LifeWise
Health Plan of Washington

MEDICAL POLICY – 7.01.44
Implantable Cardioverter-Defibrillator (ICD)

BCBSA Ref. Policy:	7.01.44	
Effective Date:	Aug 1, 2026	RELATED MEDICAL POLICIES:
Last Revised:	Jul. 27, 2026	2.02.506 Wearable Cardioverter-Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator Placement
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

Sudden cardiac arrest is when the heart stops beating. It can cause death within minutes if not treated. An implantable cardioverter defibrillator (ICD) is a device designed to monitor heart rate, and deliver an electric shock in the event of life threatening ventricular arrhythmias, such as ventricular tachycardia or ventricular fibrillation. ICDs are typically indicated for patients at high risk of sudden cardiac death due to underlying structural heart disease, or a history of prior cardiac arrest. ICDs may be implanted transvenously, with leads placed inside the heart, or subcutaneously, with the entire system positioned beneath the skin without intravascular access. This policy describes when an automatic or subcutaneous ICDs may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Medical Necessity
Automatic Implantable Cardioverter Defibrillator (ICD) - Adults	**The use of the automatic implantable cardioverter defibrillator (ICD) may be considered medically necessary in individuals aged 18 years of age or older who meet any one of the following criteria:** • **Primary prevention**: ○ Ischemic cardiomyopathy and all of the below criteria: ▪ New York Heart Association (NYHA) functional class II or III symptoms ▪ Myocardial infarction (MI) at least 40 days before ICD treatment ▪ Left ventricular ejection fraction (LVEF) of 35% or less **OR** ○ Ischemic cardiomyopathy and all of the below criteria: ▪ NYHA functional class I symptoms ▪ MI at least 40 days before ICD treatment ▪ LVEF of 30% or less **OR** ○ Nonischemic dilated cardiomyopathy and LVEF of 35% or less, after reversible causes have been excluded, and medical therapy has been optimized **OR** ○ Hypertrophic cardiomyopathy (HCM) with 1 or more of the following 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 ▪ One or more runs of non-sustained ventricular tachycardia at heart rates of greater or equal to 120 beats per minute on 24-hour Holter monitoring ▪ Prior unexplained syncope inconsistent with neurocardiogenic origin **OR** ○ Diagnosis of any 1 of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death (see **Related Coverage Indications**): ▪ Congenital long QT syndrome; or ▪ Brugada syndrome; or

Device	Medical Necessity
	▪ Short QT syndrome; or ▪ Catecholaminergic polymorphic ventricular tachycardia **OR** ○ Diagnosis of cardiac sarcoid and considered to be at high risk for sudden cardiac death (see **Related Coverage Indications**). **OR** • **Secondary prevention**: ○ Individuals with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes (e.g., acute ischemia) have been excluded. **The use of an ICD is considered investigational for all other indications in individuals aged 18 years and older.**
Automatic Implantable Cardioverter Defibrillator (ICD) - Pediatrics	**The use of the ICD may be considered medically necessary in individuals aged less than 18 years who meet any of the following criteria:** • Arrhythmogenic cardiomyopathy in individuals who are survivors of sudden cardiac arrest or sustained ventricular tachycardia that is not hemodynamically tolerated; • Brugada syndrome in individuals who are survivors of sudden cardiac arrest or have documented spontaneous sustained ventricular tachycardia; • Catecholaminergic polymorphic ventricular tachycardia in individuals who experience cardiac arrest despite maximally tolerated beta-blockers, flecainide, or cardiac sympathetic denervation; • Congenital heart disease in individuals who are survivors of sudden cardiac arrest, after reversible causes have been excluded; • Hypertrophic cardiomyopathy in individuals who are survivors of sudden cardiac arrest or have documented spontaneous sustained ventricular tachycardia; • Long QT syndrome in individuals who are survivors of sudden cardiac arrest (in combination with beta-blockers);

Device	Medical Necessity
	• Long QT syndrome in individuals who cannot take beta-blockers and for whom cardiac sympathetic denervation or other medications are not considered appropriate; • Nonischemic dilated cardiomyopathy in individuals who are survivors of sudden cardiac arrest or have documented spontaneous sustained ventricular tachycardia that is not due to completely reversible causes; • Survivors of cardiac arrest due to ventricular tachycardia or ventricular fibrillation, after reversible causes have been excluded; • Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in individuals who have undergone hemodynamic and electrophysiologic evaluation **The use of an ICD is considered investigational for all other indications in individuals aged less than 18 years.**

Subcutaneous Implantable Cardioverter Defibrillator	**The use of a subcutaneous ICD may be considered medically necessary for individuals of any age who have an indication for ICD implantation for any of the above reasons and meet all of the following criteria:**
	• Have a contraindication to a transvenous ICD due to 1 or more of the following:
	  ○ Lack of adequate vascular access
	  ○ There exists a compelling reason to preserve existing vascular access (i.e., need for chronic dialysis; younger individual with anticipated long-term need for ICD therapy)
	  ○ History of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy;
	• Have no indication for anti-bradycardia pacing;
	• Do not have ventricular arrhythmias known or anticipated to respond to anti-tachycardia pacing.
	
	The use of a subcutaneous ICD is considered investigational for individuals who do not meet the criteria outlined above.

Device	Investigational
Extravascular Implantable Cardioverter Defibrillator	**The use of an extravascular ICD is considered investigational.**

Related Coverage Indications

Criteria for ICD Implantation in Individuals with Cardiac Ion Channelopathies

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.

Criteria for ICD placement in individuals with cardiac ion channelopathies derive from results of clinical input, a 2013 consensus statement from the Heart Rhythm Society (HRS), European Heart Rhythm Association (EHRA), and the Asia-Pacific Heart Rhythm Society on the diagnosis and management of individuals with inherited primary arrhythmia syndromes, and a report from the HRS and EHRA's Second Consensus Conference on Brugada syndrome.

Indications for consideration for ICD placement for each cardiac ion channelopathy are as follows:

- Long QT syndrome (LQTS):
  - Individuals with a diagnosis of LQTS who are survivors of cardiac arrest;
  - Individuals with a diagnosis of LQTS who experience recurrent syncopal events while on β-blocker therapy.
- Brugada syndrome (BrS):
  - Individuals with a diagnosis of BrS who are survivors of cardiac arrest;
  - Individuals with a diagnosis of BrS who have documented spontaneous sustained ventricular tachycardia (VT) with or without syncope;
  - Individuals with a spontaneous diagnostic type 1 electrocardiogram (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);
  - Individuals with a diagnosis of BrS who develop ventricular fibrillation during programmed electrical stimulation.
- Catecholaminergic polymorphic ventricular tachycardia (CPVT):
  - Individuals with a diagnosis of CPVT who are survivors of cardiac arrest;

Related Coverage Indications

- Individuals with a diagnosis of CPVT who experience recurrent syncope or polymorphic/bidirectional VT despite optimal medical management, and/or left cardiac sympathetic denervation.

- Short QT syndrome (SQTS):
  - Individuals with a diagnosis of SQTS who are survivors of cardiac arrest;
  - Individuals with a diagnosis of SQTS who are symptomatic and have documented spontaneous VT with or without syncope;
  - Individuals with a diagnosis of SQTS who are asymptomatic or symptomatic and have a family history of sudden cardiac death.

NOTE: For congenital LQTS, individuals may have 1 or more clinical or historical findings other than those outlined above that could, alone or in combination, put them at higher risk for sudden cardiac death. They can include individuals with a family history of sudden cardiac death due to LQTS, infants with a diagnosis of LQTS with functional 2:1 atrioventricular block, individuals with a diagnosis of LQTS in conjunction with a diagnosis of Jervell and Lange-Nielsen syndrome or Timothy syndrome, and individuals 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 when considering the need for ICD placement.

Criteria for ICD Implantation in Individuals with Cardiac Sarcoid

Criteria for ICD placement in individuals with cardiac sarcoid derive from a 2014 consensus statement from the HRS and 2017 joint guidelines from the American Heart Association, American College of Cardiology, and HRS.

Indications for consideration of ICD placement in individuals diagnosed with cardiac sarcoid are as follows:

- Spontaneous sustained ventricular arrhythmias, including prior cardiac arrest, if meaningful survival of greater than 1 year is expected;
- Left ventricular ejection fraction (LVEF) 35% or less, despite optimal medical therapy and a period of immunosuppression (if there is active inflammation), if meaningful survival of greater than 1 year is expected;
- LVEF greater than 35%, if meaningful survival of greater than 1 year is expected; AND
  - Syncope or near-syncope, felt to be arrhythmic in etiology; OR
  - Evidence of myocardial scar by cardiac magnetic resonance imaging (MRI) or positron emission tomographic (PET) scan; OR
  - Inducible sustained ventricular arrhythmias (>30 seconds of monomorphic VT or polymorphic VT) or clinically relevant ventricular fibrillation.

Related Coverage Indications

- An indication for permanent pacemaker implantation.

Documentation Requirements

The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain the relevant history and physical

Coding

Code	Description
CPT	
0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed
0572T	Insertion of substernal implantable defibrillator electrode
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or 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
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
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
93287	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and

Code	Description
	report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system
HCPCS	
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single 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)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

This policy addresses the use of implantable cardioverter defibrillator (ICD) devices as stand-alone interventions, not as combination devices to treat heart failure (i.e., cardiac resynchronization devices) or in combination with pacemakers. Unless specified, the policy statements and rationale refer to transvenous ICDs.

Indications for pediatric ICD use are based on the 2021 Pediatric and Congenital Electrophysiology Society and Heart Rhythm Society (HRS) guidance on ICDs in children.[1]

Consideration of Age

The potential indications for use of an ICD vary widely depending on the age of the individual. The criteria for individuals less than 18 years of age reflect those differences and are based on scientific evidence and current guidelines for treatment.

Evidence Review

Description

An implantable cardioverter defibrillator (ICD) is a device designed to monitor an individual'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 ICD (S-ICD), which lacks transvenous leads, is intended to reduce lead-related complications.

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 ischemic cardiomyopathy, particularly when associated with reduced left ventricular ejection fraction (LVEF) and prior myocardial infarction (MI); 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 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, i.e., use in patients who have experienced a potentially life-threatening episode of VT (near SCD); and (2) primary prevention, i.e., use in patients who are considered at high risk for SCD but who have not yet experienced life-threatening VT or ventricular fibrillation.

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 ventricular fibrillation shock when a malignant arrhythmia is recognized.

A subcutaneous ICD (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 US Food and Drug Administration (FDA) through the premarket approval (PMA) process. The 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. Also, devices typically have approval in the secondary prevention setting for patients with previous MI and reduced ejection fraction.

Summary of Evidence

Transvenous Implantable Cardioverter Defibrillators

For individuals who have a high risk of sudden cardiac death (SCD) due to ischemic or nonischemic cardiomyopathy in adulthood who receive transvenous implantable cardioverter defibrillator (T-ICD) placement for primary prevention, the evidence includes multiple well-designed and well-conducted randomized controlled trials (RCTs) as well as systematic reviews of these trials. Relevant outcomes are overall survival (OS), 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. Randomized controlled trials assessing early implantable cardioverter defibrillator (ICD) use following recent myocardial infarction (MI) did not support a benefit for immediate versus delayed implantation for at least 40 days. For nonischemic cardiomyopathy (NICM), there are less clinical trial data, but pooled estimates of available evidence from RCTs enrolling patients with NICM 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 an improvement in the net health outcome.

For individuals who have a high risk of SCD due to hypertrophic cardiomyopathy (HCM) in adulthood who receive T-ICD placement for primary prevention, the evidence includes several large registry studies. Relevant outcomes are OS, 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 studies are considered adequate evidence to support the use of T-ICDs in patients with HCM. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a high risk of SCD due to an inherited cardiac ion channelopathy who receive T-ICD placement for primary prevention, the evidence includes small cohort studies of patients with these conditions treated with ICDs. Relevant outcomes are OS, 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 studies are considered adequate evidence to support the use of T-ICDs in patients with inherited cardiac ion channelopathy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a high risk of SCD due to cardiac sarcoid who receive T-ICD placement for primary prevention, the evidence includes small cohort studies of patients with cardiac sarcoid treated with ICDs who received appropriate shocks. Studies comparing outcomes between patients treated and untreated with ICDs are not available. However, given the relatively small number of patients with cardiac sarcoid (5% of those with systemic sarcoidosis), clinical trials are unlikely. Given the long-term high risk of SCD in patients with cardiac sarcoid, with the assumption that appropriate shocks are life-saving, these studies are considered adequate evidence to support the use of T-ICDs in patients with cardiac sarcoid who have not responded to optimal medical therapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had symptomatic life-threatening sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) or who have been resuscitated from sudden cardiac arrest (secondary prevention) who receive T-ICD placement, the evidence includes multiple well-designed and well-conducted RCTs as well as systematic reviews of these trials. Relevant outcomes are OS, 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 an improvement in the net health outcome.

Subcutaneous Implantable Cardioverter Defibrillators

For individuals who need an ICD and have a contraindication to a T-ICD but no indications for antibradycardia pacing and no antitachycardia pacing-responsive arrhythmias who receive subcutaneous ICD (S-ICD) placement, the evidence includes an RCT, nonrandomized studies, and case series. Relevant outcomes are OS, morbid events, quality of life, and treatment-related mortality and morbidity. An RCT found that S-ICD significantly decreases the risk of lead-related perioperative complications compared to T-ICD. However, this study was not powered to detect differences in the rates of failed shocks or inappropriate shocks and an extension study is ongoing. Nonrandomized controlled studies have reported success rates in terminating laboratory-induced VF that are similar to T-ICD. Case series have reported high rates of detection and successful conversion of VF, and inappropriate shock rates in the range reported for T-ICD. Given the need for ICD placement in this population at risk for SCD, with the assumption that appropriate shocks are life-saving, these studies are considered adequate evidence to support the use of S-ICDs in patients with contraindication to T-ICD. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who need an ICD and have no indications for antibradycardia pacing or antitachycardia pacing-responsive arrhythmias with no contraindication to a T-ICD, who receive S-ICD placement, the evidence includes one RCT, nonrandomized studies, and case series. Relevant outcomes are OS, morbid events, quality of life, and treatment-related mortality and morbidity. The Prospective, Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy (PRAETORIAN) trial is the only RCT on the effect of an S-ICD with health outcomes. PRAETORIAN found that S-ICD was noninferior to T-ICD on a composite outcome of complications and inappropriate shock at 48 months (hazard ratio [HR], 0.99; 95% confidence interval [CI], 0.71 to 1.39; noninferiority margin, 1.45; p=.01 for noninferiority; p=.95 for superiority). There were more device related complications in the T-ICD group and more inappropriate shocks in the S-ICD group, but the trial was not powered for these endpoints. There is uncertainty over the applicability and interpretation of PRAETORIAN based on the choice of a composite outcome with discordant results, unclear rationale for choice of the noninferiority margin, inadequate length of follow-up to determine rates of complications, and lack of reporting of quality of life data. Eight-year data from the PRAETORIAN-XL trial demonstrated no significant differences in overall device-related complications between groups, although more major and lead-related complications occurred in the T-ICD group. Another important finding was that more patients in the S-ICD group required generator replacements as a result of battery depletion. Comparative observational studies are insufficient to draw conclusions on whether there are small differences in efficacy

between the 2 types of devices and reported variable adverse event rates. Ongoing studies could provide additional evidence on complications and device safety over the longer term. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Extravascular Implantable Cardioverter Defibrillators

For individuals who need an ICD who receive an extravascular ICD (E-ICD), the evidence includes nonrandomized studies. Relevant outcomes are OS, morbid events, quality of life, and treatment-related mortality and morbidity. The largest available studies with an E-ICD reported high rates of defibrillation after implantation and a low rate of major complications, with a numerically similar rate of inappropriate shocks compared to studies with T-ICD and S-ICD. The major limitation of these studies is the lack of an active control group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

In October 2020, the BCBSA Medical Advisory Panel (MAP) reviewed the evidence for individuals who need an ICD and have no contraindication to transvenous ICD placement and agreed that for this indication, the evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some unpublished trials that may influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02845531	Implantable Cardioverter Defibrillator Versus Optimal Medical Therapy In Patients With Variant Angina	140	Jun 2031

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Manifesting as Aborted Sudden Cardiac Death (VARIANT ICD)		
Unpublished			
NCT00673842[a]	Risk Estimation Following Infarction Noninvasive Evaluation - ICD Efficacy	700	Oct 2024
NCT02787785[a]	Multicenter Automatic Defibrillator Implantation Trial With Subcutaneous Implantable Cardioverter Defibrillator (MADIT S-ICD)	40	Jun 2023

NCT: national clinical trial. [a] Denotes industry-sponsored or cosponsored trial.

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.

2020 Medical Advisory Panel

In October 2020, the BCBSA Medical Advisory Panel (MAP) reviewed the evidence for individuals who need an implantable cardioverter defibrillator (ICD) and have no contraindication to transvenous ICD (T-ICD) placement and agreed that for this indication, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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. Input focused on the use of ICDs as primary prevention for cardiac ion channelopathies and use of the subcutaneous ICD (S-ICD). Reviewers generally indicated that an ICD should be considered medically necessary for primary prevention of ventricular arrhythmias in adults and

children with a diagnosis of long QT syndrome, Brugada syndrome, short QT syndrome, and catecholaminergic polymorphic ventricular tachycardia. 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 transvenous ICD lead explantation due to complications.

2011 Input

In response to requests, input was received from 6 academic medical centers while this policy was under review in 2011. For most policy indications, including pediatric, there was general agreement from those providing input. On the question of timing of ICD placement, input was mixed, with some commenting about the potential role of early implantation in select patients. Reviewers indicated that a waiting period of 9 months for patients with nonischemic cardiomyopathy was not supported by the available evidence or consistent with the prevailing practice patterns in academic medical centers. Input emphasized the difficulty of prescribing strict time frames 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

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association/American College of Cardiology et al - Heart Failure (2022)

In 2022, the American Heart Association (AHA), American College of Cardiology (ACC), and the Heart Failure Society of America released a guideline for the management of heart failure.[109] This guideline includes ICD recommendations which are summarized in **Table 2**.

Table 2. Guideline for the Management of Heart Failure - Recommendations for Implantable Cardioverter Defibrillators

Recommendation	COR	LOE
"In patients with nonischemic DCM or ischemic heart disease at least 40 days post-MI with LVEF ≤35% and NYHA class I or II symptoms on chronic GDMT, who have reasonable expectation of meaningful survival for >1 year, ICD therapy is recommended for primary prevention of SCD to reduce total mortality."	1	A
"A transvenous ICD provides high economic value in the primary prevention of SCD particularly when the patient's risk of death caused by ventricular arrhythmia 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."		A
"In patients at least 40 days post-MI with LVEF ≤30% and NYHA class I symptoms while receiving GDMT, who have reasonable expectation of meaningful survival for >1 year, ICD therapy is recommended for primary prevention of SCD to reduce total mortality."	1	B-R
"In patients with genetic arrhythmogenic cardiomyopathy with high-risk features of sudden death, with EF ≤45%, implantation of ICD is reasonable to decrease sudden death."	2a	B-NR
"For patients whose comorbidities or frailty limit survival with good functional capacity to <1 year, ICD and CRT-D are not indicated."	No benefit	C-LD

A: high; B-NR: moderate, non-randomized; B-R: moderate, randomized; C-LD: limited data; COR: class of recommendation; CRT-D: cardiac resynchronization therapy with defibrillation; DCM: dilated cardiomyopathy; EF: ejection fraction; GDMT: guideline-directed management and therapy; ICD: implantable cardioverter defibrillator: LOE: level of evidence; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; SCD: sudden cardiac death.

American Heart Association/American College of Cardiology et al - Hypertrophic Cardiomyopathy (2024)

In 2024, the AHA and ACC published a joint Guideline for the Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy.[110] Recommendations relevant to this review are summarized in **Table 3**.

Table 3. Patient Selection for Implantable Cardioverter Defibrillator Placement in High-Risk Patients With Hypertrophic Cardiomyopathy

Recommendation	COR	LOE
For patients with HCM, and previous documented cardiac arrest or sustained ventricular tachycardia, ICD placement is recommended.	I	B-NR
For adult patients with HCM with 1 or more major risk factors for SCD, it is reasonable to offer an ICD.	2a	B-NR
For children with HCM who have 1 or more conventional risk factors, ICD placement is reasonable after considering the relatively high complication rates of long-term ICD placement in younger patients.	2a	B-NR
For patients 16 years and older with HCM and 1 or more major SCD risk factors, discussion of the estimated 5-year sudden death risk and mortality rates can be useful during the shared decision-making process for ICD placement.	2a	B-NR
In patients with HCM without risk factors, ICD placement should not be performed.	3: Harm	B-NR
In patients with HCM, ICD placement for the sole purpose of participation in competitive athletics should not be performed.	3: Harm	B-NR
In patients with HCM who are receiving an ICD, either a single chamber transvenous ICD or a subcutaneous ICD is recommended after a shared decision-making discussion that takes into consideration patient preferences, lifestyle, and expected potential need for pacing for bradycardia or ventricular tachycardia termination.	I	B-NR

B-NR: moderate, non-randomized; COR: class of recommendation; HCM: hypertrophic cardiomyopathy; ICD: implantable cardioverter defibrillator; LOE: level of evidence; SCD: sudden cardiac death.

American Heart Association/American College of Cardiology et al - Ventricular Arrhythmias and Prevention of Sudden Cardiac Death (2017)

The AHA, ACC, and Heart Rhythm Society (2017) published joint guidelines on the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death.[111] This guideline supersedes the 2008 guideline for device-based therapy of cardiac rhythm abnormalities[112], and the subsequent 2012 focused update.[113] The most up-to-date recommendations on the use of T-ICD devices from the 2017 guidelines are presented in **Tables 4** to **8**. **Table 9** summarizes the most up-to-date recommendations regarding S-ICDs.

Table 4. Recommendations on Use of Implantable Cardioverter Defibrillators as Secondary Prevention of Sudden Cardiac Death of Ischemic Heart Disease or Nonischemic Cardiomyopathy

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 sustained VT (LOE: B-NR) not due to reversible causes, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-R
"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-NR
"In patients with ischemic heart disease and unexplained syncope who have inducible sustained monomorphic VT on electrophysiological study, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-R
"In patients resuscitated from SCA due to coronary artery spasm in whom medical therapy is ineffective or not tolerated, an ICD is reasonable if meaningful survival of greater than 1 year is expected."	IIa	B-NR
"In patients resuscitated from SCA due to coronary artery spasm, an ICD in addition to medical therapy may be reasonable if meaningful survival of greater than 1 year is expected."	IIb	B-NR
"In patients with NICM 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, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	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 if meaningful survival of greater than 1 year is expected."	IIa	B-R
"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%), an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-NR
"In patients with arrhythmogenic right ventricular cardiomyopathy and syncope presumed due to VA, an ICD can be useful if meaningful survival of greater than 1 year is expected."	IIa	B-NR

B-NR: moderate, non-randomized; B-R: moderate, randomized; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; NICM: nonischemic cardiomyopathy; RVEF: right ventricular ejection fraction; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.

Table 5. Recommendations on Use of Implantable Cardioverter Defibrillators as a Primary Prevention of Ischemic Heart Disease or Nonischemic Cardiomyopathy

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, an ICD is recommended if meaningful survival of greater than 1 year is expected."	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, an ICD is recommended if meaningful survival of greater than 1 year is expected."	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
"In patients with NSVT due to prior MI, LVEF of 40% or less and inducible sustained VT or VF at electrophysiological study, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-R
"In nonhospitalized patients with NYHA class IV symptoms who are candidates for cardiac transplantation or an LVAD, an ICD is reasonable if meaningful survival of greater than 1 year is expected."	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."	IIIa	C-EO
"In patients with NICM, HF with NYHA class II-III symptoms and an LVEF of 35% or less, despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	A
"In patients with NICM due to a Lamic A/C mutation who have 2 or more risk factors (NSVT, LVEF <45%, nonmissense mutation, and male sex), an ICD can be beneficial if meaningful survival of greater than 1 year is expected."	IIa	B-NR
"In patients with NICM, HF with NYHA class I symptoms and an LVEF of 35% or less, despite GDMT, an ICD may be considered if meaningful survival of greater than 1 year is expected."	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."	IIIa	C-EO

A: high; B-NR: moderate, non-randomized; B-R: moderate, randomized; C-EO: consensus of expert opinion; CRT: cardiac resynchronization therapy; COR: class of recommendation; 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; MI: myocardial infarction; NICM: nonischemic cardiomyopathy; 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 6. Recommendations on Use of Implantable Cardioverter Defibrillators for Hypertrophic Cardiomyopathy

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, an ICD is recommended if meaningful survival of greater than 1 year is expected"	I	B-NR
"In patients with HCM and 1 or more of the following risk factors, an ICD is reasonable if meaningful survival of greater than 1 year is expected: • Maximum LV wall thickness ≥30 mm (LOE: B-NR). • SCD in 1 or more first-degree relatives presumably caused by HCM (LOE: C-LD). • 1 or more episodes of unexplained syncope within the preceding 6 months (LOE: C-LD)"	IIa	B-NR 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 an ICD is reasonable if meaningful survival of greater than 1 year is expected"	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"	IIIa	B-NR

B-NR: moderate, non-randomized; C-LD: limited data; 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 7. Recommendations on Use of Implantable Cardioverter Defibrillators for Cardiac Sarcoidosis

Recommendation	COR	LOE[c]
"In patients with cardiac sarcoidosis who have sustained VT or are survivors of SCA or have an LVEF of 35% or less, an ICD is recommended, if meaningful survival of greater than 1 year is expected."	I	B-NR
"In patients with cardiac sarcoidosis and LVEF greater than 35% who have syncope and/or evidence of myocardial scar by cardiac MRI or positron emission tomographic (PET) scan, and/or have an indication for permanent pacing, implantation of an ICD is reasonable, provided that meaningful survival of greater than 1 year is expected."	IIa	B-NR

Recommendation	COR	LOE[c]
"In patients with cardiac sarcoidosis and LVEF greater than 35%, it is reasonable to perform an electrophysiological study and to implant an ICD, if sustained VA is inducible, provided that meaningful survival of greater than 1 year is expected."	IIa	C-LD
"In patients with cardiac sarcoidosis who have an indication for permanent pacing, implantation of an ICD can be beneficial."	IIa	C-LD

B-NR: moderate, non-randomized; C-LD: limited data; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; MRI: magnetic resonance imaging; SCA: sudden cardiac arrest; VA: ventricular arrhythmia; VT: ventricular tachycardia.

Table 8. Recommendations on Use of Implantable Cardioverter Defibrillators 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, an ICD may be reasonable if meaningful survival of greater than 1 year is expected."	IIb	B-NR
"In patients with neuromuscular disorders, primary and secondary prevention ICDs are recommended for the same indications as for patients with NICM if meaningful survival of greater than 1 year is expected"	I	B-NR
"In patients with Emery-Dreifuss and limb-girdle type IB muscular dystrophies with progressive cardiac involvement, an ICD is reasonable if meaningful survival of greater than 1 year is expected."	IIa	B-NR
"In patients with myotonic dystrophy type 1 with an indication for a permanent pacemaker, an ICD may be considered to minimize the risk of SCA from VT if meaningful survival of greater than 1 year is expected."	IIb	B-NR
"In patients with a cardiac channelopathy and SCA, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-NR
"In high-risk patients with symptomatic long QT syndrome in whom a beta blocker is ineffective or not tolerated, intensification of therapy with additional medications (guided by consideration of the particular long QT syndrome type), left cardiac sympathetic denervation, and/or an ICD is recommended."	I	B-NR
"In patients with catecholaminergic polymorphic VT and recurrent sustained VT or syncope, while receiving adequate or maximally tolerated beta blocker, treatment intensification with either	I	B-NR

Recommendation	COR	LOE
combination medication therapy, left cardiac sympathetic denervation, and/or an ICD is recommended."		
"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, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-NR
"In patients with early repolarization pattern on ECG and cardiac arrest or sustained VA, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-NR
"In patients with short QT syndrome who have a cardiac arrest or sustained VA, an ICD is recommended if meaningful survival greater than 1 year is expected."	I	B-NR
"In patients resuscitated from SCA due to idiopathic polymorphic VT or VF, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-NR
"For older patients and those with significant comorbidities, who meet indications for a primary prevention ICD, an ICD is reasonable if meaningful survival of greater than 1 year is expected."	IIa	B-NR
"In patients with adult congenital heart disease with SCA due to VT or VF in the absence of reversible causes, an ICD is recommended if meaningful survival of greater than 1 year is expected."	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 if meaningful survival of greater than 1 year is expected."	IIa	B-NR

B-NR: moderate, non-randomized; C-LD: limited data; 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; NICM: nonischemic cardiomyopathy; NYHA: New York Heart Association; SCA: sudden cardiac arrest; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.

Table 9. Recommendations on Use of Subcutaneous Implantable Cardioverter Defibrillators

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

Recommendation	COR	LOE
"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."	IIIa	B-NR

B-NR: moderate, non-randomized; COR: class of recommendation; CRT: cardiac resynchronization therapy; ICD: implantable cardioverter defibrillator; LOE: level of evidence; VT: ventricular tachycardia. [a] Harm.

American Heart Association - Cardiomyopathy in Children (2023)

In 2023, the AHA published a scientific statement on cardiomyopathy in children.[114] The statement recommends a discussion of benefit and risk, including the potential for sudden death and ICD discharges. The criteria for ICD implementation in children are the same as in adults after pediatric-specific risks are taken into account.

Heart Rhythm Society et al - Position Paper (2022)

The Heart Rhythm Society, in conjunction with the European Heart Rhythm Association and the Asia Pacific Heart Rhythm Society published a position paper on several cardiac devices, including S-ICDs.[115] The authors reviewed the available literature and provided practical considerations for appropriate use. There was strong consensus that T-ICDs should be considered in all patients with an indication for preventing sudden cardiac death, and that non-T-ICDs can be considered in patients who do not require active pacing or who require a non-transvenous approach. There was general agreement that a T-ICD or leadless pacemaker could be added to a non-T-ICD if the patient develops a need for cardiac pacing. The position paper mentioned extravascular ICDs but did not provide any formal recommendations regarding their use due to a lack of available data.

Heart Rhythm Society- Arrhythmogenic Cardiomyopathy (2019)

In 2019, the Heart Rhythm Society published a consensus statement on evaluation, risk stratification, and management of arrhythmogenic cardiomyopathy.[116] Recommendations related to ICD risk stratification and placement decisions are shown in **Table 10**.

Table 10. Recommendations on Risk Stratification and Implantable Cardioverter Defibrillator Decisions

Recommendation	COR[1]	LOE[2]
In individuals with ARVC with hemodynamically tolerated sustained VT, an ICD is reasonable.	IIa	B-NR
ICD implantation is reasonable for individuals with ARVC and three major, two major and two minor, or one major and four minor risk factors for ventricular arrhythmia.	IIa	B-NR
ICD implantation may be reasonable for individuals with ARVC and two major, one major and two minor, or four minor risk factors for ventricular arrhythmia.	IIb	B-NR
In individuals with ACM with LVEF 35% or lower and NYHA class II-III symptoms and an expected meaningful survival of greater than 1 year, an ICD is recommended.	I	B-R
In individuals with ACM with LVEF 35% or lower and NYHA class I symptoms and an expected meaningful survival of greater than 1 year, an ICD is reasonable.	IIa	B-R
In individuals with ACM (other than ARVC) and hemodynamically tolerated VT, an ICD is recommended.	I	B-NR
In individuals with phospholamban cardiomyopathy and LVEF <45% or NSVT, an ICD is reasonable.	IIa	B-NR
In individuals with lamin A/C ACM and two or more of the following: LVEF <45%, NSVT, male sex, an ICD is reasonable.	IIa	B-NR
In individuals with FLNC ACM and an LVEF <45%, an ICD is reasonable.	IIa	C-LD
In individuals with lamin A/C ACM and an indication for pacing, an ICD with pacing capabilities is reasonable.	IIa	C-LD

ACM: arrhythmogenic cardiomyopathy; ARVC: arrhythmogenic right ventricular cardiomyopathy; COR: Class of Recommendation; FLNC: filamin-C; ICD: Implantable cardioverter defibrillator; LOE: Level of Evidence; LVEF: left ventricular ejection fraction; NSVT: nonsustained ventricular tachycardia; NYHA: New York Heart Association; VT: ventricular tachycardia. [1] Class I: Strong; Class IIa: Moderate; Class IIb: Weak. 2 B-R: Randomized; B-NR: nonrandomized; C-LD: limited data.

Heart Rhythm Society et al - Inherited Primary Arrhythmia Syndromes (2013)

The Heart Rhythm Society, 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 (**Table 11**).[117]

Table 11. Recommendations on Implantable Cardioverter Defibrillators in 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 syncopal 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.	IIIa
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.	IIIa
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 stand alone therapy is not indicated in an asymptomatic patient with a diagnosis of CPVT.	IIIa
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; HRS: Heart Rhythm Society; 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.

Heart Rhythm Society - Cardiac Sarcoidosis (2014)

In 2014, the Heart Rhythm Society published a consensus statement on the diagnosis and management of arrhythmias associated with cardiac sarcoidosis, including recommendations for ICD implantation in patients with cardiac sarcoidosis (**Table 12**).[38] The writing group concluded that although there are few data specific to ICD use in patients with cardiac sarcoidosis, data from the major primary and secondary prevention ICD trials were relevant to this population and recommendations from the general device guideline documents apply to this population.

Table 12. Recommendations for Implantable Cardioverter Defibrillator Implantation in Patients with Cardiac Sarcoidosis

Recommendation	COR[1]
ICD implantation is recommended in patients with cardiac sarcoidosis and one or more of the following: • Spontaneous sustained ventricular arrhythmias, including prior cardiac arrest • LVEF <35%, despite optimal medical therapy and a period of immunosuppression (if there is active inflammation).	I
ICD implantation can be useful in patients with cardiac sarcoidosis, independent of ventricular function, and one or more of the following: • An indication for permanent pacemaker implantation; • Unexplained syncope or near-syncope, felt to be arrhythmic in etiology; • Inducible sustained ventricular arrhythmias (>30 seconds of monomorphic VT or polymorphic VT) or clinically relevant VF.	IIa
ICD implantation may be considered in patients with LVEF in the range of 36%–49% and/or an RV ejection fraction <40%, despite optimal medical therapy for heart failure and a period of immunosuppression (if there is active inflammation).	IIb
ICD implantation is not recommended in patients with no history of syncope, normal LVEF/RV ejection fraction, no LGE on CMR, a negative EP study, and no indication for permanent pacing. However, these patients should be closely followed for deterioration in ventricular function. ICD implantation is not recommended in patients with one or more of the following: • Incessant ventricular arrhythmias; • Severe New York Heart Association class IV heart failure.	III

COR: Class of Recommendation; EP: electrophysiologic; ICD: implantable cardioverter defibrillator; LGE-CMR: late gadolinium-enhanced cardiovascular magnetic resonance; LOE: Level of Evidence; LVEF: left ventricular ejection fraction; RV: right ventricular; VF: ventricular fibrillation; VT: ventricular tachycardia. [1]Class I: Strong; Class IIa: Moderate; Class IIb: Weak.

Pediatric and Congenital Electrophysiology Society et al

The Pediatric and Congenital Electrophysiology Society and Heart Rhythm Society (2014) issued an expert consensus statement on the recognition and management of arrhythmias in adult congenital heart disease.[118] The statement made the following recommendations on the use of ICD therapy in adults with congenital heart disease (**Table 13**).

Table 13. Recommendations on Implantable Cardioverter Defibrillators in the Management of Congenital Heart Disease

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
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

Recommendation	COR	LOE
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.	IIIa	
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.	IIIa	

AV: atrioventricular ; CHD: congenital heart disease; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; NYHA: New York Heart Association. a Not recommended.

In 2021, the Pediatric and Congenital Electrophysiology Society and Heart Rhythm Society also issued an expert consensus statement on the indications and management of cardiovascular implantable electronic devices in pediatric patients.[1] **Table 14** summarizes recommendations for ICD therapy from this statement.

Table 14. Recommendations for Implantable Cardioverter Defibrillator Therapy in Pediatric Patients

Recommendation	COR	LOE
ICD implantation is indicated for survivors of SCA due to VT/VF if completely reversible causes have been excluded and an ICD is considered to be more beneficial than alternative treatments that may significantly reduce the risk of SCA.	I	B-NR
ICD implantation may be considered for patients with sustained VT that cannot be adequately controlled with medication and/or catheter ablation.	2b	C-EO
ICD therapy may be considered for primary prevention of SCD in patients with genetic cardiovascular diseases and risk factors for SCA or pathogenic mutations and family history of recurrent SCA.	2b	C-EO

Recommendation	COR	LOE
ICD therapy is not indicated for patients with incessant ventricular tachyarrhythmias due to risk of ICD storm.	3: Harm	C-EO
ICD therapy is not indicated for patients with ventricular arrhythmias that are adequately treated with medication and/or catheter ablation.	3: Harm	C-LD
ICD therapy is not indicated for patients who have an expected survival <1 year, even if they meet ICD implantation criteria specified in the above recommendations.	3: Harm	C-EO
ICD implantation along with the use of beta-blockade is indicated for patients with a diagnosis of LQTS who are survivors of SCA.	I	B-NR
ICD implantation is indicated in LQTS patients with symptoms in whom beta-blockade is either ineffective or not tolerated and cardiac sympathetic denervation or other medications are not considered effective alternatives.	I	B-NR
ICD therapy may be considered for primary prevention in LQTS patients with established clinical risk factors and/or pathogenic mutations.	2b	C-LD
ICD implantation is not indicated in asymptomatic LQTS patients who are deemed to be at low risk of SCA and have not been tried on beta-blocker therapy.	3: Harm	C-LD
ICD implantation is indicated in patients with a diagnosis of CPVT who experience cardiac arrest of arrhythmic syncope despite maximally tolerated beta-blocker plus flecainide and/or cardiac sympathetic denervation.	I	C-LD
ICD implantation is reasonable in combination with pharmacologic therapy with or without cardiac sympathetic denervation when aborted SCA is the initial presentation of CPVT. Pharmacologic therapy and/or cardiac sympathetic denervation without ICD may be considered as an alternative.	2a	C-LD
ICD therapy may be considered in CPVT patients with polymorphic/bidirectional VT despite optimal pharmacologic therapy with or without cardiac sympathetic denervation.	2b	C-LD
ICD implantation is not indicated in asymptomatic patients with a diagnosis of CPVT.	3: Harm	C-EO
ICD implantation is indicated in patients with a diagnosis of BrS who are survivors of SCA or have documented spontaneous sustained VT.	I	B-NR
ICD implantation is reasonable for patients with BrS with a spontaneous type I Brugada ECG pattern and recent syncope presumed due to ventricular arrhythmias.	2a	B-NR
ICD implantation may be considered in patients with syncope presumed due to ventricular arrhythmias with a type I Brugada ECG pattern only with provocative medications.	2b	C-EO
ICD implantation is not indicated in asymptomatic BrS patients in the absence of risk factors.	3: No benefit	C-EO
ICD implantation is indicated in patients with HCM who are survivors of SCA or have spontaneous sustained VT.	I	B-NR

Recommendation	COR	LOE
For children with HCM who have ≥1 primary risk factors, including unexplained syncope, massive left ventricular hypertrophy, nonsustained VT, or family history of early HCM-related SCD, ICD placement is reasonable after considering the potential complications of long-term ICD placement.	2a	B-NR
ICD implantation may be considered in patients with HCM without the above risk factors but with secondary risk factors for SCA such as extensive LGE cardiac MRI or systolic dysfunction.	2b	B-NR
ICD implantation is not indicated in patients with an identified HCM genotype in the absence of known pediatric SCA risk factors.	3: Harm	C-LD
ICD implantation is indicated in patients with ACM who have been resuscitated from SCA or sustained VT that is not hemodynamically tolerated.	I	B-NR
ICD implantation is reasonable in patients with ACM with hemodynamically tolerated sustained VT, syncope presumed due to ventricular arrhythmia, or an LVEF ≤35%.	2a	B-NR
ICD implantation may be considered in patients with inherited ACM associated with increased risk of SCD based on an assessment of additional risk factors.	2b	C-LD
ICD implantation is indicated in patients with NIDCM who either survive SCA or experience sustained VT not due to completely reversible causes.	I	B-NR
ICD implantation may be considered in patients with NIDCM and syncope or an LVEF ≤35%, despite optimal medical therapy.	2b	C-LD
ICD implantation is not recommended in patients with medication-refractory advanced heart failure who are not cardiac transplantation or left ventricular assist device candidates.	3: Harm	C-EO
ICD therapy is not indicated for patients with advanced heart failure who are urgently listed for cardiac transplantation and will remain in the hospital until transplantation, even if they meet ICD implantation criteria specified in the above recommendations.	3: No benefit	C-EO
ICD implantation is indicated for CHD patients who are survivors of SCA after evaluation to define the cause of the event and exclude any completely reversible causes.	I	B-NR
ICD implantation is indicated for CHD patients with hemodynamically unstable sustained VT who have undergone hemodynamics and EP evaluation.	I	C-LD
ICD implantation is reasonable for CHD patients with systemic LVEF <35% and sustained VT or presumed arrhythmogenic syncope.	2a	C-LD
ICD implantation may be considered for CHD patients with spontaneous hemodynamically stable sustained VT who have undergone hemodynamic and EP evaluation.	2b	C-EO
ICD implantation may be considered for CHD patients with unexplained syncope in the presence of ventricular dysfunction, nonsustained VT, or inducible ventricular arrhythmias at EP study.	2b	C-LD

Recommendation	COR	LOE
ICD implantation may be considered for CHD patients with a single or systemic right ventricular ejection fraction ≤35%, particularly in the presence of additional risk factors such as VT, arrhythmic syncope, or severe systemic AV valve insufficiency.	2b	C-EO

ACM: arrhythmogenic cardiomyopathy; AV: atrioventricular; B-NR: moderate, non-randomized; BrS: Brugada syndrome; C-EO: consensus of expert opinion; CHD: congenital heart disease; C-LD: limited data; COR: class of recommendation; CPVT: catecholaminergic polymorphic ventricular tachycardia; ECG: electrocardiogram; EP: electrophysiology; HCM: hypertrophic cardiomyopathy; ICD: implantable cardioverter defibrillator; LGE: late gadolinium-enhanced; LOE: level of evidence; LQTS: long QT syndrome; LVEF: left ventricular ejection fraction; MRI: magnetic resonance imaging; NIDCM: non-ischemic dilated cardiomyopathy; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VF: ventricular fibrillation; VT: ventricular tachycardia.

Medicare National Coverage

There is a National Coverage Determination for ICDs.[119] According to the most recent publication (effective February 15, 2018), Centers for Medicare and Medicaid Services will cover ICDs for the following patient indications:

- Patients with a personal history of sustained ventricular tachycardia (VT) or cardiac arrest due to ventricular fibrillation (VF).
- Patients with a prior myocardial infarction (MI) and a measured left ventricular ejection fraction (LVEF) ≤0.30.
- Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have New York Heart Association (NYHA) Class II or III heart failure, LVEF ≤35%.
- Patients who have severe non-ischemic dilated cardiomyopathy but no personal history of cardiac arrest or sustained VT, NYHA Class II or III heart failure, LVEF ≤35%, and been on optimal medical therapy for at least 3 months.
- Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhytmias (sustained VT or VF), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.
- Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, Elective Replacement Indicator (ERI), or device/lead malfunction.

For each group:

- Patients must be clinically stable (e.g., not in shock, from any etiology);
- LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography;
- Patients must not have:
    - Significant, irreversible brain damage; or,
    - Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or,
    - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

Regulatory Status

Transvenous Implantable Cardioverter Defibrillators

A large number of ICDs have been approved by the FDA through the PMA process (FDA product code: LWS). A 2014 review of the FDA approvals of cardiac implantable devices reported that, between 1979 and 2012, the FDA approved 19 ICDs (7 pulse generators, 3 leads, 9 combined systems) through new PMA applications.[2] Many originally approved ICDs have received multiple supplemental applications. A selective summary of some currently available ICDs is provided in **Table 15**.

In April 2021, Medtronic issued a recall of the Evera, Viva, Brava, Claria, Amplia, Compia, and Visia ICDs and cardiac resynchronization therapy defibrillators (CRT-Ds) due to an unexpected and rapid decrease in battery life.[3] The decrease in battery life is caused by a short circuit and will cause some devices to produce a "Recommended Replacement Time" warning earlier than expected. Some devices may progress from this warning to full battery depletion within as little as 1 day. The device may stop functioning if the user does not respond to the first warning. In August 2022, Medtronic issued a recall of the Cobalt XT, Cobalt, and Crome ICDs and CRT-Ds because of risk that the devices may issue a short circuit alert and deliver a reduced energy electric shock instead of delivering a second phase of high voltage therapy.[3] The reduced energy electrical shock may fail to correct an arrhythmia or may cause an irregular heartbeat. In July 2023, Medtronic issued a recall of the Cobalt XT, Cobalt, Crome, Visia AF, Visia AF MRI, Evera, Evera MRI, Prio, MRI, and Mirro MRI devices (along with some CRT-D devices) due to the potential for a reduced energy shock due to inappropriate activation of the short circuit

protection feature.[4] The FDA identified all 3 of these events as Class I recalls, the most serious type of recall, indicating a situation in which use of these devices may cause serious injuries or death.

Subcutaneous Implantable Cardioverter Defibrillators

In 2012, the Subcutaneous Implantable Defibrillator (S-ICD) System was approved by the FDA through the PMA process for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant VT, or spontaneous, frequently recurring VT that is reliably terminated with antitachycardia pacing (**Table 15**).

In 2015, the Emblem S-ICD (Boston Scientific), which is smaller and longer-lasting than the original S-ICD, was approved by the FDA through the PMA supplement process.

In February 2021, Boston Scientific issued a recall of the Emblem S-ICD because of increased risk of device fractures. The FDA designated the recall a Class I event, the most serious type of recall, indicating a situation in which there is a reasonable probability that the use of the device may cause serious injuries or death.[5]

Extravascular Implantable Cardioverter Defibrillators

In 2023, the Aurora EV-ICD MRI SureScan device was approved by the FDA for patients who are at risk of life-threatening ventricular arrhythmias and have not had a prior sternotomy and do not need pacing. This was the first extravascular ICD to be approved in the United States. Extravascular ICD leads are placed in the anterior mediastinum rather than inside the heart or veins.

Table 15. Implantable Cardioverter Defibrillators with Food and Drug Administration Approval

Device	Manufacturer	Original PMA Approval Date
Transvenous		
Ellipse/Fortify Assura Family (originally: Cadence Tiered Therapy Defibrillation System)	St. Jude Medical	Jul 1993

Device	Manufacturer	Original PMA Approval Date
Current Plus ICD (originally: Cadence Tiered Therapy Defibrillation System)	St. Jude Medical	Jul 1993
Dynagen, Inogen, Origen, and Teligen Family (originally: Ventak, Vitality, Cofient family)	Boston Scientific	Jan 1998
Evera Family (originally: Virtuosos/Entrust/Maximo/Intrisic/Marquis family)	Medtronic	Dec 1998
Subcutaneous		
Subcutaneous Implantable Defibrillator System (S-ICD)	Cameron Health; acquired by Boston Scientific	Sep 2012
Extravascular		
Aurora EV-ICD	Medtronic	Oct 2023

PMA: premarket application.

References

1. Shah MJ, Silka MJ, Silva JNA, et al. 2021 PACES Expert Consensus Statement on the Indications and Management of Cardiovascular Implantable Electronic Devices in Pediatric Patients: Developed in collaboration with and endorsed by the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA), and the Association for European Paediatric and Congenital Cardiology (AEPC) Endorsed by the Asia Pacific Heart Rhythm Society (APHRS), the Indian Heart Rhythm Society (IHRS), and the Latin American Heart Rhythm Society (LAHRS). JACC Clin Electrophysiol. Nov 2021; 7(11): 1437-1472. PMID 34794667
2. Rome BN, Kramer DB, Kesselheim AS. FDA approval of cardiac implantable electronic devices via original and supplement premarket approval pathways, 1979-2012. JAMA. Jan 2014; 311(4): 385-91. PMID 24449317
3. Heart Rhythm Society. Safety notice regarding Medtronic Cobalt XT, Cobalt, and Crome Implantable Cardioverter Defibrillators (ICD) and cardiac resynchronization therapy defibrillators (CRT-Ds). June 23, 2022. **https://www.hrsonline.org/resource/medtronic-colbalt-icd-crt-ds/**. Accessed June 19, 2026.
4. Food and Drug Administration. Medtronic Recalls Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) with Glassed Feedthrough for Risk of Low or No Energy Output During High Voltage Therapy. July 18, 2023. **https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-implantable-cardioverter-defibrillators-icds-and-cardiac-resynchronization-therapy**. Accessed June 19, 2026.
5. Food and Drug Administration. Class 1 device recall EMBLEM. January 19, 2021. **https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=185041**. Accessed June 19, 2026.
6. Butt JH, Doi SN, Thune JJ, et al. Long-Term Effect of ICDs in Nonischemic Heart Failure With Reduced Ejection Fraction: Extended Follow-Up Analysis of DANISH. J Am Coll Cardiol. Dec 16 2025; 86(24): 2402-2414. PMID 41123523
7. Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. Multicenter Automatic Defibrillator Implantation Trial Investigators. N Engl J Med. Dec 26 1996; 335(26): 1933-40. PMID 8960472

8. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med. Mar 21 2002; 346(12): 877-83. PMID 11907286

9. Bigger JT. Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary-artery bypass graft surgery. Coronary Artery Bypass Graft (CABG) Patch Trial Investigators. N Engl J Med. Nov 27 1997; 337(22): 1569-75. PMID 9371853

10. Buxton AE, Lee KL, Fisher JD, et al. A randomized study of the prevention of sudden death in patients with coronary artery disease. Multicenter Unsustained Tachycardia Trial Investigators. N Engl J Med. Dec 16 1999; 341(25): 1882-90. PMID 10601507

11. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med. Jan 20 2005; 352(3): 225-37. PMID 15659722

12. Haanschoten DM, Elvan A, Ramdat Misier AR, et al. Long-Term Outcome of the Randomized DAPA Trial. Circ Arrhythm Electrophysiol. Nov 2020; 13(11): e008484. PMID 33003972

13. Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med. Dec 09 2004; 351(24): 2481-8. PMID 15590950

14. Steinbeck G, Andresen D, Seidl K, et al. Defibrillator implantation early after myocardial infarction. N Engl J Med. Oct 08 2009; 361(15): 1427-36. PMID 19812399

15. Raviele A, Bongiorni MG, Brignole M, et al. Early EPS/ICD strategy in survivors of acute myocardial infarction with severe left ventricular dysfunction on optimal beta-blocker treatment. The BEta-blocker STrategy plus ICD trial. Europace. Jul 2005; 7(4): 327-37. PMID 16028343

16. Kadish A, Dyer A, Daubert JP, et al. Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. N Engl J Med. May 20 2004; 350(21): 2151-8. PMID 15152060

17. Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med. May 20 2004; 350(21): 2140-50. PMID 15152059

18. Strickberger SA, Hummel JD, Bartlett TG, et al. Amiodarone versus implantable cardioverter-defibrillator:randomized trial in patients with nonischemic dilated cardiomyopathy and asymptomatic nonsustained ventricular tachycardia--AMIOVIRT. J Am Coll Cardiol. May 21 2003; 41(10): 1707-12. PMID 12767651

19. Bänsch D, Antz M, Boczor S, et al. Primary prevention of sudden cardiac death in idiopathic dilated cardiomyopathy: the Cardiomyopathy Trial (CAT). Circulation. Mar 26 2002; 105(12): 1453-8. PMID 11914254

20. Køber L, Thune JJ, Nielsen JC, et al. Defibrillator Implantation in Patients with Nonischemic Systolic Heart Failure. N Engl J Med. Sep 29 2016; 375(13): 1221-30. PMID 27571011

21. Woods B, Hawkins N, Mealing S, et al. Individual patient data network meta-analysis of mortality effects of implantable cardiac devices. Heart. Nov 2015; 101(22): 1800-6. PMID 26269413

22. Jaiswal V, Taha AM, Joshi A, et al. Implantable cardioverter defibrillators for primary prevention in patients with ischemic and non-ischemic cardiomyopathy: A meta-analysis. Curr Probl Cardiol. Feb 2024; 49(2): 102198. PMID 37952790

23. Wolff G, Lin Y, Karathanos A, et al. Implantable cardioverter/defibrillators for primary prevention in dilated cardiomyopathy post-DANISH: an updated meta-analysis and systematic review of randomized controlled trials. Clin Res Cardiol. Jul 2017; 106(7): 501-513. PMID 28213711

24. Stavrakis S, Asad Z, Reynolds D. Implantable Cardioverter Defibrillators for Primary Prevention of Mortality in Patients With Nonischemic Cardiomyopathy: A Meta-Analysis of Randomized Controlled Trials. J Cardiovasc Electrophysiol. Jun 2017; 28(6): 659-665. PMID 28316104

25. Akel T, Lafferty J. Implantable cardioverter defibrillators for primary prevention in patients with nonischemic cardiomyopathy: A systematic review and meta-analysis. Cardiovasc Ther. Jun 2017; 35(3). PMID 28129469

26. Golwala H, Bajaj NS, Arora G, et al. Implantable Cardioverter-Defibrillator for Nonischemic Cardiomyopathy: An Updated Meta-Analysis. Circulation. Jan 10 2017; 135(2): 201-203. PMID 27993908

27. Wasiak M, Tajstra M, Kosior D, et al. An implantable cardioverter-defibrillator for primary prevention in non-ischemic cardiomyopathy: A systematic review and meta-analysis. Cardiol J. 2023; 30(1): 117-124. PMID 33843044

28. Earley A, Persson R, Garlitski AC, et al. Effectiveness of implantable cardioverter defibrillators for primary prevention of sudden cardiac death in subgroups a systematic review. Ann Intern Med. Jan 21 2014; 160(2): 111-21. PMID 24592496

29. Fontenla A, Martínez-Ferrer JB, Alzueta J, et al. Incidence of arrhythmias in a large cohort of patients with current implantable cardioverter-defibrillators in Spain: results from the UMBRELLA Registry. Europace. Nov 2016; 18(11): 1726-1734. PMID 26705555

30. Schinkel AF, Vriesendorp PA, Sijbrands EJ, et al. Outcome and complications after implantable cardioverter defibrillator therapy in hypertrophic cardiomyopathy: systematic review and meta-analysis. Circ Heart Fail. Sep 01 2012; 5(5): 552-9. PMID 22821634

31. Magnusson P, Gadler F, Liv P, et al. Hypertrophic Cardiomyopathy and Implantable Defibrillators in Sweden: Inappropriate Shocks and Complications Requiring Surgery. J Cardiovasc Electrophysiol. Oct 2015; 26(10): 1088-94. PMID 26178879

32. Medeiros P, Santos M, Arantes C, et al. Implantable cardioverter-defibrillator in patients with inherited arrhythmia syndromes: A systematic review. Heart Lung. 2023; 60: 1-7. PMID 36863123

33. Horner JM, Kinoshita M, Webster TL, et al. Implantable cardioverter defibrillator therapy for congenital long QT syndrome: a single-center experience. Heart Rhythm. Nov 2010; 7(11): 1616-22. PMID 20816872

34. Hernandez-Ojeda J, Arbelo E, Borras R, et al. Patients With Brugada Syndrome and Implanted Cardioverter-Defibrillators: Long-Term Follow-Up. J Am Coll Cardiol. Oct 17 2017; 70(16): 1991-2002. PMID 29025556

35. Conte G, Sieira J, Ciconte G, et al. Implantable cardioverter-defibrillator therapy in Brugada syndrome: a 20-year single-center experience. J Am Coll Cardiol. Mar 10 2015; 65(9): 879-88. PMID 25744005

36. Dores H, Reis Santos K, Adragão P, et al. Long-term prognosis of patients with Brugada syndrome and an implanted cardioverter-defibrillator. Rev Port Cardiol. Jun 2015; 34(6): 395-402. PMID 26028488

37. Roses-Noguer F, Jarman JW, Clague JR, et al. Outcomes of defibrillator therapy in catecholaminergic polymorphic ventricular tachycardia. Heart Rhythm. Jan 2014; 11(1): 58-66. PMID 24120999

38. Birnie DH, Sauer WH, Bogun F, et al. HRS expert consensus statement on the diagnosis and management of arrhythmias associated with cardiac sarcoidosis. Heart Rhythm. Jul 2014; 11(7): 1305-23. PMID 24819193

39. Plitt A, Dorbala S, Albert MA, et al. Cardiac sarcoidosis: case report, workup, and review of the literature. Cardiol Ther. Dec 2013; 2(2): 181-97. PMID 25135396

40. Mantini N, Williams B, Stewart J, et al. Cardiac sarcoid: a clinician's review on how to approach the patient with cardiac sarcoid. Clin Cardiol. 2012; 35(7): 410-5. PMID 22499155

41. Berul CI, Van Hare GF, Kertesz NJ, et al. Results of a multicenter retrospective implantable cardioverter-defibrillator registry of pediatric and congenital heart disease patients. J Am Coll Cardiol. Apr 29 2008; 51(17): 1685-91. PMID 18436121

42. Silka MJ, Kron J, Dunnigan A, et al. Sudden cardiac death and the use of implantable cardioverter-defibrillators in pediatric patients. The Pediatric Electrophysiology Society. Circulation. Mar 1993; 87(3): 800-7. PMID 8443901

43. Alexander ME, Cecchin F, Walsh EP, et al. Implications of implantable cardioverter defibrillator therapy in congenital heart disease and pediatrics. J Cardiovasc Electrophysiol. Jan 2004; 15(1): 72-6. PMID 15028076

44. Lewandowski M, Sterlinski M, Maciag A, et al. Long-term follow-up of children and young adults treated with implantable cardioverter-defibrillator: the authors' own experience with optimal implantable cardioverter-defibrillator programming. Europace. Sep 2010; 12(9): 1245-50. PMID 20650939

45. Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. N Engl J Med. Nov 27 1997; 337(22): 1576-83. PMID 9411221

46. Kuck KH, Cappato R, Siebels J, et al. Randomized comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from cardiac arrest : the Cardiac Arrest Study Hamburg (CASH). Circulation. Aug 15 2000; 102(7): 748-54. PMID 10942742

47. Connolly SJ, Gent M, Roberts RS, et al. Canadian implantable defibrillator study (CIDS) : a randomized trial of the implantable cardioverter defibrillator against amiodarone. Circulation. Mar 21 2000; 101(11): 1297-302. PMID 10725290

48. Nademanee K, Veerakul G, Mower M, et al. Defibrillator Versus beta-Blockers for Unexplained Death in Thailand (DEBUT): a randomized clinical trial. Circulation. May 06 2003; 107(17): 2221-6. PMID 12695290

49. Wever EF, Hauer RN, van Capelle FL, et al. Randomized study of implantable defibrillator as first-choice therapy versus conventional strategy in postinfarct sudden death survivors. Circulation. Apr 15 1995; 91(8): 2195-203. PMID 7697849

50. Lee DS, Green LD, Liu PP, et al. Effectiveness of implantable defibrillators for preventing arrhythmic events and death: a meta-analysis. J Am Coll Cardiol. May 07 2003; 41(9): 1573-82. PMID 12742300

51. National Institute for Health and Care Excellence (NICE). Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (Review of TA95 and TA120). 2014; **https://www.nice.org.uk/guidance/ta314/documents/arrythmias-icds-heart-failure-cardiac-resynchronisation-fad-document2**. Accessed June 19, 2026.

52. Connolly SJ, Hallstrom AP, Cappato R, et al. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. AVID, CASH and CIDS studies. Antiarrhythmics vs Implantable Defibrillator study. Cardiac Arrest Study Hamburg. Canadian Implantable Defibrillator Study. Eur Heart J. Dec 2000; 21(24): 2071-8. PMID 11102258

53. Betts TR, Sadarmin PP, Tomlinson DR, et al. Absolute risk reduction in total mortality with implantable cardioverter defibrillators: analysis of primary and secondary prevention trial data to aid risk/benefit analysis. Europace. Jun 2013; 15(6): 813-9. PMID 23365069

54. Chan PS, Hayward RA. Mortality reduction by implantable cardioverter-defibrillators in high-risk patients with heart failure, ischemic heart disease, and new-onset ventricular arrhythmia: an effectiveness study. J Am Coll Cardiol. May 03 2005; 45(9): 1474-81. PMID 15862422

55. Persson R, Earley A, Garlitski AC, et al. Adverse events following implantable cardioverter defibrillator implantation: a systematic review. J Interv Card Electrophysiol. Aug 2014; 40(2): 191-205. PMID 24948126

56. Ezzat VA, Lee V, Ahsan S, et al. A systematic review of ICD complications in randomised controlled trials versus registries: is our 'real-world' data an underestimation?. Open Heart. 2015; 2(1): e000198. PMID 25745566

57. Kirkfeldt RE, Johansen JB, Nohr EA, et al. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. Eur Heart J. May 2014; 35(18): 1186-94. PMID 24347317

58. van Rees JB, de Bie MK, Thijssen J, et al. Implantation-related complications of implantable cardioverter-defibrillators and cardiac resynchronization therapy devices: a systematic review of randomized clinical trials. J Am Coll Cardiol. Aug 30 2011; 58(10): 995-1000. PMID 21867832

59. Olde Nordkamp LR, Postema PG, Knops RE, et al. Implantable cardioverter-defibrillator harm in young patients with inherited arrhythmia syndromes: A systematic review and meta-analysis of inappropriate shocks and complications. Heart Rhythm. Feb 2016; 13(2): 443-54. PMID 26385533

60. Food and Drug Administration. Premature Insulation Failure in Recalled Riata Implantable Cardioverter Defibrillator (ICD) Leads Manufactured by St. Jude Medical, Inc.: FDA Safety Communication. 2014; https://wayback.archive-it.org/7993/20170722215745/https:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm314930.htm. Accessed March 18, 2026.

61. Hauser RG, Katsiyiannis WT, Gornick CC, et al. Deaths and cardiovascular injuries due to device-assisted implantable cardioverter-defibrillator and pacemaker lead extraction. Europace. Mar 2010; 12(3): 395-401. PMID 19946113

62. Providência R, Kramer DB, Pimenta D, et al. Transvenous Implantable Cardioverter-Defibrillator (ICD) Lead Performance: A Meta-Analysis of Observational Studies. J Am Heart Assoc. Oct 30 2015; 4(11). PMID 26518666

63. Birnie DH, Parkash R, Exner DV, et al. Clinical predictors of Fidelis lead failure: report from the Canadian Heart Rhythm Society Device Committee. Circulation. Mar 13 2012; 125(10): 1217-25. PMID 22311781

64. Hauser RG, Maisel WH, Friedman PA, et al. Longevity of Sprint Fidelis implantable cardioverter-defibrillator leads and risk factors for failure: implications for patient management. Circulation. Feb 01 2011; 123(4): 358-63. PMID 21242478

65. Poole JE, Gleva MJ, Mela T, et al. Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: results from the REPLACE registry. Circulation. Oct 19 2010; 122(16): 1553-61. PMID 20921437

66. Ricci RP, Pignalberi C, Magris B, et al. Can we predict and prevent adverse events related to high-voltage implantable cardioverter defibrillator lead failure?. J Interv Card Electrophysiol. Jan 2012; 33(1): 113-21. PMID 21882010

67. Cheng A, Wang Y, Curtis JP, et al. Acute lead dislodgements and in-hospital mortality in patients enrolled in the national cardiovascular data registry implantable cardioverter defibrillator registry. J Am Coll Cardiol. Nov 09 2010; 56(20): 1651-6. PMID 21050975

68. Faulknier BA, Traub DM, Aktas MK, et al. Time-dependent risk of Fidelis lead failure. Am J Cardiol. Jan 01 2010; 105(1): 95-9. PMID 20102898

69. Smit J, Korup E, Schønheyder HC. Infections associated with permanent pacemakers and implanted cardioverter-defibrillator devices. A 10-year regional study in Denmark. Scand J Infect Dis. Sep 2010; 42(9): 658-64. PMID 20465488

70. Nery PB, Fernandes R, Nair GM, et al. Device-related infection among patients with pacemakers and implantable defibrillators: incidence, risk factors, and consequences. J Cardiovasc Electrophysiol. Jul 2010; 21(7): 786-90. PMID 20102431

71. Sohail MR, Hussain S, Le KY, et al. Risk factors associated with early- versus late-onset implantable cardioverter-defibrillator infections. J Interv Card Electrophysiol. Aug 2011; 31(2): 171-83. PMID 21365264

72. Borleffs CJ, Thijssen J, de Bie MK, et al. Recurrent implantable cardioverter-defibrillator replacement is associated with an increasing risk of pocket-related complications. Pacing Clin Electrophysiol. Aug 2010; 33(8): 1013-9. PMID 20456647

73. Daubert JP, Zareba W, Cannom DS, et al. Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. J Am Coll Cardiol. Apr 08 2008; 51(14): 1357-65. PMID 18387436

74. Tan VH, Wilton SB, Kuriachan V, et al. Impact of programming strategies aimed at reducing nonessential implantable cardioverter defibrillator therapies on mortality: a systematic review and meta-analysis. Circ Arrhythm Electrophysiol. Feb 2014; 7(1): 164-70. PMID 24446023

75. Sterns LD, Meine M, Kurita T, et al. Extended detection time to reduce shocks is safe in secondary prevention patients: The secondary prevention substudy of PainFree SST. Heart Rhythm. Jul 2016; 13(7): 1489-96. PMID 26988379

76. Auricchio A, Schloss EJ, Kurita T, et al. Low inappropriate shock rates in patients with single- and dual/triple-chamber implantable cardioverter-defibrillators using a novel suite of detection algorithms: PainFree SST trial primary results. Heart Rhythm. May 2015; 12(5): 926-36. PMID 25637563

77. Lee DS, Krahn AD, Healey JS, et al. Evaluation of early complications related to De Novo cardioverter defibrillator implantation insights from the Ontario ICD database. J Am Coll Cardiol. Feb 23 2010; 55(8): 774-82. PMID 20170816

78. Furniss G, Shi B, Jimenez A, et al. Cardiac troponin levels following implantable cardioverter defibrillation implantation and testing. Europace. Feb 2015; 17(2): 262-6. PMID 25414480

79. Healey JS, Krahn AD, Bashir J, et al. Perioperative Safety and Early Patient and Device Outcomes Among Subcutaneous Versus Transvenous Implantable Cardioverter Defibrillator Implantations : A Randomized, Multicenter Trial. Ann Intern Med. Dec 2022; 175(12): 1658-1665. PMID 36343346

80. Carroll SL, Mondésert B, Krahn AD, et al. Device-specific quality of life: results from the ATLAS trial-avoid transvenous leads in appropriate subjects. Eur J Cardiovasc Nurs. Dec 16 2024; 23(8): 877-885. PMID 38695087

81. Gold MR, Lambiase PD, El-Chami MF, et al. Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial. Circulation. Jan 05 2021; 143(1): 7-17. PMID 33073614

82. Burke MC, Gold MR, Knight BP, et al. Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator: 2-Year Results From a Pooled Analysis of the IDE Study and EFFORTLESS Registry. J Am Coll Cardiol. Apr 28 2015; 65(16): 1605-1615. PMID 25908064

83. Gold MR, Aasbo JD, Weiss R, et al. Infection in patients with subcutaneous implantable cardioverter-defibrillator: Results of the S-ICD Post Approval Study. Heart Rhythm. Dec 2022; 19(12): 1993-2001. PMID 35944889

84. Gold MR, El-Chami MF, Burke MC, et al. Postapproval Study of a Subcutaneous Implantable Cardioverter-Defibrillator System. J Am Coll Cardiol. Aug 01 2023; 82(5): 383-397. PMID 37495274

85. Lambiase PD, Barr C, Theuns DA, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. Eur Heart J. Jul 01 2014; 35(25): 1657-65. PMID 24670710

86. Olde Nordkamp LR, Brouwer TF, Barr C, et al. Inappropriate shocks in the subcutaneous ICD: Incidence, predictors and management. Int J Cardiol. Sep 15 2015; 195: 126-33. PMID 26026928

87. Boersma L, Barr C, Knops R, et al. Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. J Am Coll Cardiol. Aug 15 2017; 70(7): 830-841. PMID 28797351

88. Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation. Aug 27 2013; 128(9): 944-53. PMID 23979626

89. Boersma L, Burke MC, Neuzil P, et al. Infection and mortality after implantation of a subcutaneous ICD after transvenous ICD extraction. Heart Rhythm. Jan 2016; 13(1): 157-64. PMID 26341604

90. Lambiase PD, Gold MR, Hood M, et al. Evaluation of subcutaneous ICD early performance in hypertrophic cardiomyopathy from the pooled EFFORTLESS and IDE cohorts. Heart Rhythm. May 2016; 13(5): 1066-1074. PMID 26767422

91. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med. Jul 01 2010; 363(1): 36-44. PMID 20463331

92. Theuns DA, Crozier IG, Barr CS, et al. Longevity of the Subcutaneous Implantable Defibrillator: Long-Term Follow-Up of the European Regulatory Trial Cohort. Circ Arrhythm Electrophysiol. Oct 2015; 8(5): 1159-63. PMID 26148819

93. Olde Nordkamp LR, Dabiri Abkenari L, Boersma LV, et al. The entirely subcutaneous implantable cardioverter-defibrillator: initial clinical experience in a large Dutch cohort. J Am Coll Cardiol. Nov 06 2012; 60(19): 1933-9. PMID 23062537

94. da Silva Menezes Júnior A, Oliveira IC, de Sousa AM, et al. Subcutaneous versus transvenous implantable cardioverter defibrillator in hypertrophic cardiomyopathy: a systematic review and meta-analysis. Cardiovasc Diagn Ther. Jun 30 2024; 14(3): 318-327. PMID 38975009

95. Knops RE, Olde Nordkamp LRA, Delnoy PHM, et al. Subcutaneous or Transvenous Defibrillator Therapy. N Engl J Med. Aug 06 2020; 383(6): 526-536. PMID 32757521

96. Olde Nordkamp LRA, de Veld JA, Ghani A, et al. Device-Related Complications in Transvenous Versus Subcutaneous Defibrillator Therapy During Long-Term Follow-Up: The PRAETORIAN-XL Trial. Circulation. Jul 22 2025; 152(3): 172-182. PMID 40279654

97. Knops RE, de Veld JA, Ghani A, et al. Quality of Life in Subcutaneous or Transvenous Implantable Cardioverter-Defibrillator Patients: A Secondary Analysis of the PRAETORIAN Trial. Circ Cardiovasc Qual Outcomes. Nov 2024; 17(11): e010822. PMID 39561235

98. Mithani AA, Kath H, Hunter K, et al. Characteristics and early clinical outcomes of patients undergoing totally subcutaneous vs. transvenous single chamber implantable cardioverter defibrillator placement. Europace. Feb 01 2018; 20(2): 308-314. PMID 28383717

99. Honarbakhsh S, Providencia R, Srinivasan N, et al. A propensity matched case-control study comparing efficacy, safety and costs of the subcutaneous vs. transvenous implantable cardioverter defibrillator. Int J Cardiol. Feb 01 2017; 228: 280-285. PMID 27865198

100. Köbe J, Hucklenbroich K, Geisendörfer N, et al. Posttraumatic stress and quality of life with the totally subcutaneous compared to conventional cardioverter-defibrillator systems. Clin Res Cardiol. May 2017; 106(5): 317-321. PMID 27878381

101. Pedersen SS, Mastenbroek MH, Carter N, et al. A Comparison of the Quality of Life of Patients With an Entirely Subcutaneous Implantable Defibrillator System Versus a Transvenous System (from the EFFORTLESS S-ICD Quality of Life Substudy). Am J Cardiol. Aug 15 2016; 118(4): 520-6. PMID 27353211

102. Brouwer TF, Yilmaz D, Lindeboom R, et al. Long-Term Clinical Outcomes of Subcutaneous Versus Transvenous Implantable Defibrillator Therapy. J Am Coll Cardiol. Nov 08 2016; 68(19): 2047-2055. PMID 27810043

103. Friedman DJ, Parzynski CS, Varosy PD, et al. Trends and In-Hospital Outcomes Associated With Adoption of the Subcutaneous Implantable Cardioverter Defibrillator in the United States. JAMA Cardiol. Nov 01 2016; 1(8): 900-911. PMID 27603935

104. Köbe J, Reinke F, Meyer C, et al. Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators: a multicenter case-control study. Heart Rhythm. Jan 2013; 10(1): 29-36. PMID 23032867

105. Friedman P, Murgatroyd F, Boersma LVA, et al. Efficacy and Safety of an Extravascular Implantable Cardioverter-Defibrillator. N Engl J Med. Oct 06 2022; 387(14): 1292-1302. PMID 36036522

106. Friedman P, Murgatroyd F, Boersma LVA, et al. Performance and Safety of the Extravascular Implantable Cardioverter Defibrillator Through Long-Term Follow-Up: Final Results From the Pivotal Study. Circulation. Jan 28 2025; 151(4): 322-332. PMID 39327797

107. Crozier I, Murgatroyd F, Amin A, et al. Periprocedural outcomes from the postmarket study of the extravascular implantable cardioverter-defibrillator: Preliminary Enlighten study results and meta-analysis. Heart Rhythm. Jan 2026; 23(1): 180-185. PMID 40172499

108. Boersma LVA, Amin A, Clémenty N, et al. Design of a post-market registry for the extravascular implantable cardioverter-defibrillator: The Enlighten Study. Heart Rhythm O2. Jan 2025; 6(1): 64-69. PMID 40224263

109. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. May 03 2022; 145(18): e876-e894. PMID 35363500

110. Ommen SR, Ho CY, Asif IM, et al. 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR Guideline for the Management of Hypertrophic Cardiomyopathy: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. Circulation. Jun 04 2024; 149(23): e1239-e1311. PMID 38718139

111. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. Oct 02 2018; 72(14): 1677-1749. PMID 29097294

112. Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. Circulation. May 27 2008; 117(21): e350-408. PMID 18483207

113. Epstein AE, DiMarco JP, Ellenbogen KA, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. Jan 22 2013; 61(3): e6-75. PMID 23265327

114. Bogle C, Colan SD, Miyamoto SD, et al. Treatment Strategies for Cardiomyopathy in Children: A Scientific Statement From the American Heart Association. Circulation. Jul 11 2023; 148(2): 174-195. PMID 37288568

115. Boersma LV, El-Chami M, Steinwender C, et al. Practical considerations, indications, and future perspectives for leadless and extravascular cardiac implantable electronic devices: a position paper by EHRA/HRS/LAHRS/APHRS. Europace. Oct 13 2022; 24(10): 1691-1708. PMID 35912932

116. Towbin JA, McKenna WJ, Abrams DJ, et al. 2019 HRS expert consensus statement on evaluation, risk stratification, and management of arrhythmogenic cardiomyopathy. Heart Rhythm. Nov 2019; 16(11): e301-e372. PMID 31078652

117. Priori SG, Wilde AA, Horie M, et al. HRS/EHRA/APHRS expert consensus statement on the diagnosis and management of patients with inherited primary arrhythmia syndromes: document endorsed by HRS, EHRA, and APHRS in May 2013 and by ACCF, AHA, PACES, and AEPC in June 2013. Heart Rhythm. Dec 2013; 10(12): 1932-63. PMID 24011539

118. Khairy P, Van Hare GF, Balaji S, et al. PACES/HRS expert consensus statement on the recognition and management of arrhythmias in adult congenital heart disease: developed in partnership between the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS). Endorsed by the governing bodies of PACES, HRS, the American College of Cardiology (ACC), the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), the Canadian Heart Rhythm Society (CHRS), and the International Society for Adult Congenital Heart Disease (ISACHD). Can J Cardiol. Oct 2014; 30(10): e1-e63. PMID 25262867

119. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4). 2018; **https://www.cms.gov/Medicare-Coverage-Database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=288**. Accessed June 19, 2026.

History

Date	Comments
01/01/97	New Policy (7.01.44 Implantable Cardioverter Defibrillator). Add to Surgery Section.
11/16/00	Archive Policy - Not denying services.
10/08/02	Replace Policy - Revision of existing policy based on 2002 TEC Assessment.
05/11/04	Replace Policy - Policy reviewed and updated with ACC guidelines and Medicare coverage; policy statement unchanged.
03/08/05	Replace Policy - Policy updated with October 2004 TEC Assessment; policy statement changed to reflect TEC findings; revised Medicare policy added.
07/11/06	Replace Policy - Policy updated with literature review; references added; policy statement unchanged; rationale revised.
02/26/07	Update Codes - No other changes.
04/10/07	Cross Reference Update - No other changes.
12/11/07	Replace Policy - Policy updated with literature review; policy statement revised to indicate that use of ICD in certain high-risk patients with hypertrophic cardiomyopathy may be considered medically necessary. References added.
01/08/08	Cross Reference Updated - No other changes.
03/11/08	Cross Reference Updated - No other changes.
01/13/09	Replace Policy - Policy updated literature search; no change to the policy statement. Title updated to delete “automatic”. References and codes added. Codes added 93279-93299, effective 1/1/09.

Date	Comments
05/12/09	Cross Reference Update - No other changes
02/09/10	Replace Policy - Policy updated with literature search; no change to the policy statement. References added.
07/12/11	Replace Policy - Policy updated with literature review through January 2011; reference numbers 13 through 21 added, clinical input reviewed. Policy statements specific to ICD indications in pediatric patients added to policy statements and rationale, conditions to consider early implantation in non-ischemic cardiomyopathy, other policy statement regarding adult patients unchanged. ICD-10 codes added to policy.
09/13/11	Replace Policy – Policy statement revised to clarify the indications in ischemic cardiomyopathy with separate indications for class II/III and class I patients. Policy statement with waiting time in nonischemic cardiomyopathy was revised based on additional clinical input. Codes updated. Policy approved with 90-day hold for provider notification, effective 2/8/12.
01/24/12	Codes updated: CPT codes 33221-33231 and 33262-33264; and HCPCS code G0448 added.
06/26/12	Related Policies reflects an updated title for 2.02.10.
11/13/12	Replace policy. Policy statement revised with addition of use of subcutaneous ICD, considered investigational for all indications. Description and rationale sections revised based on literature review through August 2012. ACCF/AHA guidelines for HCM added to clinical practice guidelines section. References 11, 13, 18, 23-25 added. Other references renumbered or removed. Added new category III CPT codes 0319T – 0328T, effective 01/01/13 to codes table. Policy statement has new investigational indication added.
12/09/13	Replace policy. Policy updated with literature review through August 31, 2013. References 13, 25, 27, and 29 added. No change to policy statements. CPT codes 0322T – 0324T removed; these are always paid; and, 33243 – 33245 also removed due to the same rationale.
06/13/14	Annual Review. Revision to policy statement made for clarity through August 2013. A clause "…after reversible causes (e.g., acute ischemia) have been excluded" added to current statement on secondary prevention in adults. The following codes were removed because they are not utilized in support of adjudication of the policy: CPT – 33202-33217, 33227-33229, 33240-33241, 33249, 33262-33264, 93279-93285, 93287-93291, 93295-9329; HCPCS – C1721—22, C1882, C1895-96, C1899; all ICD-9 and ICD-10 Procedure and Diagnosis codes.
12/17/14	Annual Review. Policy updated with literature review through September 7, 2014. References 1, 16-17, 23, 31, 33, and 35-39 added. Rationale section reorganized. Policy statements unchanged.
1/12/15	Coding update. New CPT codes 33270-33273, 93260, 93261 and 93644, effective 1/1/15, added to policy; codes 0319T-0321T and 0325T-0328T deleted as noted on policy, effective 12/31/14.

Date	Comments
12/08/15	Archive Policy (7.01.44 Implantable Cardioverter Defibrillator). Policy statement added that the ICD is medically necessary for patients with listed cardiac ion channelopathies; subcutaneous-ICD may be medically necessary in limited situations. Added ICD is considered investigational for secondary prevention when criteria are not met. Rationale and references incomplete. Policy is archived due to experience of low denials and managing the potential investigational uses of the devices on a case by case basis.
07/01/25	New policy, reinstate 7.01.44 Implantable Cardioverter Defibrillator (ICD), approved June 10, 2025, effective for dates of service on or after October 3, 2025, following 90-day provider notification. Add to Surgery section. Policy created with literature review through April 1, 2024; references added. Policy statements outline medical necessity criteria for pediatric and adult individuals. CPT 0571T included to align with criteria.
12/01/25	Coding update. Removed all of the programming and interrogation CPT codes 93260, 93261, 93282-93284, and 93289. The following codes remain on the policy as of the effective date of October 3, 2025: CPT codes 33216, 33217, 33230, 33231, 33240, 33249, 33270, 33271, 93287, 0572T; and HCPCS codes C1722, C1824, C1882, C1895, C1896, and C1899.
02/01/26	Coding update. Description for CPT code 33249 was corrected and updated.
08/01/26	Annual Review, approved July 27, 2026. Policy updated with literature review through March 20, 2026; references added. Minor editorial refinements to policy statements; intent unchanged. Removed HCPCS codes C1824 and C1882.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.