Policy Number	**SUR707.003**
Policy Effective Date	**12/15/2025**

Implantable Cardioverter Defibrillators

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

NOTE 1: This policy does not address implantable cardioverter defibrillators (ICD) combined with other pacing devices such as pacemakers for atrial fibrillation or biventricular pacemakers designed to treat heart failure. This policy addresses ICDs alone when used solely to treat individuals at risk for ventricular arrhythmias.

TRANSVENOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR
Adults
The use of the automatic implantable cardioverter defibrillator (ICD) **may be considered medically necessary** in adults who meet the following criteria:

Primary Prevention
1. Ischemic cardiomyopathy with New York Heart Association (NYHA) functional class II or III symptoms, a history of myocardial infarction (MI) at least 40 days before ICD treatment, and left ventricular ejection fraction (LVEF) of 35% or less; OR
2. Ischemic cardiomyopathy with NYHA functional class I symptoms, a history of MI at least 40 days before ICD treatment, and LVEF of 30% or less; OR

3. Nonischemic dilated cardiomyopathy and LVEF of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; OR
4. Hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in ≥1 first-degree relatives younger than 50 years; left ventricular hypertrophy >30 mm; ≥1 runs of nonsustained ventricular tachycardia (VT) at heart rates of ≥120 beats per minute on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of individuals with HCM; OR
5. Diagnosis of cardiac sarcoid and considered to be at high risk for sudden cardiac death (see Policy Guidelines section); OR
6. Diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death (see Policy Guidelines section):
   a. Congenital long QT syndrome;
   b. Brugada syndrome;
   c. Short QT syndrome; or
   d. Catecholaminergic polymorphic VT.

The use of the ICD **is considered experimental, investigational and/or unproven** in primary prevention individuals who:
1. Have had an acute MI (i.e., <40 days before ICD treatment); OR
2. Have NYHA class IV congestive heart failure (unless the individual is eligible to receive a combination cardiac resynchronization therapy ICD device); OR
3. Have had a cardiac revascularization procedure in the past 3 months (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) or are candidates for a cardiac revascularization procedure; OR
4. Have noncardiac disease that would be associated with life expectancy less than 1 year.

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 the ICD for secondary prevention **is considered experimental, investigational and/or unproven** for individuals who do not meet the criteria for secondary prevention.

Pediatrics

The use of the ICD **may be considered medically necessary** in pediatric individuals who meet ANY of the following criteria:
1. Survivors of cardiac arrest due to VT or ventricular fibrillation (VF), after reversible causes have been excluded; OR
2. Long QT syndrome in individuals who are survivors of sudden cardiac arrest (in combination with beta-blockers); OR

3. Long QT syndrome in individuals who cannot take beta-blockers and for whom cardiac sympathetic denervation or other medications are not considered appropriate; OR
4. Catecholaminergic polymorphic VT in individuals who experience cardiac arrest despite maximally tolerated beta-blockers, flecainide, or cardiac sympathetic denervation; OR
5. Brugada syndrome in individuals who are survivors of sudden cardiac arrest or have documented spontaneous sustained VT; OR
6. Hypertrophic cardiomyopathy in individuals who are survivors of sudden cardiac arrest or have documented spontaneous sustained VT; OR
7. Arrhythmogenic cardiomyopathy in individuals who are survivors of sudden cardiac arrest or sustained VT that is not hemodynamically tolerated; OR
8. Nonischemic dilated cardiomyopathy in individuals who are survivors of sudden cardiac arrest or have documented spontaneous sustained VT that is not due to completely reversible causes; OR
9. Congenital heart disease in individuals who are survivors of sudden cardiac arrest, after reversible causes have been excluded; OR
10. Symptomatic, sustained VT in association with congenital heart disease in individuals who have undergone hemodynamic and electrophysiologic evaluation.

The use of the ICD **is considered experimental, investigational and/or unproven** for all other indications in pediatric individuals.

SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

The use of a subcutaneous ICD **may be considered medically necessary** for adult or pediatric individuals who have an indication for ICD implantation for primary or secondary prevention for any of the above reasons and meet ALL of the following criteria:

1. Have no indication for antibradycardia pacing; AND
2. Do not have ventricular arrhythmias known or anticipated to respond to antitachycardia pacing; AND
3. Have a contraindication to a transvenous ICD due to 1 or more of the following:
   a. Lack of adequate vascular access;
   b. Compelling reason to preserve existing vascular access (i.e., need for chronic dialysis; younger individual with anticipated long-term need for ICD therapy); or
   c. History of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy.

The use of a subcutaneous ICD **is considered experimental, investigational and/or unproven** for individuals who do not meet the criteria outlined above.

EXTRAVASCULAR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

The use of an extravascular ICD (also known as a substernal ICD) **is considered experimental, investigational and/or unproven**.

Policy Guidelines

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

Criteria for Implantable Cardioverter Defibrillator 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;
  - 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 2: 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; OR
- Infants with a diagnosis of LQTS with functional 2:1 atrioventricular block; OR
- 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 Implantable Cardioverter Defibrillator 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 (AHA), American College of Cardiology (ACC), 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
  - Enducible sustained ventricular arrhythmias (>30 seconds of monomorphic VT or polymorphic VT) or clinically relevant ventricular fibrillation.
- An indication for permanent pacemaker implantation.

Description

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

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

Several automatic ICDs have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (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.

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 1.

NOTE 3: Several FDA website links in this section of the policy are no longer functional and therefore are left as accessed in 2024. 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. (4) 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. (5) 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 1).

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. (6)

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 1. 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
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.

Rationale

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

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

TRANSVENOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS FOR PRIMARY PREVENTION

Clinical Context and Therapy Purpose

The purpose of transvenous implantable cardioverter defibrillator (T-ICD) placement is to provide a treatment option that is an alternative to or an improvement on existing therapies in

individuals with a high risk of sudden cardiac death (SCD) due to ischemic or nonischemic cardiomyopathy (NICM), inherited cardiac ion channelopathy, or cardiac sarcoid.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with a high risk of SCD due to ischemic or NICM, inherited cardiac ion channelopathy, or cardiac sarcoid.

Interventions
The therapy being considered is T-ICD placement. An implantable cardioverter defibrillator (ICD) is a device designed to monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death.

Comparators
Comparators of interest include medical management without ICD placement. Guideline-based medical management for ischemic cardiovascular disease includes antihypertensive therapy and antiarrhythmic medications. Medical management for cardiac sarcoid includes steroid therapy.

Outcomes
The general outcomes of interest are overall survival (OS), morbid events, quality of life, treatment-related mortality, and treatment-related morbidity. Table 2 describes outcomes of interest related to quality of life and treatment-related morbidity for individuals at high risk of SCD due to ischemic or non-ischemic cardiomyopathy.

Table 2. Outcomes of Interest for Individuals at High Risk of Sudden Cardiac Death due to Ischemic or Non-ischemic Cardiomyopathy in Adulthood

Outcomes	Details	Timing
Quality of life	Can be assessed by patient reported data such as surveys and questionnaires	1 week to 5 years
Treatment-related morbidity	Can be assessed by rates of adverse events, including inappropriate shock, lead failure, infection, and other complications	1 week to 5 years

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;

- Studies with duplicative or overlapping populations were excluded.

Primary Prevention in Adults

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

Ischemic Cardiomyopathy and Nonischemic Dilated Cardiomyopathy

Randomized Controlled Trials

At least 14 RCTs of ICDs for primary prevention have been conducted. Six were in populations with ischemic cardiomyopathy with prior myocardial infarction (MI; usually ≥3 weeks post-MI):

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

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

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

Six trials were conducted in populations with NIDCM:

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

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

Most trials for both ischemic cardiomyopathy and NICM have reported results consistent with a mortality benefit for ICD in patients with left ventricular systolic dysfunction or with heart failure and reduced ejection fraction, although not all trials were powered for the mortality outcome and some findings were not statistically significant. However, the DINAMIT, IRIS, and BEST-ICD trials did not support a mortality benefit for ICD in the early weeks following MI, and CABG Patch showed no benefit in patients having recently undergone coronary

revascularization. Another notable exception is the 2016 DANISH trial, which enrolled primarily outpatients with NICM in stable condition who were almost all receiving ß-blockers or angiotensin-converting enzyme inhibitors, with the majority also receiving mineralocorticoid-receptor antagonists. While overall mortality did not differ significantly between the ICD and medical therapy groups in DANISH, SCD was significantly reduced in the ICD group (4% vs. 8%; hazard ratio [HR], 0.50; 95% confidence interval [CI], 0.31 to 0.82).

Table 3. Characteristics and Results of Randomized Controlled Trials of Implantable Cardioverter Defibrillators for Primary Prevention

Trial	Participants	Treatment Groups		Mean Follow-up	Mortality Results	
		Group	n		Hazard Ratio	95% CI
ICM with Prior MI						
MADIT (1996) (7)	• LVEF ≤35% • Asymptomatic unsustained VT • MI ≥3 wk prior • Inducible VT • NYHA class I-III	• ICD • Standard therapy	• 95 • 101	27 mo (trial stopped early by DSMB)	0.46	• 0.26 to 0.82
MADIT II (2002) (8)	• LVEF ≤30% • No history of VT • MI ≥1 mo prior • NYHA class I-III	• ICD • Standard therapy	• 742 • 490	20 mo Trial (stopped early by DSMB)	0.69	• 0.51 to 0.93
CABG Patch (1997) (9)	• Scheduled for CABG • LVEF ≤35% • No sustained VT or VF • Signal-averaged ECG abnormalities • 82% had prior MI, time since MI not reported	• ICD during CABG • No ICD	• 446 • 454	32 mo	1.07	• 0.81 to 1.42
MUSTT (1999) (10)	• LVEF ≤40% • Asymptomatic unsustained VT • Inducible VT • MI ≥4 d prior (median, »3 y prior) • No sustained VT or VF	• EPS-guided therapy (AAD with or without ICD) (202 got ICD) • Standard therapy	• 351 • 353	39 mo	5-y outcomes[b]: • EPS-guided vs standard therapy: 0.80 • ICD vs AAD alone: 0.42	• 0.64 to 1.01 • 0.29 to 0.61
SCD HeFT (2005) (11)	• LVEF ≤35% • NYHA class II-III • 52% received ICM	Ischemic patients: • ICD • Amiodarone • Placebo	• 431 • 426 • 453	45 mo	ICD vs. placebo • Ischemic: 0.79[a]	• 0.60 to 1.04

	• Treated with ACE inhibitors and beta-blockers				• Overall: 0.77[a]	• 0.62 to 0.96
DAPA (2020) (12)	• LVEF <30% within 4 days post-STEMI • Primary VF • Killip class ≥2 • TIMI flow <3 after PCI	• ICD • Standard therapy	• 131 • 135	3 years in 89% of patients	• 3-y outcomes: • ICD vs standard therapy: 0.37 • 9-y outcomes: • ICD vs standard therapy: 0.58	• 0.15 to 0.95 • 0.37 to 0.91
ICM with Recent MI						
DINAMIT (2004) (13)	• LVEF ≤35% • NYHA class I-III • MI in preceding 6-40 d (mean, 18 d) • No sustained VT or VF for >48 h after index MI • Reduced HR variability or elevated resting HR	• ICD • Standard therapy	• 332 • 342	30 mo	1.08	• 0.76 to 1.55
IRIS (2009) (14)	• MI in preceding 5 to 31 d • At least 1 of the following: a. LVEF ≤40% and resting HR ≥90 bpm or unsustained VT	• ICD • Standard therapy	• 445 • 453	37 mo	1.04	• 0.81 to 1.35
BEST-ICD (2005) (15)	• LVEF ≤35% • NYHA class I-III • No unsustained VT or sustained ventricular arrhythmias (except primary VF) • MI in preceding 5 to 30 d • At least 1 other risk factor	• EPS-guided therapy (24 got ICD) • Standard therapy	• 79 • 59	540 d	1-year mortality[d] • EPS-guided therapy: 14% • Conven-tional therapy: 18% 2-y mortality[d] • EPS-guided	

					therapy: 20% • Conven-tional therapy: 29.5%	
Nonischemic cardiomyopathy						
DEFINITE (2004) (16)	• LVEF ≤35% • NYHA class II-IV	• ICD and medical therapy • Medical therapy alone	• 229 • 229	29 mo	0.65 (0.40 to 1.06)	
SCD HeFT (2005) (11)	• LVEF ≤35% • NYHA class II-III • 48% with non-ICM • Treated with ACE inhibitor and beta-blockers	Nonischemic patients: • ICD • Amiodarone • Placebo	• 398 • 419 • 394	45 mo	• ICD vs. placebo • Non-ischemic: 0.73[a] • Overall: 0.77[a]	• 0.50 to 1.07 • 0.62 to 0.96
COMPANION (2004) (17)	• LVEF ≤35% • NYHA class III-IV • DCM	Nonischemic patients: • CRT-D • Medical therapy • CRT	• 270 • 127 • 285	16 mo	• CRT-D vs medical therapy • Non-ischemic: 0.50 • Overall: 0.64	• 0.29 to 0.88 • 0.48 to 0.86
AMIOVIRT (2003) (18)	• LVEF ≤35% • NYHA class I-III • DCM • Asymptomatic unsustained VT	• ICD • Amiodarone	• 51 • 52	2 years	1-year survival[d] • ICD: 96% • Amio-darone: 90% 2-year survival[d] • ICD: 88% • Amio-darone: 87%	
CAT (2002) (19)	• LVEF ≤30% • NYHA class II-III • No symptomatic VT, VF, or bradycardia • Recent-onset DCM	• ICD • Control	• 50 • 54	23 mo (trial stopped early due to low event rates)	• ICD: 4 deaths (8%)[d] • Control: 2 deaths (3.7%)	
DANISH (2016) (20)	• LVEF ≤35% • NYHA class II-IV • 58% received CRT	• ICD and medical therapy	• 556 • 560	5.6 years	0.87	• 0.68 to 1.12

	• Almost all patients on ACE inhibitors or beta-blockers; ○ 60% treated with mineralo-corticoid-receptor antagonist	• Medical therapy				

AAD: antiarrhythmic drugs; ACE: angiotensin-converting enzyme; CABG: coronary artery bypass grafting; CI: confidence interval; CRT: cardiac resynchronization therapy; CRT-D: cardiac resynchronization therapy implantable cardioverter defibrillator; d: day; DCM: dilated cardiomyopathy; DSMB: Data Safety Monitoring Board; ECG: electrocardiogram; EPS: electrophysiologic study; HR: heart rate; ICD: implantable cardioverter defibrillator; ICM: ischemic cardiomyopathy; mo: month; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; RCT: randomized controlled trial; STEMI: ST-elevation myocardial infarction; TIMI Thrombolysis in Myocardial Infarction; VF: ventricular fibrillation; VT: ventricular tachycardia; wk: week; yr: year.

[a] 97.5% CI.

[b] Relative risk.

[c] Median.

[d] Hazard ratio not given, no significant differences.

Systematic Reviews

Characteristics and results of systematic reviews of primary prevention ICD trials are described in Tables 4 and 5. Woods et al. (2015) published an individual patient data network meta-analysis of primary prevention RCTs evaluating implantable cardiac devices, including studies of patients with heart failure and reduced ejection fraction and excluding studies of patients with recent MI or coronary revascularization. (21) The COMPANION, DEFINITE, MADIT, MADIT II, SCD HeFT, AMIOVIRT, and CAT trials were included, representing 6134 patients for the direct ICD comparisons and 12638 patients overall. Jaiswal et al. (2024) conducted a meta-analysis of 13 RCTs in patients with both ICM and NICM (including all RCTs listed in Table 3 except BEST-ICD), which found that all-cause mortality and SCD were significantly lower with ICD therapy compared to standard therapy. (22) These outcomes were significant when patients with ICM and NICM were analyzed separately, as well as together.

Subsequent systematic reviews and meta-analyses of ICD trials in NICM incorporated the 2016 DANISH trial results. (23-27) Two reviews published in 2017 included the CAT, AMIOVIRT, DEFINITE, SCD HeFT, COMPANION, and DANISH trials; one review published in 2021 included the CAT, AMIOVIRT, DEFINITE, and DANISH trials; other reviews included all but the COMPANION trial. The majority of the reviews concluded that there was a statistically significant overall reduction in mortality for ICD versus medical therapy, ranging from 20% to 23%, even with the inclusion of the null DANISH results.

The risk for death varies by age, sex, and clinical characteristics such as left ventricular ejection fraction (LVEF) and time since revascularization and comorbid conditions (e.g., diabetes, kidney disease). Meta-analyses have examined whether there is a beneficial effect on mortality of ICD in these subgroups. Earley et al. (2014) conducted a review of evidence for the Agency for Healthcare Research and Quality on use of ICD across important clinical subgroups. (28) Reviewers included 10 studies that provided subgroup analyses. Subgroup data were available from at least 4 studies for sex, age (<65 years vs. ≥65 years), and QRS interval (<120 ms vs. ≥120 ms); they were combined to calculate a relative odds ratio (OR) using random-effects meta-analyses. Other comparisons of subgroups were not meta-analyzed because too few studies compared them; however, no consistent differences between subgroups were found across studies for diabetes. The Woods et al. (2015) individual patient data network meta-analysis (described previously) also examined ICD and medical therapy in various subgroups and similarly concluded that ICD reduced mortality in patients with heart failure and reduced ejection fraction for QRS intervals less than 120 ms, 120 to 149 ms, and 150 ms or higher, ages less than 60 years and 60 years and older, and for men. (21) However, the effect on mortality in women was not statistically significant (HR, 0.93; 95% CI, 0.73 to 1.18).

Table 4. Characteristics of Systematic Reviews & Meta-Analysis of Implantable Cardioverter Defibrillators for Primary Prevention

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Jaiswal et al. (2020) (22)	1996-2020	13	Patients with ICM or NICM who received ICD	7857	RCT	Mean 3.1 years
Woods et al. (2015) (21)	1990-2010	13	Patients with heart failure who received ICD	12,638 (17 to 2,521)	RCT	NR
Earley et al. (2014) (28)	1996-2010	14	Adults eligible to receive an ICD for primary prevention of SCD	NR	RCT, Nonrandomized comparative studies	NR

ICD: implantable cardioverter defibrillator; ICM: ischemic cardiomyopathy; NICM: non-ischemic cardiomyopathy; NR: not reported; RCT: randomized controlled trial; SCD: sudden cardiac death.

Table 5. Results of Systematic Reviews & Meta-Analysis of Implantable Cardioverter Defibrillators for Primary Prevention

Study	Mortality

Jaiswal et al. (2020) (22)	**Estimated Effect of ICD on All-Cause Mortality Compared with MT**
Overall population	0.69 (95% CI, 0.55 to 0.87)
ICM	0.66 (95% CI, 0.45 to 0.96)
NICM	0.75 (95% CI, 0.62 to 0.89)
Woods et al. (2015) (21)	**Estimated Effect of ICD on Mortality Compared with MT**
	0.71 (95% CI, 0.63 to 0.80)
Earley et al. (2014) (28)	**Mortality Benefit of Variables (ROR)**
Sex	0.95 (95% CI, 0.75 to 1.27)
Age	0.93 (95% CI, 0.73 to 1.20)
QRS Interval	1.13 (95% CI, 0.82 to 1.54)

CI: confidence interval; ICD: implantable cardioverter defibrillator; ICM: ischemic cardiomyopathy; NICM: non-ischemic cardiomyopathy; MT: medical therapy; ROR: relative odds ratio.

Registry Studies

Fontenla et al. (2016) reported on results from the Spanish UMBRELLA Registry, a multicenter, observational, prospective nationwide registry of 1514 patients implanted with Medtronic ICDs equipped with remote monitoring who were enrolled between 2012 and 2013. (29) The mean age of enrollees was 64 years; 82% of the patients were men; and 65% received an ICD for primary prevention. Fifty-one percent of the patients had ischemic heart disease, 30% had NICM, 7% had HCM, 3% had Brugada syndrome (BrS), and 1.4% had long QT syndrome (LQTS). Mean follow-up was 26 months. The cumulative incidence of sustained ventricular arrhythmias was 15% (95% CI, 13% to 16%) at 1 year, 23% (95% CI, 21% to 25%) at 2 years, and 31% (95% CI, 28% to 34%) at 3 years. Thirteen percent of the episodes of sustained ventricular arrhythmias self-terminated and did not require shocks. One hundred seventy-five (12%) patients had 482 appropriate shocks, and 76 (5%) patients had 190 inappropriate shocks.

<u>High-Risk Hypertrophic Cardiomyopathy</u>

Schinkel et al. (2012) conducted a systematic review and meta-analysis of 27 observational studies (16 cohorts, 2190 patients) reporting outcomes after ICD therapy for HCM. (30) Most patients (83%) received an ICD for primary prevention of SCD. The mean age was 42, 38% of patients were women, and patients had a mean of 1.8 risk factors for SCD. With a mean follow-up of 3.7 years, 14% of patients had an appropriate ICD intervention with an annualized rate of 3.3%. Twenty percent of patients had an inappropriate ICD intervention, for an annualized rate of 4.8%. The annualized cardiac mortality rate was 0.6%, the noncardiac mortality rate was 0.4%, and heart transplantation rate was 0.5%.

Magnusson et al. (2015) reported on outcomes for 321 patients with HCM treated with an ICD and enrolled in a Swedish registry. (31) Over a mean follow-up of 5.4 years, appropriate ICD discharges in response to VT or VF occurred in 77 (24%) patients, corresponding to an annual rate of appropriate discharges of 5.3%. At least 1 inappropriate shock occurred in 46 (14.3%) patients, corresponding to an annualized event rate of 3.0%. Ninety-two (28.7%) patients required at least 1 surgical intervention for an ICD-related complication, with a total of 150 ICD-related reinterventions. Most reinterventions (n=105 [70%]) were related to lead dysfunction.

Inherited Cardiac Ion Channelopathy

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

Systematic Review

Medeiros et al. (2023) conducted a systematic review of 36 studies in 2750 patients with inherited arrhythmia syndromes (LQTS, short QT syndrome, BrS, CPVT, and early repolarization syndrome) who received ICD therapy. (32) Mean follow-up in the included studies was 69 months. Appropriate and inappropriate therapy occurred in 21% and 20% of patients overall, respectively. Appropriate therapy was more common than inappropriate therapy in the setting of CPVT, early repolarization, and LQTS. Inappropriate therapy was more common than appropriate therapy in patients with BrS and short QT syndrome. Inappropriate therapy consisted of SVT in 44% of cases, oversensing or device malfunction in 35% of cases, and other mechanisms in 21% of cases. Complications of ICD therapy were prevalent (22%), most commonly lead malfunction (46% overall) and infection (13% overall). This analysis is limited by inclusion of observational studies and incomplete information about the type of ICD device used.

Long QT Syndrome

Horner et al. (2010) reported on outcomes for 51 patients with genetically confirmed LQTS treated with an ICD from 2000 to 2010 who were included in a single-center retrospective analysis of 459 patients with genetically confirmed LQTS. (33) Of patients treated with ICDs, 43 (84%) received the device as primary prevention. Twelve (24%) patients received appropriate VF or torsades de pointes-terminated ICD shocks. Factors associated with appropriate shocks included secondary prevention indications (p=.008), QT corrected duration greater than 500 ms (p<.001), non-*LQT3* genotype (p=.02), documented syncope (p=.05), documented torsades de pointes (p=.003), and a negative sudden family death history (p<.001). Inappropriate shocks were delivered in 15 (29%) patients. Patients with the *LQT3* genotype only received inappropriate shocks.

Brugada Syndrome

Hernandez-Ojeda et al. (2017) reported on results from a single-center registry of 104 patients with BrS who were treated with ICDs. (34) Ten (9.6%) patients received an ICD for secondary prevention and 94 (90.4%) patients received an ICD for primary prevention. During an average 9.3-year follow-up, 21 (20.2%) patients received a total of 81 appropriate shocks. In multivariate analysis, type 1 electrocardiogram (ECG) with syncope and secondary prevention indication were significant predictors of appropriate therapy. Nine (8.7%) patients received 37 inappropriate shocks. Twenty-one (20.2%) patients had other ICD-related complications.

Conte et al. (2015) described outcomes for a cohort of 176 patients with spontaneous or drug-induced Brugada type 1 ECG findings who received an ICD at a single institution and were followed for at least 6 months. (35) Before ICD implantation, 14.2% of subjects had a history of aborted SCD due to sustained spontaneous ventricular arrhythmias, 59.7% had at least 1 episode of syncope, and 25.1% were asymptomatic. Over a mean follow-up of 83.8 months, 30 (17%) patients had spontaneous sustained ventricular arrhythmias detected. Sustained ventricular arrhythmias were terminated by ICD shocks in 28 (15.9%) patients and antitachycardia pacing in 2 (1.1%) patients. However, 33 (18.7%) patients experienced inappropriate shocks.

Dores et al. (2015) reported on results of a Portuguese registry that included 55 patients with BrS, 36 of whom were treated with ICDs for primary or secondary prevention. (36) Before ICD placement, 52.8% of subjects were asymptomatic, 30.6% had a history of syncope with suspected arrhythmic cause, and 16.7% had a history of aborted SCD. Over a mean follow-up of 74 months, 7 patients experienced appropriate shocks, corresponding to an incidence rate of 19.4% and an annual event rate of 2.8%. In multivariable analysis, predictors of appropriate shocks were a history of aborted SCD (HR, 7.87; 95% CI, 1.27 to 49.6; p=.027) and nonsustained VT during follow-up (HR, 6.73; 95% CI, 1.27 to 35.7; p=.025).

Catecholaminergic Polymorphic Ventricular Tachycardia

Roses-Noguer et al. (2014) reported on results of a small retrospective study of 13 patients with CPVT who received an ICD. (37) The indication for ICD therapy was syncope despite maximal β-blocker therapy in 6 (46%) patients and aborted SCD in 7 (54%) patients. Over a median follow-up of 4.0 years, 10 (77%) patients received a median of 4 shocks. For 96 shocks, 87 ECGs were available for review. Of those, 63 (72%) were appropriate and 24 (28%) inappropriate. Among appropriate shocks, 20 (32%) restored sinus rhythm.

Cardiac Sarcoid

Sarcoidosis is a systemic granulomatous disease of unknown etiology, with a worldwide prevalence of about 4.7 to 64 in 100,000. (38) The annual incidence of sarcoidosis in the United States has been estimated at 10.9 per 100,000 in White individuals and 35.5 per 100,000 in Black individuals. Cardiac involvement occurs in about 5% of systemic sarcoidosis cases. Steroid therapy is recommended as first-line treatment based on small cohort studies showing benefit, although there is conflicting evidence about its efficacy on long-term disease outcomes. (39)

Mantini et al. (2012) published a review on the diagnosis and management of cardiac sarcoid, including a treatment algorithm. (40) Limited evidence from small cohort studies suggested that an ICD could prevent dangerous arrhythmias or SCD even in patients with a relatively preserved LVEF. Evidence from case series also suggested that programmed electrical stimulation could identify patients with cardiac sarcoid with electrical instability and help to determine who should get ICD.

Subsection Summary: Transvenous Implantable Cardioverter Defibrillator for Primary Prevention in Adults

Ischemic Cardiomyopathy and Nonischemic Dilated Cardiomyopathy

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

Hypertrophic Cardiomyopathy

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

Inherited Cardiac Ion Channelopathy

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

Cardiac Sarcoid

The evidence related to the use of ICDs in patients with cardiac sarcoid 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 lifesaving, 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.

Primary Prevention in Pediatric Populations

There is limited direct evidence on the efficacy of ICDs in the pediatric population. Most published studies have retrospectively analyzed small case series that included mixed populations with mixed indications for device placement. Some representative series are reviewed next.

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

Silka et al. (1993) compiled a database of 125 pediatric patients treated with an ICD through a query of the manufacturers of commercially available devices. (42) Indications for ICD placement were survivors of cardiac arrest (95 [76%] patients), drug-refractory VT (13 [10%] patients), and syncope with heart disease and inducible VT (13 [10%] patients). During a mean follow-up of 31 months, 73 (59%) patients received at least 1 appropriate shock and 25 (20%) received at least 1 inappropriate shock. Actual rates of SCD-free survival were 97% at 1 year, 95% at 2 years, and 90% at 5 years.

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

Subsection Summary: Primary Prevention in Pediatric Populations

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

TRANSVENOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS FOR SECONDARY PREVENTION

Clinical Context and Therapy Purpose

The purpose of T-ICD placement is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with life-threatening ventricular tachyarrhythmia or fibrillation or who have been resuscitated from sudden cardiac arrest.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with life-threatening ventricular tachyarrhythmia or fibrillation or who have been resuscitated from sudden cardiac arrest.

Interventions
The therapy being considered is T-ICD placement. An ICD is a device designed to monitor a patient's heart rate, recognize VF or VT, and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death.

Comparators
Comparators of interest include medical management without ICD placement.

Outcomes
The general outcomes of interest are OS, morbid events, quality of life, treatment-related mortality, and treatment-related morbidity.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Secondary Prevention in Adults
At least 5 trials comparing ICD plus medical therapy with medical therapy alone have been conducted in the secondary prevention setting: the Antiarrhythmics Versus Implantable Defibrillators (AVID) trial (45) (N=1016), Cardiac Arrest Survival in Hamburg (CASH) trial (46) (N=288), Canadian Implantable Defibrillator Study (CIDS) (47) (N=659), Defibrillator Versus Beta-Blockers for Unexplained Death in Thailand (DEBUT) (48) trial (N=66; pilot, n=20; main study, n=46), and Wever et al. (1995) (49) (N=60). The trials are shown in Table 6. The mean length of follow-up varied from 18 to 57 months across trials. Lee et al. (2003) combined the AVID, CASH, CIDS, and Wever et al. (1995) trials in a meta-analysis of secondary prevention trials. (50) The mortality analysis included 2023 participants and 518 events. In combined estimates, the ICD group had a significant reduction in both mortality (HR, 0.75; 95% CI, 0.64 to 0.87) and SCD (HR, 0.50; 95% CI, 0.34 to 0.62) compared with the group receiving medical

therapy alone. To support National Institute for Health and Care Excellence guidance on the use of ICDs, AVID, CASH, CIDS, and the pilot DEBUT participants were combined in a meta-analysis. (51) The results were similar, indicating a reduction in mortality for ICDs compared with medical therapy alone (relative risk [RR], 0.75; 95% CI, 0.61 to 0.93). Two other meta-analyses that included AVID, CIDS, and CASH reached similar conclusions. (52, 53)

Table 6. Randomized Controlled Trials of Implantable Cardioverter Defibrillators for Secondary Prevention

Trials	Participants	Treatment Groups		Mortality Results	
		Group	N	RR	95% CI
AVID (1997) (45)	Patients resuscitated from near-fatal VT/VF, SVT with syncope, or SVT with LVEF ≤ 40% and symptoms	• ICD • AAD	• 507 • 509	0.66	0.51 to 0.85
CASH (2000) (46)	Patients resuscitated from cardiac arrest due to sustained ventricular arrhythmia	• ICD • Amiodarone • Metoprolol	• 99 • 92 • 97	0.82	0.60 to 1.11
CIDS (2000) (47)	Patients with VF, out-of-hospital cardiac arrest requiring defibrillation, VT with syncope, VT with rate ≥ 150/min causing presyncope or angina in patients with LVEF ≤ 35% or syncope with inducible VT	• ICD • Amiodarone	• 328 • 331	0.85	0.67 to 1.10
Wever et al. (1995) (49)	Patients with previous MI and resuscitated cardiac arrest due to VT or VF and inducible VT	• ICD • AAD	• 29 • 31	0.39	0.14 to 1.08
DEBUT (2003) (48)	Patients with SUDS or probable SUDS survivors with ECG abnormalities showing a RBBB-like pattern with ST elevation in the right	Pilot: • ICD • Beta-blocker therapy Main trial:	 • 10 • 10 • 37	• RR not calculable (DSMB stopped trial early due to	

	precordial leads and inducible VT/VF	• ICD • beta-blocker therapy	• 29	efficacy of ICD) • 7 deaths in beta-blockers vs 0 in ICD	

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

An analysis by Chan and Hayward (2005) using the National Veterans Administration database previously confirmed that this mortality benefit is generalizable to the clinical setting. (54) A cohort of 6996 patients in the National Veterans Administration database, from 1995 to 1999, who had new-onset ventricular arrhythmia and preexisting ischemic heart disease and congestive heart failure were included. Of those, 1442 patients had received an ICD. Mortality was determined through the National Death Index at 3 years from the hospital discharge date. The cohort was stratified by quintiles of a multivariable propensity score created using many demographic and clinical confounders. The propensity score-adjusted mortality reduction for ICD compared with no ICD was an RR of 0.72 (95% CI, 0.69 to 0.79) for all-cause mortality and an RR of 0.70 (95% CI, 0.63 to 0.78) for cardiovascular mortality.

Subsection Summary: Secondary Prevention in Adults

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

Secondary Prevention in Pediatric Populations

There is limited direct evidence on the efficacy of ICDs in the pediatric population. Most published studies have retrospectively analyzed small case series that included mixed populations with mixed indications for device placement. Some representative series were reviewed above (see Primary Prevention in Pediatric Populations section).

Subsection Summary: Secondary Prevention in Pediatric Populations

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

Adverse Events Associated With Transvenous Implantable Cardioverter Defibrillators

Systematic Reviews: Mixed Adverse Events

Characteristics and results of systematic reviews of adverse events associated with T-ICDs are described in Tables 7 and 8. Persson et al. (2014) conducted a systematic review of adverse events following ICD placement. (55) In-hospital serious adverse event rates ranged from 1.2% to 1.4%, most frequently pneumothorax (0.4% to 0.5%) and cardiac arrest (0.3%).

In another systematic review of adverse events following ICD placement, Ezzat et al. (2015) compared event rates reported in clinical trials of ICDs with those reported in the U.S. National Cardiovascular Data Registry. (56) Complication rates in the RCTs were higher than those in the U.S. registry, which reports only in-hospital complications (9.1% in the RCTs vs. 3.08% in the U.S. registry; p<.01). The overall complication rate was similar to that reported by Kirkfelt et al. (2014), in a population-based cohort study including all Danish patients who underwent a cardiac implantable electronic device procedure from 2010 to 2011 (562 [9.5%] of 5918 patients with at least 1 complication). (57)

van Rees et al. (2011) reported on results of a systematic review of RCTs assessing implant-related complications of ICDs and cardiac resynchronization therapy (CRT) devices. (58) Reviewers included 18 trials and 3 subgroup analyses. Twelve trials assessed ICDs, 4 of which used both thoracotomy and nonthoracotomy ICDs (n=951) and 8 of which used nonthoracotomy ICDs (n=3828). For nonthoracotomy ICD placement, the rates for in-hospital and 30-day mortality were 0.2% and 0.6%, respectively, and pneumothorax was reported in 0.9% of cases. For thoracotomy ICD placement, the average in-hospital mortality rate was 2.7%. For nonthoracotomy ICD placement, the overall lead dislodgement rate was 1.8%.

Olde Nordkamp et al. (2016) reported on a systematic review and meta-analysis of studies reporting on ICD complications in individuals with inherited arrhythmia syndromes. (59) Reviewers included 63 cohort studies with a total of 4916 patients (710 [10%] with arrhythmogenic right VT; 1037 [21%] with BrS; 28 [0.6%] with CPVT; 2466 [50%] with HCM; 162 [3.3%] with lamin *A/C* gene variants; 462 [9.4%] with LQTS; 51 [1.0%] with short QT syndrome).

Table 7. Systematic Reviews & Meta-Analysis Characteristics for Adverse Events Associated With Transvenous Implantable Cardioverter Defibrillators

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Persson et al. (2014) (55)	2005-2012	• 53 trials; • 35 cohorts	Patients receiving ICD placement	NR	Cohort studies	NR
Ezzat et al. (2015) (56)	2001-2011	18	Patients receiving ICD placement	6,796 (16 to 1,530)	RCTs	NR
Olde Nordkamp	1997-2014	63	Patients with	4,916 (NR)	Cohort studies	NR

et al. (2016) (59)			inherited arrhythmia syndromes receiving ICD placement			

ICD: implantable cardioverter defibrillator; NR: not reported; RCT: randomized controlled trials.

Table 8. Systematic Reviews & Meta-Analysis Results for Adverse Events Associated with Transvenous Implantable Cardioverter Defibrillators

Study	Rate of Adverse Events	Rates of Specific Complications
Persson et al. (2014) (55)		
Range	1.2% to 1.4%[1]	• Device-related: <0.1% to 6.4% • Lead-related: <0.1% to 3.9% • Infection: 0.2% to 3.7% • Inappropriate shock: 3% to 21%
Ezzat et al. (2015) (56)	9.1 (95% CI, 6.4% to 12.6%)	• Access-related: 2.1% (95% CI, 1.3% to 3.3%) • Lead-related: 5.8% (95% CI, 3.3% to 9.8%) • Generator-related: 2.7% (95% CI, 1.3% to 5.7%) • Infection: 1.5% (95% CI, 0.8% to 2.6%)
Olde Nordkamp et al. (2016) (59)	22% (4.4% per year; 95% CI, 3.6% to 5.2%; p<0.001)	• Lead malfunction: 10.3% • Infection: 3.0% (0.53% per year) • Inappropriate shock: 20% (4.7% per year; 95% CI, 4.2% to 5.3%; p<0.001)

CI: confidence interval.

[1] Only serious adverse events, which included cardiac arrest, cardiac perforation, cardiac valve injury, coronary venous dissection, hemothorax, pneumothorax, deep phlebitis, transient ischemic attack, stroke, myocardial infarction, pericardial tamponade, arteriovenous fistula, and in one study, lead dislodgement.

Systematic Reviews: Specific Complications

Lead Failure

The failure of leads in specific ICD devices led the U.S. Food and Drug Administration (FDA) to require St. Jude Medical to conduct 3-year postmarket surveillance studies to address concerns related to premature insulation failure and important questions related to follow-up of affected patients. (60) An evaluation by Hauser et al. (2010) found that 57 deaths and 48 serious cardiovascular injuries associated with device-assisted ICD or pacemaker lead extraction were reported to the FDA's Manufacturers and User Defined Experience database. (61)

Providencia et al. (2015) reported on a meta-analysis of 17 observational studies evaluating the performance of 49871 leads (5538 Durata, 10605 Endotak Reliance, 16119 Sprint Quattro, 11709 Sprint Fidelis, 5900 Riata). (62) Overall, the incidence of lead failure was 0.93 per 100 lead-years (95% CI, 0.88 to 0.98). In an analysis of studies restricted to head-to-head comparisons of leads, there were no significant differences in lead failure rates among nonrecalled leads (Endotak Reliance, Durata, Sprint Quattro).

Birnie et al. (2012) reported on clinical predictors of failure for 3169 Sprint Fidelis leads implanted from 2003 to 2007 at 11 centers participating in the Canadian Heart Rhythm Society study. (63) A total of 251 lead failures occurred, corresponding to a 5-year lead failure rate of 16.8%. Factors associated with higher failure rates included female sex (HR, 1.51; 95% CI, 1.14 to 2.04; p=.005), axillary vein access (HR, 1.94; 95% CI, 1.23 to 3.04), and subclavian vein access (HR, 1.63; 95% CI, 1.08 to 2.46). In a study from 3 centers reporting on predictors of Fidelis lead failures, compared with Quattro lead failures, Hauser et al. (2011) reported a failure rate for the Fidelis lead of 2.81% per year (vs. 0.42% per year for Quattro leads; p<.001). (64)

In a large prospective multicenter study, Poole et al. (2010) reported on complication rates associated with generator replacements and/or upgrade procedures of pacemaker or ICD devices, which included 1031 patients without a planned transvenous lead replacement (cohort 1) and 713 with a planned transvenous lead replacement (cohort 2). (65) A total of 9.8% and 21.9% of cohort 1 and 19.2% and 25.7% of cohort 2 had a single chamber ICD and a dual chamber ICD, respectively, at baseline. Overall periprocedural complication rates for those with a planned transvenous lead replacement were cardiac perforation in 0.7%, pneumothorax or hemothorax in 0.8%, cardiac arrest in 0.3%, and, most commonly, need to reoperate because of lead dislodgement or malfunction in 7.9%. Although rates were not specifically reported for ICD replacements, complication rates were higher for ICDs and CRT devices than pacemakers.

Ricci et al. (2012) evaluated the incidence of lead failure in a cohort of 414 patients given an ICD with Sprint Fidelis leads. (66) Patients were followed for a median of 35 months. Lead failures occurred in 9.7% (40/414) of patients, for an annual rate of 3.2% per patient-year. Most lead failures (87.5%) were due to lead fracture. The median time until recognition of lead failure, or until an adverse event, was 2.2 days. A total of 22 (5.3%) patients received an inappropriate shock due to lead failure.

Cheng et al. (2010) examined the rate of lead dislodgements in patients enrolled in a national cardiovascular registry. (67) Of 226,764 patients treated with an ICD between 2006 and 2008, lead dislodgement occurred in 2628 (1.2%). Factors associated with lead dislodgement were New York Heart Association (NYHA) class IV heart failure, atrial fibrillation or atrial flutter, a combined ICD and CRT device, and having the procedure performed by a non-electrophysiologist. Lead dislodgement was associated with an increased risk for other cardiac adverse events and death.

In another single-center study, Faulknier et al. (2010) reported on the time-dependent hazard of failure of Sprint Fidelis leads. (68) Over an average follow-up of 2.3 years, 38 (8.9%) of 426

leads failed. There was a 3-year lead survival rate of 90.8% (95% CI, 87.4% to 94.3%), with a hazard of fracture increasing exponentially over time by a power of 2.13 (95% CI, 1.98 to 2.27; p<.001).

Infection Rates

Several publications have reported on infection rates in patients receiving an ICD. Smit et al. (2010) published a retrospective, descriptive analysis of the types and distribution of infections associated with ICDs over a 10-year period in Denmark. (69) Of 91 total infections identified, 39 (42.8%) were localized pocket infections, 26 (28.6%) were endocarditis, 17 (18.7%) were ICD-associated bacteremic infections, and 9 (9.9%) were acute postsurgical infections. Nery et al. (2010) reported on the rate of ICD-associated infections among consecutive patients treated with an ICD at a tertiary referral center. (70) Twenty-four of 2417 patients had infections, for a rate of 1.0%. Twenty-two (91.7%) of the 24 patients with infections required device replacement. Factors associated with infection were device replacement (vs. de novo implantation) and use of a complex device (e.g., combined ICD plus CRT or dual-/triple-chamber devices). Sohail et al. (2011) performed a case-control study evaluating the risk factors for an ICD-related infection in 68 patients and 136 matched controls. (71) On multivariate analysis, the presence of epicardial leads (OR, 9.7; p=.03) and postoperative complications at the insertion site (OR, 27.2; p<.001) were significant risk factors for early infection. For late-onset infections, hospitalization for more than 3 days (OR, 33.1; p<.001 for 2 days vs. 1 day) and chronic obstructive pulmonary disease (OR, 9.8; p=.02) were significant risk factors.

Borleffs et al. (2010) also reported on complications after ICD replacement for pocket-related complications, including infection or hematoma, in a single-center study. (72) Of 3161 ICDs included, 145 surgical reinterventions were required for 122 ICDs in 114 patients. Ninety-five (66%) reinterventions were due to infection, and the remaining 50 (34%) were due to other causes. Compared with first-implanted ICDs, the occurrence of surgical reintervention in replacements was 2.5 (95% CI, 1.6 to 3.7) times higher for infection and 1.7 (95% CI, 0.9 to 3.0) times higher for non-infection-related causes.

Inappropriate Shocks

Inappropriate shocks may occur with ICDs due to faulty sensing or sensing of atrial arrhythmias with rapid ventricular conduction. These shocks may lead to a reduced quality of life and risk of ventricular arrhythmias. In the MADIT II trial (described above), 1 or more inappropriate shocks occurred in 11.5% of ICD subjects and were associated with a greater likelihood of mortality (HR, 2.29; 95% CI, 1.11 to 4.71; p=.02). (73)

Tan et al. (2014) conducted a systematic review to identify outcomes and adverse events associated with ICDs with built-in therapy-reduction programming. (74) Six randomized trials and 2 nonrandomized cohort studies (N=7687 patients) were included (3598 with conventional ICDs, 4089 therapy-reduction programming). A total of 267 (4.9%) patients received inappropriate ICD shocks, 99 (3.4%) in the therapy-reduction group and 168 (6.9%) in the conventional programming group (RR, 0.50; 95% CI, 0.37 to 0.61; p<.001). Therapy-reduction

programming was associated with a significantly lower risk of death than conventional programming (RR, 0.30; 95% CI, 0.16 to 0.41; p<.001.)

Sterns et al. (2016) reported on results of an RCT comparing a strategy using a prolonged VF detection time to reduce inappropriate shocks with a standard strategy among secondary prevention patients. (75) This trial reported on a prespecified subgroup analysis of the PainFree SST trial, which compared standard with prolonged detection in patients receiving an ICD for secondary prevention. Patients treated for secondary prevention indications were randomized to a prolonged VF detection period (n=352) or a standard detection period (n=353). At 1-year, arrhythmic syncope-free rates were 96.9% in the intervention group, and 97.7% in the control group (rate difference, -1.1%; 90% lower confidence limit, -3.5%; above the prespecified noninferiority margin of -5%; p=.003 for noninferiority).

Auricchio et al. (2015) assessed data from the PainFree SST trial, specifically newer ICD programming strategies for reducing inappropriate shocks. (76) A total of 2790 patients with an indication for ICD placement were given a device programmed with a SmartShock Technology designed to differentiate between ventricular arrhythmias and other rhythms. The inappropriate shock incidence for dual-/triple-chamber ICDs was 1.5% at 1 year (95% CI, 1.0% to 2.1%), 2.8% at 2 years (95% CI, 2.1% to 3.8%), and 3.9% at 3 years (95% CI, 2.8% to 5.4%).

Other Complications

Lee et al. (2010) evaluated rates of early complications among patients enrolled in a prospective, multicenter population-based registry of all newly implanted ICDs in Ontario, from 2007 through 2009. (77) Of 3340 patients receiving an ICD, major complications (lead dislodgement requiring intervention, myocardial perforation, tamponade, pneumothorax, infection, skin erosion, hematoma requiring intervention) within 45 days of implantation occurred in 4.1% of new implants. Major complications were more common in women, in patients who received a combined ICD-CRT device, and in patients with a left ventricular end-systolic size of larger than 45 mm. Direct implant-related complications were associated with a major increase in early death (HR, 24.9; p<.01).

Furniss et al. (2015) prospectively evaluated changes in high-sensitivity troponin T levels and ECG results that occur during ICD placement alone, ICD placement with testing, and ICD testing alone. (78) The 13 subjects undergoing ICD placement alone had a median increase in high-sensitivity troponin T level of 95% (p=.005), while the 13 undergoing implantation and testing had a median increase of 161% (p=.005). Those undergoing testing alone demonstrated no significant change in high-sensitivity troponin T levels.

SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS IN INDIVIDUALS WITH A CONTRAINDICATION TO A TRANSVENOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

Clinical Context and Therapy Purpose

The purpose of subcutaneous implantable cardioverter defibrillators (S-ICD) placement in individuals with a contraindication to transvenous T-ICD is to provide a treatment option that is

an alternative to or an improvement on existing therapies such as medical management without ICD placement.

The following PICO was used to select literature to inform this policy.

Populations
The population of interest is individuals who need an ICD and have a contraindication to a T-ICD.

There are no defined guidelines for the selection of S-ICD versus T-ICD. Currently, S-ICDs are generally considered in the following situations:

- Individuals at high risk of infection, inadequate venous access, and any individuals without a pacing indication.
- Younger individuals due to the expected longevity of the implanted leads and a desire to avoid chronic transvenous leads (e.g., individuals with HCM, congenital cardiomyopathies, or inherited channelopathies).
- Individuals at high risk for bacteremia, such as individuals on hemodialysis or with chronic indwelling endovascular catheters.
- Individuals with challenging vascular access or prior complications with T-ICDs.

Interventions
The therapy being considered is S-ICD. An ICD is a device designed to monitor an individual's heart rate, recognize VF or VT, and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. A S-ICD, which lacks transvenous leads, is intended to reduce lead-related complications. The S-ICD is intended for individuals who have standard indications for an ICD, but who do not require pacing for bradycardia or antitachycardia overdrive pacing for VT. The S-ICD is proposed to benefit individuals with limited vascular access (including individuals undergoing renal dialysis or children) or those who have had complications requiring T-ICDs explantation.

The S-ICD is comprised of a pulse generator and single shocking coil running along the left parasternal margin. These are both implanted subcutaneously without endovascular access. The electrode is designed to be implanted using anatomical landmarks only without the need for fluoroscopy or other medical imaging systems during the surgical implant procedure.

Comparators
The comparator of interest is medical management without ICD placement.

Outcomes
The general outcomes of interest are OS, morbid events, quality of life, treatment-related mortality, and treatment-related morbidity. Table 9 describes outcomes of interest related to quality of life and treatment-related morbidity for individuals who need an ICD and have a contraindication to a T-ICD.

Table 9. Outcomes of Interest for Individuals Who Need an Implantable Cardioverter Defibrillator and Have a Contraindication to a Transvenous Implantable Cardioverter Defibrillator

Outcomes	Details	Timing
Quality of life	Can be assessed by patient reported data such as surveys and questionnaires	1 week to 5 years
Treatment-related mortality	Can be assessed by rates of adverse events, including inappropriate shock, lead failure, infection, and other complications	1 week to 5 years

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Randomized Trials

Healey et al. (2022) published 2.5-year interim results of the randomized, multicenter Avoid Transvenous Leads in Appropriate Subjects (ATLAS S-ICD) trial. (79) This trial included 544 individuals (141 female) with a primary or secondary prevention indication for an ICD who were younger than 60 years, had a cardiogenic phenotype, or had prespecified risk factors for lead complications. Of those, 503 were randomized to S-ICD (n=251) or T-ICD (n=252). The mean age of the included patients was 49 years. The primary outcome focused on perioperative complications that were lead-related. Within 6 months of implantation, perioperative, lead-related complications occurred in 1 patient (0.4%) with an S-ICD and in 12 patients (4.8%) with T-ICD (risk difference, -4.4%; 95% CI, -6.9 to -1.9; p=.001). Overall, complications between groups were similar at 6 months, including device-related infection requiring surgery (S-ICD, 11 patients vs. T-ICD, 14 patients; risk difference, -1.2; 95% CI, -2.4 to 0.1). More patients in the S-ICD group experienced ICD site pain on the day of implant (p<.001) and 1 month later (p=.035) compared to T-ICD patients. There were no differences in pain scores at 6 months. After a follow-up of 2.5 years, there was a trend for more inappropriate shocks with S-ICD (S-ICD, 16 patients vs. T-ICD, 7 patients; HR, 2.37; 95% CI, 0.98 to 5.77), but no increase in failed appropriate ICD shocks (HR, 0.61; 95% CI, 0.15 to 2.57); however, this trial was not powered to detect differences in clinical shock outcomes. Although the ATLAS trial found a decreased risk of lead-related perioperative complications, it was underpowered to detect differences in clinical shock outcomes; extended follow-up is ongoing.

Nonrandomized Trials

Several nonrandomized trials and registry studies have reported outcomes for patients receiving a S-ICD, with follow up periods up to 5.8 years (Table 10). The Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry (EFFORTLESS) is a multicenter European registry reporting outcomes for patients treated with S-ICD. Several publications from EFFORTLESS (Evaluation of Factors Impacting Clinical Outcome and Cost Effectiveness of the S-ICD), the pivotal trial submitted to the FDA for the investigational device exemption, and other studies are summarized in Table 10. In the EFFORTLESS registry, among 472 enrolled patients, the complication-free rate was 94% at 360 days and there was a 13.1% inappropriate shock rate at 3 years' follow-up. Gold et al. (2021) reported 18-month data from the UNTOUCHED study, a multinational, prospective trial designed to assess the performance of the S-ICD in primary prevention patients with a low LVEF and NYHA II/III heart failure or coronary artery disease. (80) At 18 months, the complication-free rate was 92.7% and the inappropriate shock-free rate was 95.9%. One-year data from the S-ICD Post Approval Study and 18-month data from the UNTOUCHED study have been published; these studies are ongoing. The S-ICD System Post-Approval Study (PAS) is a nonrandomized, standard-of-care registry in the United States that has prospectively enrolled and followed S-ICD recipients. (81) Over the first 1-year postimplantation, complications were observed in 119 patients, with a complication-free rate at 1 year of 92.5%. The most common complication was device system infection in 44 of 1637 patients. Gold et al. (2022) reported on the 3-year postimplantation follow-up data of the S-ICD PAS. (82) Within 3 years, infection was observed in 55 patients (3.3%), with 69% of infections occurring within 90 days of implantation and the majority (92.7%) within 1 year of implantation. No patient included in the registry had more than 1 infection, and no infections occurred after 2 years in the cohort. The annual post-infection mortality rate was 0.6%. Based on their findings, the authors developed a risk score for likelihood of developing an infection, with diabetes, age ≥55 years, previous ICD implant, or LVEF ≤30% all identified as contributing risk to S-ICD-related infection. This risk score has not been externally validated. The S-ICD PAS study has been completed (NCT01736618), but 5-year results have yet to be published. Five-year data from the PAS should provide more information on longer-term adverse events such as lead failure and the need for device replacement.

Table 10. Summary of Nonrandomized Trials of Subcutaneous Implantable Cardioverter Defibrillators

Study; Trial	Countries	N	Mean FU	Results	
				Outcomes	**Values**
Burke et al. (2020) (115) S-ICD PAS NCT01736618	U.S.	1637	1 y	• Complication-free rate at 1 y • Appropriate shock rate at 1 y • Inappropriate shocks at 1 y • Death at 1 y	• 92.5% • 5.3% • 6.5% • 5.4%

Gold et al. (2021) (80) UNTOUCHED	U.S., Canada, Europe	1111	18 months	• Inappropriate shock-free rate at 18 months • Appropriate shock-free rate at 18 months • Complication-free rate at 18 months • Overall survival rate at 18 months	• 94.8% • 94.3% • 92.7% • 94.9%
Lambiase et al. (2014) (83); Olde Nordkamp et al. (2015) (84); Boersma et al. (2017) (85) EFFORTLESS S-ICD Registry	10 European countries	• 985 • 928 • 697 • 498 • 300 • 82	• 3.1 y • 1 y • 2 y • 3 y • 4 y • 5 y	• Complication rates by 360 d • Inappropriate shocks by 360 d • Complication rates through follow-up • Inappropriate shocks through follow-up • Appropriate shocks through follow-up	• 8.4% • 8.1% • 11.7% • 11.7% • 13.5%
Weiss et al. (2013) (86) IDE study	U.S., U.K., New Zealand, Netherlands	330	11 mo	• Implanted successfully • Complication-free at 180 d • Inappropriate shocks • Episodes of discrete spontaneous VT or VF, all successfully converted	• 95% • 99% • 13% • 38

Burke et al. (2015) (81); Boersma et al. (2016) (87); Lambiase et al. (2016) (88) EFFORTLESS and IDE studies	Multiple European countries, U.S., New Zealand	882	651 d	• Complications within 3 y
				• Infections requiring device removal or revision
				• Annual mortality rate
				• 2-y cumulative mortality
				• Incidence of therapy for VT or VF:
				  ○ 1 year
				  ○ 2 years
				  ○ 3 years
				• Incidence of inappropriate shock at 3 y
					• 11%
					• 1.7%
					• 1.6%
					• 3.2%
					
					• 5.3%
					• 7.9%
					• 10.5%
					• 13.1%

Bardy et al. (2010) (89);	Europe, New Zealand	55	5.8 y	• Devices replaced • Devices explanted • Replaced with T-ICD	• 26 (47%) • 5 (9%)

Theuns et al. (2015) (90)				• Shocks recorded in 16 (29%) patients	• 4 (7%) • 119
Olde Nordkamp et al. (2012) (91)	Netherlands	118	18 mo	• All device-related complications • Infections • Dislodgements of device/leads • Skin erosion • Battery failure • Replaced with T-ICD • Appropriate shocks experienced in 8 patients • Total inappropriate shocks delivered to 15 (13%) patients • Deaths (cancer, progressive heart failure)	• 14% • 5.9% • 3.3% • 1.7% • 1.7% • 1 (0.8%) • 45 • 33 • 2

d: day(s); FU: follow-up; mo: month(s); S-ICD: subcutaneous implantable cardioverter defibrillator; T-ICD: transvenous implantable cardioverter defibrillator; U.K.: United Kingdom; U.S.: United States; VF: ventricular fibrillation; VT: ventricular tachycardia; y: year(s).

Section Summary: Subcutaneous-Implantable Cardioverter Defibrillators in Individuals with a Contraindication to a Transvenous Implantable Cardioverter Defibrillator

An RCT found that S-ICD significantly decreased 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 studies have suggested that S-ICDs are as effective as T-ICDs at terminating laboratory-induced ventricular arrhythmias. Data from large patient registries have suggested that S-ICDs are effective at terminating ventricular arrhythmias when they occur. Given the need for cardioverter defibrillation for SCD risk in this population, with the assumption that appropriate shocks are lifesaving, these studies suggest S-ICDs, in patients with contraindication to T-ICD, are likely improvements over medical management alone.

SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS IN INDIVIDUALS WITH NO CONTRAINDICATION TO A TRANSVENOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

Clinical Context and Therapy Purpose

The purpose of S-ICD placement in individuals with no contraindication to a T-ICD is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The population of interest is individuals who need an ICD and have no contraindication to a T-ICD.

There are no defined guidelines for the selection of S-ICD versus T-ICD. Currently, S-ICDs are generally considered in the following situations:

- Individuals at high risk of infection, inadequate venous access, and any patient without a pacing indication.
- Younger individuals due to the expected longevity of the implanted leads and a desire to avoid chronic transvenous leads (e.g., patients with HCM, congenital cardiomyopathies, or inherited channelopathies).
- Individuals at high risk for bacteremia, such as individuals on hemodialysis or with chronic indwelling endovascular catheters.
- Individuals with challenging vascular access or prior complications with T-ICDs.

Interventions

The therapy being considered is S-ICD. An ICD is a device designed to monitor an individual's heart rate, recognize VF or VT, and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. An S-ICD, which lacks transvenous leads, is intended as an alternative to T-ICD to reduce lead-related complications. The S-ICD is comprised of a pulse generator and single shocking coil running along the left parasternal margin. These are both implanted subcutaneously without endovascular access. The electrode is designed to be implanted using anatomical landmarks only without the need for fluoroscopy or other medical imaging systems during the surgical implant procedure.

Comparators

The comparator of interest is T-ICD placement.

Outcomes

The general outcomes of interest are OS, morbid events, quality of life, treatment-related mortality, and treatment-related morbidity. Outcomes should be assessed from 1 week to 5 years or longer.

Specific outcomes include the following:

- Sudden cardiac death;
- All-cause mortality;
- Adverse events including nonlead-related complications (device infection, hematoma, pneumothorax, pericardial effusion), inappropriate shocks, device failure; and lead-related complications;
- Cardiovascular mortality;
- Health-related quality of life;
- Hospital re-admission.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Systematic Review

da Silva Menezes Júnior et al. (2024) conducted a systematic review and meta-analysis to compare the safety and efficacy of S-ICDs versus T-ICDs in patients with HCM. (92) A crosswalk of studies included in the systematic review is provided in Table 11. Table 12 outlines the characteristics of this meta-analysis. Seven observational studies were included, encompassing 4347 patients (1022 with S-ICD and 3325 with T-ICD). The results demonstrated that the incidence of appropriate shocks (primary outcome) (OR, 0.49; 95% CI, 0.22 to 1.08; p=.08) and inappropriate shocks (secondary outcome) (OR, 1.03; 95% CI, 0.57 to 1.84; p=.93) did not differ significantly between groups (see Table 13). However, the S-ICD group experienced significantly fewer device-related complications (OR, 0.52; 95% CI, 0.30 to 0.89; p=.02).

Table 11. Comparison of Studies Included in SR & M-A

Study	da Silva Menezes Júnior (2024) (92)
Francia (2023)	●
Buongiorno (2022)	●
Jankelson (2022)	●
Steiger (2019)	●
Klein (2017)	●
Timmers (2017)	●
Lambiase (2016)	●

M-A: meta-analysis; SR: systematic review.

Table 12. SR & M-A Characteristics

Study	Dates	Trials	Participants	N (range)	Design	Duration (mean)
da Silva Menezes Júnior (2024) (92)	2004 to 2023	7	Patients with HCM who were implanted with S-ICD or T-ICD	4347 (27 to 2289)	Cohort	6 months to 8 years

M-A: meta-analysis; S-ICD: subcutaneous implantable cardioverter defibrillator; SR: systematic review; T-ICD: transvenous implantable cardioverter defibrillator.

Table 13. SR & M-A Results

Study	Appropriate shocks	Inappropriate shocks	Device-related complications
da Silva Menezes Júnior (2024) (92)			
S-ICD (events/total)	78/994	113/1022	22/375
T-ICD (events/total)	432/3149	52/3101	298/2044
Pooled effect (95% CI)	OR, 0.49 (0.22 to 1.08)	OR, 1.03 (0.57 to 1.84)	OR, 0.52 (0.30 to 0.89)
I^2	75%	65%	4&

CI: confidence interval; M-A: meta-analysis; OR: odds ratio; S-ICD: subcutaneous implantable cardioverter defibrillator; SR: systematic review; T-ICD: transvenous implantable cardioverter defibrillator.

Randomized Controlled Trials

The Prospective, Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy (PRAETORIAN) trial was a noninferiority RCT that compared S-ICD to T-ICD in 849 patients with an indication for ICD but no indication for pacing (Table 14). (93) The trial is the only RCT on the effect of an S-ICD with health outcomes. Patients were eligible if they were 18 years and older with a class I or IIa indication for ICD therapy for primary or secondary prevention, according to professional society guidelines, and no indication for pacing. The median age of enrolled patients was 63 years (interquartile range, 55 to 70). Most enrolled patients were diagnosed with ischemic and nonischemic cardiomyopathy and 19.7% were women. The median LVEF was 30%.

The primary endpoint in PRAETORIAN was the composite of device-related complications and inappropriate shocks (see Table 14 for outcome definitions). The trial was designed to test the hypothesis of noninferiority of the S-ICD as compared with the T-ICD with respect to the time from device implantation to the first occurrence of a primary endpoint event. The primary analysis was the modified intention-to-treat (ITT) cohort (i.e., patients were analyzed in accordance to the treatment group to which they were originally assigned, regardless of withdrawals, losses to follow-up, or crossovers). Patients who did not receive a device and patients who proved ineligible for 1 of the treatments due to incomplete or inadequate screening were excluded from this analysis. In the as-treated cohort, patients were analyzed in the group of the specific ICD type which they received at initial implantation regardless of randomization result, withdrawals, losses to follow-up, or crossovers. The noninferiority margin for the upper boundary of the 95% CI for the HR was set at 1.45.

The trial's main results are summarized in Tables 15 to 16. The S-ICD was noninferior to the T-ICD on the composite endpoint of device-related complications and inappropriate shocks. The HR for the primary endpoint was 0.99 (95% CI, 0.71 to 1.39; noninferiority margin, 1.45; p=.01 for noninferiority; p=.95 for superiority). Results for the modified ITT analysis and as-treated analysis did not differ. 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. Secondary endpoints and mortality results are summarized in Table 16. There were

more deaths from any cause in the S-ICD group than in the T-ICD group (16.4% vs. 13.1%; HR, 1.23; 95% CI, 0.89 to 1.70), but the number of SCDs did not differ between groups (18 in each group). There were more appropriate shocks in the S-ICD group (19.2% vs. 11.5%; HR, 1.52; 95% CI, 1.08 to 2.12). Other secondary endpoints did not differ between the groups.

While the rate of SCD in the PRAETORIAN trial was low (18 patients in each group), the number of overall deaths was 151 and actually occurred more frequently than the composite outcome (Table 16). The HR for all-cause mortality was 1.23 (95% CI, 0.89 to 1.70). The PRAETORIAN trial investigators conducted competing risks analyses to account for discontinuation of follow-up before the primary endpoint had occurred in 1) the modified ITT population with competing risk of death, and 2) the true ITT population with competing risk of death and discontinuation of follow-up. These analyses led to consistent estimates of the HR (and 95% CI) for the primary endpoint.

Device and lead complications occurred more frequently in the T-ICD group (Table 17).

Table 14a. PRAETORIAN Trial Characteristics

Study	Countries	Sites	Dates	Participants
PRAETORIAN Knops et al. (2020) (93)				
	Europe (92.4%) and U.S.	39	March 2011 through January 2017	Eligibility: 18 years and older; Class I or IIa indication for ICD therapy for primary or secondary prevention, according to professional society guidelines. Exclusions: Previous ICD implantation, unsuitability for S-ICD therapy according to QRS-T–wave sensing analysis, and indications for either bradycardia pacing or biventricular pacing.

ICD: implantable cardioverter defibrillator; PRAETORIAN: Prospective, Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy; S-ICD: subcutaneous implantable cardioverter defibrillator; U.S.: United States.

Table 14b. PRAETORIAN Trial Characteristics

Study	Interventions		Primary Endpoint Definitions
PRAETORIAN Knops et al. (2020) (93)			
	Active	**Comparator**	
	S-ICD (n = 426)	T-ICD (n = 423)	Composite of device-related complications and inappropriate shocks. Inappropriate shocks were defined as shock therapy for anything else but VF or VT. For example, supraventricular tachycardia with fast ventricle response (including sinus tachycardia and atrial fibrillation), T-wave oversensing, detection of physiological- or

			other non-cardiac activity and lead- or device failure. Complications included: • device infection that led to the extraction of the lead or generator; • pocket hematoma that led to drainage, blood transfusion, or prolongation of hospitalization; • device-related thrombotic events; • pneumothorax or hemothorax that led to intervention or prolongation of hospitalization; • cardiac perforation or tamponade; • lead repositioning or replacement; • other complications related to the lead or generator that led to medical or surgical intervention.

ICD: implantable cardioverter defibrillator; PRAETORIAN: Prospective, Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy; S-ICD: subcutaneous implantable cardioverter defibrillator; T-ICD: transvenous implantable cardioverter defibrillator; VF: ventricular fibrillation; VT: ventricular tachycardia.

Table 15. PRAETORIAN Trial Results - Primary Composite Endpoint and Components

Study	Endpoint (4-year cumulative incidence)	S-ICD (n=426)	T-ICD (n=423)	Hazard Ratio (95% CI)
PRAETORIAN **Knops et al. (2020) (93)**	Primary composite endpoint (modified ITT analysis)	68 (15.1%)	68 (15.7%)	0.99 (0.71 to 1.39); p=.01 for noninferiority; p=.95 for superiority
	Device-related complication	31 (5.9%)	44 (9.8%)	0.69 (0.44 to 1.09)
	Inappropriate shock	41 (9.7%)	29 (7.3%)	1.43 (0.89 to 2.30)
	Primary composite endpoint (as-treated analysis)	68/428 (15.9%)	68/421 (16.2%)	0.98 (0.70 to 1.37)

CI: confidence interval; ICD: implantable cardioverter defibrillator; ITT: intention-to-treat; PRAETORIAN: Prospective, Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy; S-ICD: subcutaneous implantable cardioverter defibrillator; T-ICD: transvenous implantable cardioverter defibrillator.

Table 16. PRAETORIAN Trial Results - Secondary Endpoints

Study	End Point	S-ICD (N=426)	T-ICD (N=423)	Hazard Ratio (95% CI)
PRAETORIAN **Knops et al. (2020) (93)**	Death from any cause	83 (16.4%)	68 (13.1%)	1.23 (0.89 to 1.70)
	Sudden cardiac death	18 (4.2%)	18 (4.3%)	
	Other cardiovascular death	34 (8.0%)	28 (6.6%)	
	Noncardiovascular death	31 (7.3%)	22 (5.2%)	
	Appropriate shock therapy	83 (19.2%)	57 (11.5%)	1.52 (1.08 to 2.12)
	Antitachycardia pacing (appropriate)	6 (0.6%)	54 (12.9%)	
	Antitachycardia pacing (inappropriate)	1 (0.3%)	30 (7.2%)	
	Major adverse cardiac event	64 (13.3%)	80 (16.4%)	0.80 (0.57 to 1.11)
	Hospitalization for heart failure	79 (17.4%)	74 (16.1%)	1.08 (0.79 to 1.49)
	Crossover to other study device	18 (4.3%)	11 (2.7%)	1.64 (0.77 to 3.47)

CI: confidence interval; ICD: implantable cardioverter defibrillator; PRAETORIAN: Prospective, Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy; S-ICD: subcutaneous implantable cardioverter defibrillator; T-ICD: transvenous implantable cardioverter defibrillator.

Table 17. PRAETORIAN Trial Results - Specific Complications

Study	Endpoint	S-ICD (N=426)	T-ICD (N=423)
PRAETORIAN **Knops et al. (2020) (93)**	Complications within the first 30 days	3.8%	4.7%
	Lead-related complications	1.4%	6.6%
	Device-related complications	31 (5.9%)	44 (9.8%)
	Infection	4 (1 lead-related)	8 (5 lead-related)

	Bleeding	8	2
	Thrombotic event	1	2
	Pneumothorax	0	4
	Lead perforation	0	4
	Tamponade	0	2
	Lead repositioning	2	7
	Other lead or device complication	19	20
	Lead replacement	3	9
	Device malfunction	4	6
	Sensing issues	4	0
	Pacing indication	5	1
	Implantation failure	0	3
	Defibrillation test failure	3	0
	Pain or discomfort	2	3

CI: confidence interval; ICD: implantable cardioverter defibrillator; PRAETORIAN: Prospective, Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy; S-ICD: subcutaneous implantable cardioverter defibrillator; T-ICD: transvenous implantable cardioverter defibrillator.

Knops et al. (2024) reported on quality-of-life outcomes in patients enrolled in PRAETORIAN. (94) Using the Duke Activity Status Index (DASI) and the 36-Item Short Form Health Survey (SF-36), the study found no significant differences in quality of life between device types at baseline, discharge, 12 months, or 30 months. At discharge, both groups experienced significant declines in DASI (−4.9 points; 95% CI, −6.3 to −3.6; p<.001) and bodily pain (−6.8 points; 95% CI, −9.5 to −4.1; p<.001), while mental health remained unchanged (−0.4 points; 95% CI, −2.0 to 1.2; p=.63). These effects were not sustained at longer follow-up. Among patients who experienced a shock within 90 days of completing a questionnaire (n=29), quality of life was significantly worse in social functioning (p=.008) and role limitations due to emotional problems (p=.001), though not in mental health (p=.104). These effects were similar regardless of shock appropriateness or device type. No significant quality of life differences were observed among patients who experienced complications requiring invasive intervention (n=22), and subgroup analyses revealed no differences by sex or age, though patients with BMI <25 kg/m² had better mental health scores at 30 months with TV-ICD than with S-ICD (p=.02).

Study relevance, design, and conduct limitations of PRAETORIAN are summarized in Tables 18 and 19. The choice of a composite primary endpoint poses several challenges to interpreting the results of PRAETORIAN. In PRAETORAN, the components of the composite endpoint were discordant; device-related complications were expected to favor S-ICD and inappropriate shocks were expected to favor T-ICD. The timing of the components of the composite outcome assessment is important in interpreting the study results and explaining expected treatment results to patients. Early benefit could favor 1 treatment over another, and results could change with longer follow-up. This is an important point to consider when assessing complications such

as lead failure, which continue to increase over the life of the device. Additionally, because the composite was not used in earlier trials of the active comparator, there is no historical data on which to derive the expected performance of the active control. The inappropriate shock rate was based on results from the MADIT-RT trial, which compared programmed high-rate or delayed T-ICD therapy, and the expected rate of complications was based on results from MADIT-RT and the SCD-HeFT trial, which compared amiodarone to T-ICD. To estimate the expected event rate in PRAETORIAN, the researchers combined these 2 endpoints to arrive at the expected 17.2% event rate for the composite primary outcome. The study authors do not cite any previous RCTs that used the composite endpoint of complications and inappropriate shocks. All-cause mortality was a primary endpoint in several previous RCTs of T-ICD. However, the PRAETORIAN trial protocol (2012) noted that all-cause mortality was not chosen as the primary endpoint because "mortality event rates in both groups are presumed to be low, leading to an extremely large trial size if this would serve as a primary endpoint." The protocol also states that safety and efficacy of the S-ICD have been demonstrated in earlier trials and that the composite endpoint was "preferred above all-cause mortality, as practical, reasonably achievable, and pertinent to most cardiologists."

Another major limitation of PRAETORIAN was that the median 48-month follow-up was not long enough to determine complications over the life of the device. In fact, the PRAETORIAN study authors note in their discussion, "longer-term follow-up of this cohort will be important because the incidence of lead-related complications increases over time with the transvenous ICD and because battery longevity is a limiting factor for the subcutaneous ICD." Five-year data from the S-ICD PAS should provide more information on longer-term adverse events such as lead failure and need for device replacement.

Quality of life data from PRAETORIAN shows that while the type of ICD does not influence long-term quality of life, the experience of receiving a shock—appropriate or not—can transiently negatively affect patients' emotional and social well-being.

Finally, the under enrollment of women in the trial (19.7%) potentially limits the applicability of its results, although a subgroup analysis by sex was consistent with the primary analysis on the composite endpoint (HR in women, 0.65; 95% CI, 0.28 to 1.47).

Table 18. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Compartor[c]	Outcomes[d]	Duration of Follow-up[e]
PRAETORIAN **Knops et al. (2020) (93)**	4. Women under-enrolled (19.7%)			6. Composite endpoint with discordant outcomes	2. 4-year median follow-up not sufficient to assess complications over the life of the device

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 19. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
PRAETORIAN **Knops et al. (2020) (93)**		2. Clinical-events committee was not blinded to treatment assignment	2. Quality of life data collected but not yet published			5. Rationale for choice of noninferiority margin unclear

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Comparative Observational Studies

Several observational studies have directly compared T-ICD to S-ICD. These studies are briefly described in Table 20. All studies were performed in the U.S. and/or Europe. Nonrandomized controlled studies have reported success rates in terminating laboratory-induced VF that are similar to T-ICD. However, there is scant evidence on comparative clinical outcomes of both

types of ICD over longer periods. Adverse event rates are uncertain, with variable rates reported.

Table 20. Summary of Observational Comparative Studies of Subcutaneous Implantable Cardioverter Defibrillators and Transvenous Implantable Cardioverter Defibrillators

Study	Study Type	N	Follow-up	Results			
				Outcomes	T-ICD	S-ICD	DC T-ICD
Mithani et al. (2018) (95)	Matching based on dialysis status, sex, age	182 (91 matched pairs)	180 days	• Inappropriate shocks • Infection requiring explant • Death from all causes • Total with adverse event or death	2.2% 1.1% 2.2% 7.7%	1.1% 3.3% 2.2% 5.5%	
Honarbakhsh et al. (2017) (96)	Propensity matched case-control	138 (69 matched pairs)	32 months[a]	• Total device-related complication • Infections • Inappropriate shocks • Failure to cardiovert VA	29% 5.8% 8.7% 1.4%	9% 1.4% 4.3% 1.4%	
Kobe et al. (2017) (97)	Sex- and age-matched case control	120 (60 pairs); 84 pairs analyzed	942 days vs 622 days	• Post-traumatic stress disorder • Major depression • SF-12 physical well-being score • SF-12 mental well-being score	14.3% 9.5% 40 52	14.3% 4.8% 47 52	
Pedersen et al. (2016) (98)	Retrospective analysis of propensity-matched cohort	334 (167 matched pairs)	6 months	• SF-12 physical well-being score • SF-12 mental well-being score	43 45	44 45	
Brouwer et al. (2016) (99)	Retrospective analysis of propensity-	280 (140 matched pairs)	5 years	• Overall complications	18% 11.5%	14% 0.8%	

	matched cohort			• Lead complications • Non-lead complications • Infections • Appropriate ICD intervention (HR=2.4; 95% CI, NR; p=0.01) • Inappropriate ICD intervention (HR=1.3; 95% CI, NR; p=0.42) • Survival	2.2% 3.6% 31% 30% 95%	9.9% 4.1% 17% 21% 96%	
Friedman et al. (2016) (100)	Retrospective analysis of propensity-matched cohort from NCDR for ICD	5,760 (1,920 matched groups)	NR	• Any in-hospital complications • Deaths • Infections • Lead dislodgements • Pneumothorax	0.6% 0.1% 0% 0.2% 0.2%	0.9% 0.2% 0.05% 0.1% 0%	1.5% 0.05% 0.1% 0.6% 0.3%
Kobe et al. (2013) (101)	Sex- and age-matched case-control	138 (69 matched pairs)	217 days[a]	• Pericardial effusion • Successful termination of induced VF • Appropriate shocks • Inappropriate shocks	1 91% 9 3	0 90% 3 5	

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

Section Summary: Subcutaneous Implantable Cardioverter Defibrillators In Patients With No Contraindications to a Transvenous Implantable Cardioverter Defibrillator

The 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 (HR, 0.99; 95% 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. 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. In a systematic review of cohort studies comparing S-ICD and T-ICD in patients with HCM, the S-ICD group experienced significantly fewer device-related complications, with no significant differences in appropriate or inappropriate shocks between treatments. Ongoing studies could provide additional evidence on complications and device safety over the longer term.

EXTRAVASCULAR IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

Clinical Context and Therapy Purpose

The purpose of extravascular ICD (E-ICD) placement in individuals with no contraindication to a T-ICD is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The population of interest is individuals who need an ICD.

There are no defined guidelines for the selection of E-ICD versus T-ICD.

Interventions

The therapy being considered is E-ICD. An ICD is a device designed to monitor an individual's heart rate, recognize VF or VT, and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. An E-ICD is intended as an alternative to T-ICD to reduce lead-related complications, and as an alternative to S-ICD since S-ICD are less effective at stopping ventricular arrhythmias. The E-ICD lead is placed substernally at the anterior mediastinum, and the pulse generator is placed at the left midaxillary region. The pulse generator size and energy capacity are similar to T-ICD devices, which overcomes some of the limitations of S-ICD devices. However, E-ICD still have a risk of cardiac injury or perforation.

Comparators

The comparator of interest is T-ICD placement.

Outcomes

The general outcomes of interest are OS, morbid events, quality of life, treatment-related mortality, and treatment-related morbidity. Outcomes should be assessed from 1 week to 5 years or longer.

Specific outcomes include the following:

- Sudden cardiac death;

- All-cause mortality;
- Adverse events including nonlead-related complications (device infection, hematoma, pneumothorax, pericardial effusion), inappropriate shocks, device failure; and lead-related complications;
- Cardiovascular mortality;
- Health-related quality of life;
- Hospital re-admission.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Nonrandomized Study

Following several smaller preliminary studies with E-ICD, Friedman et al. (2022) published a prospective, nonrandomized, global clinical study in patients who received an E-ICD. (102) All patients had a class I or IIa indication for ICD placement (81.6% for primary prevention, 18.0% for secondary prevention). At baseline, 83.9% had cardiomyopathy, 42.7% had ventricular arrhythmias, and 13.9% had atrial fibrillation. The primary efficacy endpoint was successful defibrillation at implantation, and safety was assessed for 6 months. Of the entire study population (N=356), 302 patients were successfully defibrillated after ventricular arrhythmia was induced; 98.7% of these patients had successful defibrillation. At 6 months, 92.6% of patients had not experienced a major complication. Major complications occurred in 23 patients, none of which had further sequelae. Inappropriate shocks (n=118) occurred in 29 patients during follow-up (median number of shocks per patient, 2). The most common reasons for inappropriate shocks were P-wave oversensing (34 episodes) and lead noise (19 episodes). Tables 21 and 22 summarize the characteristics and results, respectively.

Table 21. Summary of Key Nonrandomized Trial Characteristics

Study	Study Type	Country	Dates	Participants	Treatment	Follow-Up
Friedman et al. (2022) (102)	Prospective	U.S., Europe, Asia, Oceania	2019-2021	Patients with a class I or IIa indication for ICD for primary or secondary prevention	E-ICD	Mean, 10.6 months

E-ICD: extravascular implantable cardioverter defibrillator; ICD: implantable cardioverter defibrillator; U.S.: United States.

Table 19. Summary of Key Nonrandomized Trial Results

Study	Successful Defibrillation after Implantation	Freedom from Major System- or Procedure-Related Complications for 6 Months	Inappropriate Shocks
Friedman et al. (2022) (102)	N=302	N=299	N=299
E-ICD	98.7%	92.6%	9.7%

E-ICD: extravascular implantable cardioverter defibrillator.

Friedman et al. (2025) conducted a 3-year follow-up of a prospective, nonrandomized global clinical study on patients with E-ICDs. (103) The results showed that all shock therapies for spontaneous ventricular arrhythmias were 100% successful (27/27). However, the inappropriate shock rate rose to 17.5%, primarily due to P-wave oversensing. Freedom from system- or procedure-related major complications was 89%, with lead dislodgment (n=9) and infections (n=8) being the most common complications.

Section Summary: Extravascular Implantable Cardioverter Defibrillators

The largest available study 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 the study is the lack of an active control group.

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 1 systematic review, 1 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. 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. In a systematic review of cohort studies comparing S-ICD to T-ICD in patients with HCM, the S-ICD group experienced significantly fewer device-related complications, but there were no significant differences in appropriate and inappropriate shocks between treatments. 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 study 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 the study 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.

Practice Guidelines and Position Statements

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. (104) This guideline includes ICD recommendations which are summarized in Table 23.

Table 23. 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 updated a joint Guideline for the Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy. (105) Recommendations relevant to this review are summarized in Table 24.

Table 24. 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 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. (106) This guideline supersedes the 2008 guideline for device-based therapy of cardiac rhythm abnormalities (107) and the subsequent 2012 focused update. (108) The most up-to-date recommendations on the use of T-ICD devices from the 2017 guidelines are presented in Tables 25 to 29. Table 30 summarizes the most up-to-date recommendations regarding S-ICDs.

Table 25. Recommendations on Use of Implantable Cardioverter Defibrillators as Secondary Prevention of Sudden Cardiac Death of Ischemic Heart Disease or Nonischemic Cardiomyopathy

Recommendations	COR	LOE

"In patients with ischemic heart disease, who either survive SCA due to VT/VF or experience hemodynamically unstable VT (LOE: B-R) or stable VT (LOE: B-NR) not due to reversible causes, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-R B-NR
“A transvenous ICD provides intermediate value in the secondary prevention of SCD particularly when the patient's risk of death due to a VA is deemed high and the risk of nonarrhythmic death (either cardiac or noncardiac) is deemed low based on the patient's burden of comorbidities and functional status."		B-R
"In patients with ischemic heart disease and unexplained syncope who have inducible sustained monomorphic VT on electrophysiological study, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-NR
"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) (1-4) or stable VT (LOE: B-NR) (5) not due to reversible causes, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-R B-NR
"In patients with NICM who experience syncope presumed to be due to VA and who do not meet indications for a primary prevention ICD, an ICD or an electrophysiological study for risk stratification for SCD can be beneficial if meaningful survival of greater than 1 year is expected."	IIa	B-NR
“In patients with arrhythmogenic right ventricular cardiomyopathy and an additional marker of increased risk of SCD (resuscitated SCA, sustained VT, significant ventricular dysfunction with RVEF or LVEF ≤35%), and 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 26. Recommendations on Use of ICDs as a Primary Prevention of Ischemic Heart Disease or Nonischemic Cardiomyopathy

Recommendations	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 post revascularization, 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 post revascularization, 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."	III[a]	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."	III[a]	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; ICD: implantable cardioverter defibrillator; 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 27. 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."	III[a]	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 28. Recommendations on Use of Implantable Cardioverter Defibrillators for Cardiac Sarcoidosis

Recommendation	COR	LOE

"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
"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 29. 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 combination medication therapy, left cardiac sympathetic denervation, and/or an ICD is recommended."	I	B-NR
"In patients with Brugada syndrome with spontaneous type 1 Brugada electrocardiographic pattern and cardiac arrest, sustained VA or a recent history of syncope presumed due to VA, 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 30. 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
"In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted."	III[a]	B-NR

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. (109) 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. (110) 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. (111) Recommendations related to ICD risk stratification and placement decisions are shown in Table 31.

Table 31. 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 32). (112)

Table 32. 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.	III[a]
Brugada syndrome	
ICD implantation is recommended in patients with a diagnosis of BrS who: • Are survivors of a cardiac arrest; and/or • Have documented spontaneous sustained VT with or without syncope.	I
ICD implantation can be useful in patients with a spontaneous diagnostic type I ECG who have a history of syncope judged to be likely caused by ventricular arrhythmias.	IIa
ICD implantation may be considered in patients with a diagnosis of BrS who develop VF during programmed electrical stimulation (inducible patients).	IIb
ICD implantation is not indicated in asymptomatic BrS patients with a drug-induced type I ECG and on the basis of a family history of SCD alone.	III[a]
Catecholaminergic polymorphic ventricular tachycardia	
ICD implantation is recommended for patients with a diagnosis of CPVT who experience cardiac arrest, recurrent syncope or polymorphic/bidirectional VT despite optimal medical management, and/or left cardiac sympathetic denervation.	I
ICD as a stand-alone therapy is not indicated in an asymptomatic patient with a diagnosis of CPVT	III[a]
Short QT syndrome	
ICD implantation is recommended in symptomatic patients with a diagnosis of SQTS who: • Are survivors of cardiac arrest; and/or • Have documented spontaneous VT with or without syncope.	I
ICD implantation may be considered in asymptomatic patients with a diagnosis of SQTS and a family history of sudden cardiac death.	IIb

BrS: Brugada syndrome; COR: class of recommendation; CPVT: catecholaminergic polymorphic ventricular tachycardia; ECG: electrocardiogram; 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 33). (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 33. 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. (113) The statement made the following recommendations on the use of ICD therapy in adults with congenital heart disease (Table 34).

Table 34. 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
ICD therapy may be considered in adults with CHD and syncope of unknown origin with hemodynamically significant sustained ventricular tachycardia or fibrillation inducible at electrophysiologic study.	Ib	B
ICD therapy may be considered for nonhospitalized adults with CHD awaiting heart transplantation.	Ib	C
ICD therapy may be considered for adults with syncope and moderate or complex CHD in whom there is a high clinical suspicion of ventricular arrhythmia and in whom thorough invasive and noninvasive investigations have failed to define a cause.	Ib	C
Adults with CHD and advanced pulmonary vascular disease (Eisenmenger syndrome) are generally not considered candidates for ICD therapy.	III[a]	
Endocardial leads are generally avoided in adults with CHD and intracardiac shunts. Risk assessment regarding hemodynamic circumstances, concomitant anticoagulation, shunt closure prior to endocardial lead placement, or alternative approaches for lead access should be individualized.	III[a]	

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

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 35 summarizes recommendations for ICD therapy from this statement.

Table 35. 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
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
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
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: coronary 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. (114) According to the most recent publication (effective February 15, 2018), Centers for Medicare and Medicaid Services will cover ICDs for the following patient indications:

1. Patients with a personal history of sustained ventricular tachycardia (VT) or cardiac arrest due to ventricular fibrillation (VF).
2. Patients with a prior myocardial infarction (MI) and a measured left ventricular ejection fraction (LVEF) ≤0.30.

3. 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%.
4. 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.
5. Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained VT or VF), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.
6. 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:
1. Patients must be clinically stable (e.g., not in shock, from any etiology);
2. LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography;
3. 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.

Ongoing and Unpublished Clinical Trials
Some unpublished trials that may influence this policy are listed in Table 36.

Table 36. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT02845531	Implantable Cardioverter Defibrillator Versus Optimal Medical Therapy In Patients With Variant Angina Manifesting as Aborted Sudden Cardiac Death (VARIANT ICD)	140	Jun 2030
NCT00673842[a]	Risk Estimation Following Infarction Noninvasive Evaluation - ICD Efficacy	700	Dec 2024
NCT01296022[a]	Randomized Trial to Study the Efficacy and Adverse Effects of the Subcutaneous and Transvenous Implantable Cardioverter Defibrillator (ICD) in Patients With a Class I or Ila Indication for ICD Without an Indication for Pacing	850	Dec 2023 (extended follow-up)
NCT02787785[a]	Multicenter Automatic Defibrillator Implantation Trial With Subcutaneous	40	Oct 2023

	Implantable Cardioverter Defibrillator (MADIT S-ICD)		

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

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, 0614T, 33216, 33217, 33218, 33220, 33223, 33230, 33231, 33240, 33241, 33243, 33244, 33249, 33262, 33263, 33264, 33270, 33271, 33272, 33273, 93260, 93261, 93282, 93283, 93284, 93285, 93287, 93289, 93295, 93296, 93297, 93298, 93640, 93641, 93642, 93644
HCPCS Codes	C1721, C1722, C1882, C1895, C1896, C1899, G0448, [Deleted 1/1/2024: G2066]

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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):385-391. PMID 24449317
3. Food and Drug Administration. Medtronic Recalls Evera, Viva, Brava, Claria, Amplia, Compia, and Visia Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy (CRT-Ds) Due to Risk of Shortened Battery Life. Apr 12, 2021. Available at <https://www.fda.gov> (accessed April 1, 2024).
4. Food and Drug Administration. Medtronic Recalls Cobalt XT, Cobalt and Crome ICDs and CRT-Ds for Risk that Devices May Issue a Short Circuit Alert and Deliver Reduced Energy

Shock During High Voltage Therapy. Aug 19, 2022. Available at <https://www.fda.gov> (accessed April 1, 2024).
5. 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. Jul 18, 2023. Available at <https://www.fda.gov> (accessed April 2, 2025).
6. Food and Drug Administration. Boston Scientific recalls EMBLEM S-ICD Subcutaneous Electrode (Model 3501) due to risk of fractures. Feb 10, 2021. Available at <https://www.fda.gov> (accessed April 1, 2024).
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):1933-1940. 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):877-883. 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):1569-1575. 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):1882-1890. 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):225-237. 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):2481-2488. PMID 15590950
14. Steinbeck G, Andresen D, Seidl K, et al. Defibrillator implantation early after myocardial infarction. N Engl J Med. Oct 8 2009; 361(15):1427-1436. PMID 19812399
15. Raviele A, Bongiomi 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):327-337. 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):2151-2158. 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):2140-2150. 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):1707-1712. 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):1453-1458. 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):1221-1230. 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):1800-1806. 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 non-ischemic 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):111-121. PMID 24592496
29. Fontenla A, Martinez-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. Eurospace. 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):552-559. 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):1088-1094. 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):1616-1622. 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):879-888. PMID 25744005
36. Dores H, Reis Santos K, Adragao 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, Bogus F, et al. HRS expert consensus statement on the diagnosis and management of arrhythmias associated with cardiac sarcoidosis. Heart Rhythm. Jul 2014; 11(7):1305-1323. 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):181-197. 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):410-415. 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):1685-1691. 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):800-807. 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):72-76. 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):1245-1250. 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):1576-1583. 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):748-754. 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):1297-1302. 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):2221-2226. 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):2195-2203. 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):1573-1582. 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). Available at <https://www.nice.org.uk> (accessed April 2, 2025).
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):2071-2078. 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):813-819. 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):1474-1481. 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. Mar 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):1186-1194. 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):443-454. 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). Available at <https://www.fda.gov> (accessed April 1, 2024).
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. Nov 2015; 4(11):e002418. 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):1217-1225. 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):358-363. 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):1553-1561. 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):113-121. 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):1651-1656. 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):95-99. PMID 20102898
69. Smit J, Korup E, Schonheyder 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):658-664. 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):786-790. 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):171-183. 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):1013-1019. 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 8 2008; 51(14):1357-1365. 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):164-170. 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):1489-1496. 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):926-936. PMID 25637563
77. Lee OS, 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):774-782. 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):262-266. 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. 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
81. 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
82. 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
83. 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 2014; 35(25):1657-1665. PMID 24670710
84. 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; 195:126-133.PMID 26026928
85. 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
86. Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation. Aug 27 2013; 128(9):944-953. PMID 23979626

87. 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):157-164. PMID 26341604
88. 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
89. 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
90. 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):1159-1163. PMID 26148819
91. 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):1933-1939. PMID 23062537
92. 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
93. 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
94. 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
95. 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
96. 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
97. Köbe J, Hucklenbroich K, Geisendorfer 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
98. 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):520-526. PMID 27353211
99. 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
100. 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
101. 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

102. 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
103. 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
104. 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
105. Ommen SR, Ho CY, Asif IM, et al. Peer Review Committee Members. 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 2024; 149(23):e1239-e1311. PMID 38718139
106. 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 Cardio logy/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
107. 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
108. 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-e75. PMID 23265327
109. 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
110. 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
111. 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
112. Priori SG, Wilde AA, Rorie 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):1932-1963. PMID 24011539
113. 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
114. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4) (2018). Available at <https://www.cms.gov> (accessed April 2, 2025).
115. Burke MC, Aasbo JD, El-Chami MF, et al. 1-Year Prospective Evaluation of Clinical Outcomes and Shocks: The Subcutaneous ICD Post Approval Study. JACC Clin Electrophysiol. Nov 2020; 6(12):1537-1550. PMID 33213814

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/15/2025	Document updated. The following change was made to Coverage: Moved content from NOTEs 2-4 to Policy Guidelines section; no change to intent. Added reference 92, 94, 103, 105 and 115.
02/15/2025	Document updated with literature review. The following changes were made to Coverage: 1) Updated Coverage statements specific to pediatric indications for implantable cardioverter defibrillators; and 2) Added experimental, investigational and/or unproven statement for extravascular implantable cardioverter defibrillators. Added references 1, 3-5, 12, 22, 27, 32, 79, 82, 100, 104, 106 and 107; others removed.
01/01/2024	Reviewed. No changes.
10/01/2022	Document updated with literature review. Coverage unchanged. Added/updated the following references: 2, 21, 74, 85, 93, 96, and 102.

08/01/2021	Reviewed. No changes.
11/15/2020	Document updated with literature review. The following changes were made to Coverage: 1) Added conditional coverage of an automatic implantable cardioverter defibrillator (ICD) in adults for primary prevention for diagnosis of cardiac sarcoid; and 2) Added a NOTE 2 specific to criteria for ICD implantation in patients with cardiac sarcoid. Added references: 29-31 and 94.
11/01/2019	Document updated with literature review. Coverage revised to include specific criteria for ICD implantation in patients with cardiac ion channelopathies as well as clinical or historical findings for patients with congenital long QT syndrome. References revised; some references removed; added references 25, 48, 69, 78, 93. Title changed from Automatic Implantable Cardioverter Defibrillator (AICD) and Subcutaneous Implantable Cardioverter Defibrillator (S-ICD).
08/15/2017	Reviewed. No changes.
09/01/2016	Document partially updated. 1) Coverage language for subcutaneous ICD (S-ICD®) modified to remove the wording “for patients <45 years of age who meet the criteria for an AICD listed” and replaced with the wording “who have an indication for ICD implantation for primary or secondary prevention”. 2) Added the following to the bulleted criteria regarding pacing: no indication for biventricular pacing/resynchronization therapy; and no ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing; 3) changed to describe the previously described conditions for "increased procedural risk" conditions for transvenous ICD's to "contraindicated" for clarification.
08/15/2016	Document updated with literature review. The following conditions were added to the coverage statement for: “Patient’s with familial or inherited conditions with a high risk of life-threatening VT’s” such as: Brugada syndrome, short QT syndrome, or catecholaminergic polymorphic ventricular tachycardia. In addition, the following coverage criteria was modified or added regarding the medically necessary statement for subcutaneous ICD (S-ICD®): “for patients <45 years of age who meet the criteria for an AICD listed above AND both of the following: 1) There is no indication for antibradycardia pacing; and 2) When placement of the transvenous AICD is associated with increased procedural risk as evidenced by the patient having one of the following documented indications: Complex congenital heart disease or challenging vascular access, high risk for systemic infection, Multiple prior transvenous endocardial leads, Compelling reason to preserve existing vascular access (i.e., need for chronic dialysis; younger patient with anticipated long-term need for ICD therapy), or History of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy.
05/01/2015	Reviewed. No changes.

12/01/2014	CPT/HCPCS code(s) updated
09/01/2014	Document updated with literature review. The use of an FDA approved subcutaneous implantable cardioverter-defibrillator (S-ICD) is considered medically necessary when meeting criteria for an AICD listed above AND when placement of the transvenous AICD is associated with increased procedural risk as evidenced by the patient having one of the following documented indications: 1) Congenital heart disease that limits intracavitary lead placements, 2) Obstructed venous access, 3) Chronic indwelling catheters, or 4) Immunocompromised. CPT/HCPCS code(s) updated.
01/01/2013	Policy updated with literature review. The following was added: The use of a subcutaneous implantable defibrillator system (S-ICD) is considered experimental, investigational and unproven. Title changed from "Automatic Implantable Cardioverter Defibrillator (AICD)". CPT/HCPCS code(s) updated.
06/01/2012	Document updated with literature review. The following was added: 1) "New York Heart Association (NYHA) functional Class II or Class III symptoms" was added to the criteria for Primary Prevention for ischemic cardiomyopathy with a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 35% or less, 2) "ischemic cardiomyopathy with NYHA functional Class I symptoms, was added to the criteria for Primary Prevention with a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 30% or less" 3) "The use of the AICD may be considered medically necessary in children who meet any of the noted criteria in the coverage section. 4) "The use of the ICD is considered experimental, investigational and unproven for all other indications in pediatric patients". CPT/HCPCS code(s) updated.
03/15/2010	Intermediate partial policy update. Positive coverage criteria change for secondary prevention. Added the following additional indication for coverage: Patients with familial or inherited conditions with a high risk of life-threatening VT's such as long QT syndrome or hypertrophic cardiomyopathy.
06/15/2009	Coverage and rationale section revised. Removed requirement of more than nine months duration of symptomatic nonischemic dilated cardiomyopathy. Rationale modified.
05/01/2009	CPT/HCPCS code(s) updated
01/15/2009	Revised/updated entire document
11/15/2006	Revised/updated entire document
10/24/2003	Revised/updated entire document
03/01/2000	CPT/HCPCS code(s) updated
02/01/1998	Revised/updated entire document
11/01/1999	CPT/HCPCS code(s) updated
05/01/1995	Revised/updated entire document
10/01/1994	Revised/updated entire document
04/01/1992	Revised/updated entire document

05/01/1990	New medical document