances, ICD implantation is not indicated in asymptomatic LQTS patients who have not been tried on beta-blocker therapy	III ^a
Brugada syndrome	
ICD implantation is recommended in patients with a diagnosis of BrS who: Are survivors of a cardiac arrest and/or Have documented spontaneous sustained VT with or without syncope.	I
ICD implantation can be useful in patients with a spontaneous diagnostic type I ECG who have a history of syncope judged to be likely caused by ventricular arrhythmias.	IIa
ICD implantation may be considered in patients with a diagnosis of BrS who develop VF during programmed electrical stimulation (inducible patients).	IIb
ICD implantation is not indicated in asymptomatic BrS patients with a drug-induced type I ECG and on the basis of a family history of SCD alone.	III ^a
Catecholaminergic polymorphic ventricular tachycardia	
ICD implantation is recommended for patients with a diagnosis of CPVT who experience cardiac arrest, recurrent syncope or polymorphic/bidirectional VT despite optimal medical management, and/or left cardiac sympathetic denervation.	I
ICD as a standalone therapy is not indicated in an asymptomatic patient with a diagnosis of CPVT	III ^a
Short QT syndrome	
ICD implantation is recommended in symptomatic patients with a diagnosis of SQTS who: Are survivors of cardiac arrest and/or Have documented spontaneous VT with or without syncope.	I
ICD implantation may be considered in asymptomatic patients with a diagnosis of SQTS and a family history of sudden cardiac death.	IIb

BrS: Brugada syndrome; COR: class of recommendation; CPVT: catecholaminergic polymorphic ventricular tachycardia; ECG: electrocardiogram; ICD: implantable cardioverter defibrillator; LQTS: long QT syndrome; SCD: sudden cardiac death; SQTS: short QT syndrome; VF: ventricular fibrillation; VT: ventricular tachycardia.

^a Not recommended.

Pediatric and Congenital Electrophysiology Society and Heart Rhythm Society

The Pediatric and Congenital Electrophysiology Society and HRS (2014) issued an expert consensus statement on the recognition and management of arrhythmias in adult congenital heart disease. The statement made the following recommendations on the use of ICD therapy in adults with congenital heart disease (see Table 16).⁹³

Table 16. Guidelines on the Management of CHD

Recommendation	COR	LOE
ICD therapy is indicated in adults with CHD who are survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable ventricular tachycardia after evaluation to define the cause of the event and exclude any completely reversible etiology.	I	B
ICD therapy is indicated in adults with CHD and spontaneous sustained ventricular tachycardia who have undergone hemodynamic and electrophysiologic evaluation.	I	B
ICD therapy is indicated in adults with CHD and a systemic left ventricular ejection fraction <35%, biventricular physiology, and NYHA class II or III symptoms.	I	B

Recommendation	COR	LOE
ICD therapy is reasonable in selected adults with tetralogy of Fallot and multiple risk factors for sudden cardiac death, such as left ventricular systolic or diastolic dysfunction, nonsustained ventricular tachycardia, QRS duration >180 ms, extensive right ventricular scarring, or inducible sustained ventricular tachycardia at electrophysiologic study.	IIa	B
ICD therapy may be reasonable in adults with a single or systemic right ventricular ejection fraction <35%, particularly in the presence of additional risk factors such as complex ventricular arrhythmias, unexplained syncope, NYHA functional class II or III symptoms, QRS duration >140 ms, or severe systemic AV valve regurgitation.	IIb	C
ICD therapy may be considered in adults with CHD and a systemic ventricular ejection fraction <35% in the absence of overt symptoms (NYHA class I) or other known risk factors.	Ib	C
ICD therapy may be considered in adults with CHD and syncope of unknown origin with hemodynamically significant sustained ventricular tachycardia or fibrillation inducible at electrophysiologic study.	Ib	B
ICD therapy may be considered for nonhospitalized adults with CHD awaiting heart transplantation.	Ib	C
ICD therapy may be considered for adults with syncope and moderate or complex CHD in whom there is a high clinical suspicion of ventricular arrhythmia and in whom thorough invasive and noninvasive investigations have failed to define a cause.	Ib	C
Adults with CHD and advanced pulmonary vascular disease (Eisenmenger syndrome) are generally not considered candidates for ICD therapy.	III ^a	
Endocardial leads are generally avoided in adults with CHD and intracardiac shunts. Risk assessment regarding hemodynamic circumstances, concomitant anticoagulation, shunt closure prior to endocardial lead placement, or alternative approaches for lead access should be individualized.	III ^a	

AV: arteriovenous; CHD: coronary heart disease; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; NYHA: New York Heart Association.

^a Not recommended.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2014) published guidance on ICDs and cardiac resynchronization therapy for arrhythmias and heart failure.⁹⁴ The guidance made the following evidence-based recommendations:

“Implantable cardioverter defibrillators (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.”

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 17.

Table 14. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02121158	Efficacy and Safety of ICD Implantation in the Elderly	100	Aug 2019
NCT01296022 ^a	A PRospective, rAndomizEd Comparison of subcuTaneOus and tRansvenous ImplANtable Cardioverter Defibrillator Therapy (PRAETORIAN)	850	Dec 2019
NCT00673842 ^a	Efficacy of Implantable Defibrillator Therapy After a Myocardial Infarction (REFINE-ICD)	1000	Dec 2021
NCT02845531	Implantable Cardioverter Defibrillator Versus Optimal Medical Therapy In Patients With Variant Angina Manifesting as Aborted Sudden Cardiac Death (VARIANT ICD)	140	Jun 2023

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.**CODING**

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

- 33216 Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
- 33217 Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
- 33218 Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator
- 33220 Repair of 2 transvenous electrodes for permanent pacemaker or implantable defibrillator
- 33223 Relocation of skin pocket for implantable defibrillator
- 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 electrode(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 of 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

- 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
- 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
- 93282 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; single lead transvenous implantable defibrillator system
- 93283 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; dual lead transvenous implantable defibrillator system
- 93284 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; multiple lead transvenous implantable defibrillator system
- 93289 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; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements
- 93640 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement;
- 93641 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator
- 93642 Electrophysiologic evaluation of single or dual chamber transvenous pacing cardioverter-defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

- 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)
- C1721 Cardioverter-defibrillator, dual chamber (implantable)
- C1722 Cardioverter-defibrillator, single chamber (implantable)
- C1882 Cardioverter-defibrillator, other than single or dual chamber (implantable)
- C1895 Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
- C1896 Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
- C1899 Lead, pacemaker/cardioverter-defibrillator combination (implantable)

ICD-10 Diagnoses

- I42.1 Obstructive hypertrophic cardiomyopathy
- I42.2 Other hypertrophic cardiomyopathy
- I42.8 Other cardiomyopathies
- I45.89 Other specified conduction disorders
- I46.2 Cardiac arrest due to underlying cardiac condition
- I46.8 Cardiac arrest due to other underlying condition
- I46.9 Cardiac arrest, cause unspecified
- I45.81 Long QT syndrome
- I47.2 Ventricular tachycardia
- I49.01 Ventricular fibrillation
- I49.9 Cardiac arrhythmia, unspecified
- Q20.0 Common arterial trunk
- Q20.1 Double outlet right ventricle
- Q20.2 Double outlet left ventricle
- Q20.3 Discordant ventriculoarterial connection
- Q20.4 Double inlet ventricle
- Q20.5 Discordant atrioventricular connection
- Q20.6 Isomerism of atrial appendages
- Q20.8 Other congenital malformations of cardiac chambers and connections
- Q20.9 Congenital malformation of cardiac chambers and connections, unspecified
- Q21.0 Ventricular septal defect
- Q21.1 Atrial septal defect
- Q21.2 Atrioventricular septal defect
- Q21.3 Tetralogy of Fallot
- Q21.4 Aortopulmonary septal defect
- Q21.8 Other congenital malformations of cardiac septa
- Q22.0 Pulmonary valve atresia
- Q22.1 Congenital pulmonary valve stenosis
- Q22.2 Congenital pulmonary valve insufficiency
- Q22.3 Other congenital malformations of pulmonary valve
- Q22.4 Congenital tricuspid stenosis
- Q22.5 Ebstein's anomaly
- Q22.6 Hypoplastic right heart syndrome
- Q22.8 Other congenital malformations of tricuspid valve
- Q23.0 Congenital stenosis of aortic valve
- Q23.1 Congenital insufficiency of aortic valve

Q23.2	Congenital mitral stenosis
Q23.3	Congenital mitral insufficiency
Q23.4	Hypoplastic left heart syndrome
Q23.8	Other congenital malformations of aortic and mitral valves
Q24.0	Dextrocardia
Q24.1	Levocardia
Q24.2	Cor triatriatum
Q24.3	Pulmonary infundibular stenosis
Q24.4	Congenital subaortic stenosis
Q24.5	Malformation of coronary vessels
Q24.6	Congenital heart block
Q24.8	Other specified congenital malformations of heart
Q24.9	Congenital malformation of heart, unspecified

REVISIONS

04-22-2011	<p>Description section updated</p> <p>In Policy section:</p> <ul style="list-style-type: none"> Clarified wording for C. Automatic External Defibrillators for Home Use <p>From: "The use of automatic external defibrillators by lay persons is considered experimental and investigational because they have not been proven to reduce mortality compared to implantable cardioverter defibrillators or cardiopulmonary resuscitation by first responders.</p> <p>The coverage of automatic external defibrillators used by lay persons is an exclusion of the member's contract."</p> <p>To: "The purchase or rental of an automated external defibrillator is an exclusion of the member's contract."</p> <ul style="list-style-type: none"> There is no change in the policy intent. <p>In Coding section:</p> <ul style="list-style-type: none"> Removed CPT code: 33222 <p>Rationale section added</p> <p>References updated</p>
02-01-2012	<p>In Policy section:</p> <ul style="list-style-type: none"> In A 7 removed the word "documented" to read, "Ischemic dilated cardiomyopathy (IDCM) with NYHA Class II or III heart failure, prior myocardial infarction (MI), at least 40 days post MI, and measured left ventricular ejection fraction (LVEF) less than or equal to 35%;" In B 1 added <p>"b. ischemic dilated cardiomyopathy; or</p> <p>c. non-ischemic dilated cardiomyopathy with NYHA Class II or III heart failure and left ventricular ejection fraction (LVEF) less than or equal to 35%"</p> <ul style="list-style-type: none"> In B 2 removed the following indications: <p>"a. Patients with a history of an acute myocardial infarction (MI) within the last 40 days</p> <p>b. Patients with drug-refractory class IV congestive heart failure (CHF) who are not candidates for heart transplantation</p> <p>c. Patients with a history of psychiatric disorders that interfere with the necessary care and follow-up</p> <p>d. Patients in whom a reversible triggering factor for VT/VF can be definitely identified, such as ventricular tachyarrhythmias in evolving acute myocardial infarction or electrolyte abnormalities</p> <p>e. Patients with terminal illnesses"</p> <p>In Coding section:</p>

	<ul style="list-style-type: none"> ▪ Revised CPT nomenclature (effective 01/01/12): 33218, 33220, 33224, 33225, 33226, 33240, 33241, 33249 ▪ Added CPT codes (effective 01/01/12): 33230, 33231, 33262, 33263, 33264 ▪ Added Diagnosis codes: 411.0, 412, 414.00-414.07, 425.11, 425.18, 426.82, 745.0-745.9, 746.0-746.9
04-08-2013	<p>Updated Description section</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Updated Implantable Cardioverter-Defibrillators (ICD) policy wording to the current wording from: "A. Implantable Cardioverter-Defibrillators The use of an implantable cardioverter-defibrillator is considered medically necessary for the treatment of ventricular tachyarrhythmias and for the prevention of sudden cardiac death when one of the following indications is present: 1. History of cardiac arrest due to ventricular fibrillation (VF) or ventricular tachycardia (VT) and which is not due to reversible or transient causes; or 2. Spontaneous sustained VT, in patients with structural heart disease; or 3. Spontaneous sustained VT, in patients without structural heart disease, that is not amenable to other treatments; or 4. Syncope of undetermined origin with clinically relevant, hemodynamically significant, sustained VT or VF induced at electrophysiological study when drug therapy is ineffective, not tolerated, or not preferred; or 5. Familial or inherited conditions with a high risk for life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy; or 6. Previous myocardial infarction and coronary artery disease (CAD), at least 40 days post myocardial infarction and three months post coronary artery revascularization surgery with an ejection fraction equal to or less than 35% after maximal medical therapy; or 7. Ischemic dilated cardiomyopathy (IDCM) with NYHA Class II or III heart failure, prior myocardial infarction (MI), at least 40 days post MI, and measured left ventricular ejection fraction (LVEF) less than or equal to 35%; or 8. Non-ischemic dilated cardiomyopathy (NIDCM) of greater than 9 months duration along with, NYHA Class II or III heart failure, and measured LVEF less than or equal to 35%." ▪ Added indication for Subcutaneous ICD as experimental / investigational to read, "The use of a subcutaneous ICD is considered experimental / investigational for all indications in adult and pediatric patients." ▪ Updated Wearable Cardioverter-Defibrillators policy wording to the current wording from: "B. Wearable Cardioverter Defibrillators (WCD) 1. The wearable cardioverter defibrillator is considered medically necessary for patients at high-risk of sudden cardiac arrest, who meet the following criteria: a. Patients must meet the medical necessity criteria for an implantable cardioverter defibrillator (ICD); or b. ischemic dilated cardiomyopathy; or c. non-ischemic dilated cardiomyopathy with NYHA Class II or III heart failure and left ventricular ejection fraction (LVEF) less than or equal to 35% AND d. Patients must have ONE of the following documented medical contraindications to ICD implantation: 1) Patients awaiting a heart transplantation - on waiting list and meets medical necessity criteria for heart transplantation; or 2) Patients with a previously implanted ICD that requires explantation due to infection with waiting period before ICD reinsertion; or 3) Patients with an infectious process or other temporary condition that precludes initial implantation of an ICD. 2. The wearable cardioverter defibrillator is considered not medically necessary for all other indications." <p>Updated Rationale section</p>

	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added CPT codes: 0319T, 0320T, 0321T, 0322T, 0323T, 0324T, 0325T, 0326T, 0327T, 0328T (effective 01-01-2013) ▪ Removed CPT codes: 33202, 33203, 33226 as these codes were determined to be not applicable to this policy. ▪ Updated nomenclature for CPT codes: 33218, 93292, 93745 <p>Removed Revision details from the 08-3-2010 revision.</p> <p>Updated References</p>
01-01-2014	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Revised nomenclature for CPT code: 33223 (Eff 01-01-2014) ▪ Added ICD-10 codes.
01-01-2015	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added CPT Codes: 33270, 33271, 33272, 33273, 93260, 93261, 93644 (Effective January 1, 2015) ▪ Deleted CPT Codes: 0319T, 0320T, 0321T, 0322T, 0323T, 0324T, 0325T, 0326T, 0327T, 0328T (Effective January 1, 2015)
05-01-2016	<p>Policy title revised from "Cardioverter-Defibrillators." Policy separated into "Implantable Cardioverter Defibrillators" and "Wearable Cardioverter Defibrillators."</p> <p>Updated Description section.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ In Item I, removed "Implantable Cardioverter-Defibrillators (ICD)" and added "Adults." ▪ In Item I A, removed "one of" to read "The use of the automatic implantable cardioverter defibrillator (ICD) may be considered medically necessary in adults who meet the following criteria:" ▪ Added Item I A 1. Previous numbered items are now alpha. ▪ In Item I A 1 a, removed "no" and "for" and added "New York Heart Association (NYHA) functional class II or class III symptoms" and "a". ▪ Added Item I A 1 b. ▪ In Item I A 1 d, added "(history of premature HCM-related sudden death in 1 or more first degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin)" and "by a physician experienced in the care of patients with HCM." ▪ Added Item I A 1 e. ▪ Removed previous Item I A 4. ▪ Item I A 2 includes "after reversible causes (eg, acute ischemia) have been excluded. ▪ Added Item I C. ▪ Added Section II. ▪ In Section III, revised subcutaneous ICD from experimental / investigational to medically necessary with criteria. ▪ Removed information regarding Wearable Cardioverter-Defibrillators and Automatic External Defibrillators for Home Use. ▪ Added Policy Guidelines. <p>Updated Rationale section.</p> <p>Updated References section.</p>
11-09-2016	<p>Updated Description section.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ In Item I A 1 d, added "or arrhythmogenic right ventricular cardiomyopathy" and "cardiomyopathy" and removed "HCM" to read, "Hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter

	<p>monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with cardiomyopathy."</p> <ul style="list-style-type: none"> ▪ In Item II A 4, added "or arrhythmogenic right ventricular cardiomyopathy" and "cardiomyopathy" and removed "HCM" to read, "Hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with cardiomyopathy."
	Updated Rationale section.
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Corrected nomenclature to CPT code 33273. ▪ Removed CPT/HCPCS codes: 00534, 33224, 33225, 93287, 93295, 93296, C1777, C1895, C1896, C1899. ▪ Removed ICD-10 codes: I24.1, I25.10, I25.110, I25.111, I25.118, I25.2, I25.710, I25.711, I25.718, I25.720, I25.721, I25.728, I25.730, I25.731, I25.738, I25.750, I25.751, I25.758, I25.760, I25.761, I25.768, I25.791, I25.798, I25.810, I25.811, I25.812, I42.0, I42.5, I47.0, I49.02. ▪ Added ICD-10 codes: I45.89, I46.2, I46.8, I46.9.
	Updated References section.
07-11-2017	Updated Description section.
	<p>In Policy Section:</p> <ul style="list-style-type: none"> ▪ In Item III A 1 b, added "younger patient with anticipated long-term need for ICD therapy" to read, "compelling reason to preserve existing vascular access (ie, need for chronic dialysis; younger patient with anticipated long-term need for ICD therapy);" ▪ In Policy Guidelines, updates made to items 2 and 3 b.
	Updated Rationale section.
	Updated References section.
07-18-2018	Updated Description section.
	Updated Rationale section.
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added HCPCS codes: C1895, C1896, C1899. ▪ Removed ICD-9 codes.
	Updated References section.

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