



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Implantable Cardioverter Defibrillator

Table of Contents

- [Policy: Commercial](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

Policy Number: 070

BCBSA Reference Number: 7.01.44 (For Plan internal use only)

Related Policies

- Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure, #101
- Wearable Cardioverter Defibrillators, #042

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Transvenous Implantable Cardioverter Defibrillator

Adults

The use of the automatic implantable cardioverter defibrillator (ICD) may be considered **MEDICALLY NECESSARY** in individuals who meet the following criteria:

Primary Prevention

- Ischemic cardiomyopathy with New York Heart Association (NYHA) functional Class II or Class III symptoms, a history of myocardial infarction at least 40 days before ICD treatment and left-ventricular ejection fraction of 35% or less; **OR**
- Ischemic cardiomyopathy (IDCM) with NYHA functional Class I symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 30% or less; **OR**
- Non-ischemic dilated cardiomyopathy (NIDCM) and left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; **OR**
- Hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 or more runs of non-sustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of individuals with HCM.

- Diagnosis of any one of the following cardiac ion channelopathies* and considered to be at high risk for sudden cardiac death:
 - congenital long QT syndrome; **OR**
 - Brugada syndrome; **OR**
 - short QT syndrome; **OR**
 - catecholaminergic polymorphic ventricular tachycardia.
- Diagnosis of cardiac sarcoid** and considered to be at high risk for sudden cardiac death.

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 (eg, acute ischemia) have been excluded.

The use of the ICD is considered **INVESTIGATIONAL** for primary prevention individuals who meet the following:

- Have had an acute myocardial infarction (i.e., less than 40 days before ICD treatment); **OR**
- Have NYHA Class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy ICD device); **OR**
- Have had cardiac revascularization procedure in the past 3 months (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) or are candidates for a cardiac revascularization procedure; **OR**
- Have non-cardiac disease that would be associated with life expectancy less than 1 year.

The use of the ICD for secondary prevention is considered **INVESTIGATIONAL** 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:

- Survivors of cardiac arrest due to ventricular tachycardia or ventricular fibrillation, after reversible causes have been excluded
- Long QT syndrome in individuals who are survivors of sudden cardiac arrest (in combination with beta-blockers)
- Long QT syndrome in individuals who cannot take beta-blockers and for whom cardiac sympathetic denervation or other medications are not considered appropriate
- Catecholaminergic polymorphic ventricular tachycardia in individuals who experience cardiac arrest despite maximally tolerated beta-blockers, flecainide, or cardiac sympathetic denervation
- Brugada syndrome in individuals who are survivors of sudden cardiac arrest or have documented spontaneous sustained ventricular tachycardia
- Hypertrophic cardiomyopathy in individuals who are survivors of sudden cardiac arrest or have documented spontaneous sustained ventricular tachycardia
- Arrhythmogenic cardiomyopathy in individuals who are survivors of sudden cardiac arrest or sustained ventricular tachycardia that is not hemodynamically tolerated
- Nonischemic dilated cardiomyopathy in individuals who are survivors of sudden cardiac arrest or have documented spontaneous sustained ventricular tachycardia that is not due to completely reversible causes
- Congenital heart disease in individuals who are survivors of sudden cardiac arrest, after reversible causes have been excluded
- symptomatic, sustained ventricular tachycardia in association with congenital heart disease in individuals who have undergone hemodynamic and electrophysiologic evaluation.

The use of the ICD is considered [INVESTIGATIONAL](#) for all other indications in pediatric patients.

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:

- Have a contraindication to a transvenous ICD due to one or more of the following: (1) lack of adequate vascular access; (2) compelling reason to preserve existing vascular access (ie, need for chronic dialysis; younger individual with anticipated long-term need for ICD therapy); or (3) history of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy.
- Have no indication for antibradycardia pacing; **AND**
- Do not have ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing.

The use of a subcutaneous ICD is considered [INVESTIGATIONAL](#) for individuals who do not meet the criteria outlined above.

Extravascular Implantable Cardioverter Defibrillator

The use of an extravascular ICD is considered [INVESTIGATIONAL](#).

Policy Guidelines

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

***Criteria for ICD Implantation in Individuals with Cardiac Ion Channelopathies**

Individuals with cardiac ion channelopathies may have a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes, in which case they should be considered for ICD implantation for *secondary* prevention, even if they do not meet criteria for primary prevention.

Criteria for ICD placement in individuals with cardiac ion channelopathies derive from results of clinical input, a 2013 consensus statement from the 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 (Priori et al [2013]), 2017 guidelines from ACC, AHA, and HRS on the management of heart failure (Al-Khatib et al [2017]), 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 syncope 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 or are asymptomatic or symptomatic and have a family history of sudden cardiac death.

****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 Heart Rhythm Society (HRS) and 2017 joint guidelines from the American Heart Association, American College of Cardiology, and HRS.

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

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

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

| | Outpatient |
|--|--|
| Commercial Managed Care (HMO and POS) | Prior authorization is not required . |
| Commercial PPO and Indemnity | Prior authorization is not required . |

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria **MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO and Indemnity:**

CPT Codes

| CPT codes: | Code Description |
|------------|---|
| 33216 | Insertion of transvenous electrode; single chamber (one electrode) permanent pacemaker or single chamber pacing cardioverter-defibrillator |
| 33217 | Dual chamber (two electrodes) permanent pacemaker or dual chamber pacing cardioverter-defibrillator |
| 33249 | Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber |
| 33270 | Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed |
| 33271 | Insertion of subcutaneous implantable defibrillator electrode |

HCPCS Codes

| HCPCS codes: | Code Description |
|--------------|---|
| C1721 | Cardioverter-defibrillator, dual chamber (implantable) |
| C1722 | Cardioverter-defibrillator, single chamber (implantable) |
| C1882 | Cardioverter-defibrillator, other than single or dual chamber (implantable) |

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and/or HCPCS codes above if medical necessity criteria are met:

ICD-10-CM Diagnosis Codes

| ICD-10-CM diagnosis codes: | Code Description |
|----------------------------|--|
| D86.85 | Sarcoid myocarditis |
| D86.89 | Sarcoidosis of other sites |
| I25.5 | Ischemic cardiomyopathy |
| I25.6 | Silent myocardial ischemia |
| I25.89 | Other forms of chronic ischemic heart disease |
| I25.9 | Chronic ischemic heart disease, unspecified |
| I42.1 | Obstructive hypertrophic cardiomyopathy |
| I42.2 | Other hypertrophic cardiomyopathy |
| I42.0 | Dilated cardiomyopathy |
| I42.5 | Other restrictive cardiomyopathy |
| I45.81 | Long QT syndrome |
| I45.89 | Other specified conduction disorders |
| I46.2 | Cardiac arrest due to underlying cardiac condition |
| I46.8 | Cardiac arrest due to other underlying condition |
| I46.9 | Cardiac arrest, cause unspecified |
| I47.0 | Re-entry ventricular arrhythmia |
| I47.20 | Ventricular tachycardia, unspecified |
| I47.21 | Torsades de pointes |
| I47.29 | Other ventricular tachycardia |
| I49.01 | Ventricular fibrillation |
| I49.8 | Other specified cardiac arrhythmias |

| | |
|--------|---|
| I49.9 | Cardiac arrhythmia, unspecified |
| Q24.8 | Other specified congenital malformations of heart |
| Z86.74 | Personal history of sudden cardiac arrest |

The following CPT and HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

| | |
|-------|---|
| 0571T | Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed |
| 0572T | Insertion of substernal implantable defibrillator electrode |
| 0573T | Removal of substernal implantable defibrillator electrode |
| 0574T | Repositioning of previously implanted substernal implantable defibrillator-pacing electrode |
| 0580T | Removal of substernal implantable defibrillator pulse generator only |
| 0614T | Removal and replacement of substernal implantable defibrillator pulse generator |

Description

Ventricular Arrhythmia and Sudden Cardiac Death

The risk of ventricular arrhythmia and sudden cardiac death (SCD) may be significantly increased in various cardiac conditions such as ischemic cardiomyopathy, particularly when associated with reduced left ventricular ejection fraction (LVEF) and prior myocardial infarction (MI); nonischemic dilated cardiomyopathy with reduced LVEF; hypertrophic cardiomyopathy and additional risk factors; congenital heart disease, particularly with recurrent syncope; and cardiac ion channelopathies.

Treatment

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

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

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

Several automatic ICDs have been approved by the 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.

Summary

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.

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 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. 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.

Policy History

| Date | Action |
|----------------|--|
| 10/2024 | Annual policy review. Policy updated with literature review through April 1, 2024; references added. Policy statements and policy guidelines for pediatric indications updated. Clarified coding information. Effective 10/1/2024. |
| 7/2023 | Annual policy review. Minor editorial refinements to policy statements; intent unchanged |
| 10/2022 | Clarified coding information. |
| 7/2022 | Annual policy review. References added. Policy statements unchanged. |
| 6/2021 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |
| 1/2021 | Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference. |
| 10/2020 | Annual policy review. New medically necessary indications described for patients with cardiac sarcoid with conditions. Clarified coding information. Effective 10/1/2020. |
| 6/2019 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |
| 6/2018 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |
| 1/2018 | Clarified coding information. |
| 7/2017 | Annual policy review. New references added |
| 7/2016 | Annual policy review. New references added |
| 4/2016 | Annual policy review. Policy statement added that the ICD is considered investigational for secondary prevention patients who do not meet medical necessity criteria for secondary prevention. Effective 4/1/2016. |
| 3/2016 | Annual policy review. ICD medically necessary for patients with cardiac ion channelopathies with conditions; S-ICD medically necessary in limited situations. Effective 3/1/2016. |
| 1/2015 | Clarified coding information. |
| 6/2014 | Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015. |
| 5/2014 | Annual policy review. Policy statement on secondary prevention in adults clarified. Effective 5/1/2014. |
| 4/2013 | Annual policy review. New investigational indications described. Effective 4/1/2013. |
| 11/2011-4/2012 | Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements. |
| 1/1/2012 | Reviewed 4/2011 Medical Policy Group – Cardiology and Pulmonology. No changes to policy statements. |
| 4/2010 | Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements. |
| 3/2010 | Annual policy review. No changes to policy statements. |
| 4/2009 | Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements. |
| 2/2009 | Annual policy review. No changes to policy statements. |
| 12/2008 | New policy describing covered and non-covered indications. Effective 12/2008. |

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

References

1. Shah MJ, Silka MJ, Silva JNA, et al. 2021 PACES Expert Consensus Statement on the Indications and Management of Cardiovascular Implantable Electronic Devices in Pediatric Patients: Developed in collaboration with and endorsed by the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA), and the Association for European Paediatric and Congenital Cardiology (AEPC) Endorsed by the Asia Pacific Heart Rhythm Society (APHRS), the Indian Heart Rhythm Society (IHRS), and the Latin American Heart Rhythm Society (LAHRS). *JACC Clin Electrophysiol*. Nov 2021; 7(11): 1437-1472. PMID 34794667
2. Rome BN, Kramer DB, Kesselheim AS. FDA approval of cardiac implantable electronic devices via original and supplement premarket approval pathways, 1979-2012. *JAMA*. Jan 2014; 311(4): 385-91. PMID 24449317
3. 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. April 12, 2021. <https://public4.pagefreezer.com/browse/FDA/12-02-2024T12:33/https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-evera-viva-brava-claria-amplia-compia-and-visia-implantable-cardioverter>. 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. August 19, 2022. <https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-cobalt-xt-cobalt-and-crome-icds-and-crt-ds-risk-devices-may-issue-short-circuit>. 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. July 18, 2023. <https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-implantable-cardioverter-defibrillators-icds-and-cardiac-resynchronization-therapy>. Accessed April 1, 2024.
6. Food and Drug Administration. Boston Scientific Recalls EMBLEM S-ICD Subcutaneous Electrode (Model 3501) Due to Risk of Fractures. February 10, 2021. <https://public4.pagefreezer.com/browse/FDA/12-02-2024T12:33/https://www.fda.gov/medical-devices/medical-device-recalls/boston-scientific-recalls-emblem-s-icd-subcutaneous-electrode-model-3501-due-risk-fractures>. 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): 1933-40. PMID 8960472
8. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med*. Mar 21 2002; 346(12): 877-83. PMID 11907286
9. Bigger JT. Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary-artery bypass graft surgery. Coronary Artery Bypass Graft (CABG) Patch Trial Investigators. *N Engl J Med*. Nov 27 1997; 337(22): 1569-75. PMID 9371853
10. Buxton AE, Lee KL, Fisher JD, et al. A randomized study of the prevention of sudden death in patients with coronary artery disease. Multicenter Unsustained Tachycardia Trial Investigators. *N Engl J Med*. Dec 16 1999; 341(25): 1882-90. PMID 10601507
11. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med*. Jan 20 2005; 352(3): 225-37. PMID 15659722
12. Haanschoten DM, Elvan A, Ramdat Misier AR, et al. Long-Term Outcome of the Randomized DAPA Trial. *Circ Arrhythm Electrophysiol*. Nov 2020; 13(11): e008484. PMID 33003972
13. Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. *N Engl J Med*. Dec 09 2004; 351(24): 2481-8. PMID 15590950
14. Steinbeck G, Andresen D, Seidl K, et al. Defibrillator implantation early after myocardial infarction. *N Engl J Med*. Oct 08 2009; 361(15): 1427-36. PMID 19812399

15. Raviele A, Bongiorno MG, Brignole M, et al. Early EPS/ICD strategy in survivors of acute myocardial infarction with severe left ventricular dysfunction on optimal beta-blocker treatment. The BETA-blocker STRategy plus ICD trial. *Europace*. Jul 2005; 7(4): 327-37. PMID 16028343
16. Kadish A, Dyer A, Daubert JP, et al. Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. *N Engl J Med*. May 20 2004; 350(21): 2151-8. PMID 15152060
17. Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. *N Engl J Med*. May 20 2004; 350(21): 2140-50. PMID 15152059
18. Strickberger SA, Hummel JD, Bartlett TG, et al. Amiodarone versus implantable cardioverter-defibrillator: randomized trial in patients with nonischemic dilated cardiomyopathy and asymptomatic nonsustained ventricular tachycardia--AMIOVIRT. *J Am Coll Cardiol*. May 21 2003; 41(10): 1707-12. PMID 12767651
19. Bänsch D, Antz M, Boczor S, et al. Primary prevention of sudden cardiac death in idiopathic dilated cardiomyopathy: the Cardiomyopathy Trial (CAT). *Circulation*. Mar 26 2002; 105(12): 1453-8. PMID 11914254
20. Køber L, Thune JJ, Nielsen JC, et al. Defibrillator Implantation in Patients with Nonischemic Systolic Heart Failure. *N Engl J Med*. Sep 29 2016; 375(13): 1221-30. PMID 27571011
21. Woods B, Hawkins N, Mealing S, et al. Individual patient data network meta-analysis of mortality effects of implantable cardiac devices. *Heart*. Nov 2015; 101(22): 1800-6. PMID 26269413
22. Jaiswal V, Taha AM, Joshi A, et al. Implantable cardioverter defibrillators for primary prevention in patients with ischemic and non-ischemic cardiomyopathy: A meta-analysis. *Curr Probl Cardiol*. Feb 2024; 49(2): 102198. PMID 37952790
23. Wolff G, Lin Y, Karathanos A, et al. Implantable cardioverter/defibrillators for primary prevention in dilated cardiomyopathy post-DANISH: an updated meta-analysis and systematic review of randomized controlled trials. *Clin Res Cardiol*. Jul 2017; 106(7): 501-513. PMID 28213711
24. Stavrakis S, Asad Z, Reynolds D. Implantable Cardioverter Defibrillators for Primary Prevention of Mortality in Patients With Nonischemic Cardiomyopathy: A Meta-Analysis of Randomized Controlled Trials. *J Cardiovasc Electrophysiol*. Jun 2017; 28(6): 659-665. PMID 28316104
25. Akel T, Lafferty J. Implantable cardioverter defibrillators for primary prevention in patients with nonischemic cardiomyopathy: A systematic review and meta-analysis. *Cardiovasc Ther*. Jun 2017; 35(3). PMID 28129469
26. Golwala H, Bajaj NS, Arora G, et al. Implantable Cardioverter-Defibrillator for Nonischemic Cardiomyopathy: An Updated Meta-Analysis. *Circulation*. Jan 10 2017; 135(2): 201-203. PMID 27993908
27. Wasiak M, Tajstra M, Kosior D, et al. An implantable cardioverter-defibrillator for primary prevention in non-ischemic cardiomyopathy: A systematic review and meta-analysis. *Cardiol J*. 2023; 30(1): 117-124. PMID 33843044
28. Earley A, Persson R, Garlitski AC, et al. Effectiveness of implantable cardioverter defibrillators for primary prevention of sudden cardiac death in subgroups a systematic review. *Ann Intern Med*. Jan 21 2014; 160(2): 111-21. PMID 24592496
29. Fontenla A, Martínez-Ferrer JB, Alzueta J, et al. Incidence of arrhythmias in a large cohort of patients with current implantable cardioverter-defibrillators in Spain: results from the UMBRELLA Registry. *Europace*. Nov 2016; 18(11): 1726-1734. PMID 26705555
30. Schinkel AF, Vriesendorp PA, Sijbrands EJ, et al. Outcome and complications after implantable cardioverter defibrillator therapy in hypertrophic cardiomyopathy: systematic review and meta-analysis. *Circ Heart Fail*. Sep 01 2012; 5(5): 552-9. PMID 22821634
31. Magnusson P, Gadler F, Liv P, et al. Hypertrophic Cardiomyopathy and Implantable Defibrillators in Sweden: Inappropriate Shocks and Complications Requiring Surgery. *J Cardiovasc Electrophysiol*. Oct 2015; 26(10): 1088-94. PMID 26178879
32. Medeiros P, Santos M, Arantes C, et al. Implantable cardioverter-defibrillator in patients with inherited arrhythmia syndromes: A systematic review. *Heart Lung*. 2023; 60: 1-7. PMID 36863123
33. Horner JM, Kinoshita M, Webster TL, et al. Implantable cardioverter defibrillator therapy for congenital long QT syndrome: a single-center experience. *Heart Rhythm*. Nov 2010; 7(11): 1616-22. PMID 20816872

34. Hernandez-Ojeda J, Arbelo E, Borrás R, et al. Patients With Brugada Syndrome and Implanted Cardioverter-Defibrillators: Long-Term Follow-Up. *J Am Coll Cardiol*. Oct 17 2017; 70(16): 1991-2002. PMID 29025556
35. Conte G, Sieira J, Ciconte G, et al. Implantable cardioverter-defibrillator therapy in Brugada syndrome: a 20-year single-center experience. *J Am Coll Cardiol*. Mar 10 2015; 65(9): 879-88. PMID 25744005
36. Dores H, Reis Santos K, Adragão P, et al. Long-term prognosis of patients with Brugada syndrome and an implanted cardioverter-defibrillator. *Rev Port Cardiol*. Jun 2015; 34(6): 395-402. PMID 26028488
37. Roses-Noguer F, Jarman JW, Clague JR, et al. Outcomes of defibrillator therapy in catecholaminergic polymorphic ventricular tachycardia. *Heart Rhythm*. Jan 2014; 11(1): 58-66. PMID 24120999
38. Birnie DH, Sauer WH, Bogun F, et al. HRS expert consensus statement on the diagnosis and management of arrhythmias associated with cardiac sarcoidosis. *Heart Rhythm*. Jul 2014; 11(7): 1305-23. PMID 24819193
39. Plitt A, Dorbala S, Albert MA, et al. Cardiac sarcoidosis: case report, workup, and review of the literature. *Cardiol Ther*. Dec 2013; 2(2): 181-97. PMID 25135396
40. Mantini N, Williams B, Stewart J, et al. Cardiac sarcoid: a clinician's review on how to approach the patient with cardiac sarcoid. *Clin Cardiol*. 2012; 35(7): 410-5. PMID 22499155
41. Berul CI, Van Hare GF, Kertesz NJ, et al. Results of a multicenter retrospective implantable cardioverter-defibrillator registry of pediatric and congenital heart disease patients. *J Am Coll Cardiol*. Apr 29 2008; 51(17): 1685-91. PMID 18436121
42. Silka MJ, Kron J, Dunnigan A, et al. Sudden cardiac death and the use of implantable cardioverter-defibrillators in pediatric patients. *The Pediatric Electrophysiology Society. Circulation*. Mar 1993; 87(3): 800-7. PMID 8443901
43. Alexander ME, Cecchin F, Walsh EP, et al. Implications of implantable cardioverter defibrillator therapy in congenital heart disease and pediatrics. *J Cardiovasc Electrophysiol*. Jan 2004; 15(1): 72-6. PMID 15028076
44. Lewandowski M, Sterlinski M, Maciag A, et al. Long-term follow-up of children and young adults treated with implantable cardioverter-defibrillator: the authors' own experience with optimal implantable cardioverter-defibrillator programming. *Europace*. Sep 2010; 12(9): 1245-50. PMID 20650939
45. Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. *N Engl J Med*. Nov 27 1997; 337(22): 1576-83. PMID 9411221
46. Kuck KH, Cappato R, Siebels J, et al. Randomized comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from cardiac arrest : the Cardiac Arrest Study Hamburg (CASH). *Circulation*. Aug 15 2000; 102(7): 748-54. PMID 10942742
47. Connolly SJ, Gent M, Roberts RS, et al. Canadian implantable defibrillator study (CIDS) : a randomized trial of the implantable cardioverter defibrillator against amiodarone. *Circulation*. Mar 21 2000; 101(11): 1297-302. PMID 10725290
48. Nademanee K, Veerakul G, Mower M, et al. Defibrillator Versus beta-Blockers for Unexplained Death in Thailand (DEBUT): a randomized clinical trial. *Circulation*. May 06 2003; 107(17): 2221-6. PMID 12695290
49. Wever EF, Hauer RN, van Capelle FL, et al. Randomized study of implantable defibrillator as first-choice therapy versus conventional strategy in postinfarct sudden death survivors. *Circulation*. Apr 15 1995; 91(8): 2195-203. PMID 7697849
50. Lee DS, Green LD, Liu PP, et al. Effectiveness of implantable defibrillators for preventing arrhythmic events and death: a meta-analysis. *J Am Coll Cardiol*. May 07 2003; 41(9): 1573-82. PMID 12742300
51. National Institute for Health and Care Excellence (NICE). Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (Review of TA95 and TA120). 2014; <https://www.nice.org.uk/guidance/ta314/documents/arrythmias-icds-heart-failure-cardiac-resynchronisation-fad-document2>. Accessed April 1, 2024.
52. Connolly SJ, Hallstrom AP, Cappato R, et al. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. AVID, CASH and CIDS studies. *Antiarrhythmics vs Implantable Defibrillator study. Cardiac Arrest Study Hamburg. Canadian Implantable Defibrillator Study. Eur Heart J*. Dec 2000; 21(24): 2071-8. PMID 11102258

53. Betts TR, Sadarmin PP, Tomlinson DR, et al. Absolute risk reduction in total mortality with implantable cardioverter defibrillators: analysis of primary and secondary prevention trial data to aid risk/benefit analysis. *Europace*. Jun 2013; 15(6): 813-9. PMID 23365069
54. Chan PS, Hayward RA. Mortality reduction by implantable cardioverter-defibrillators in high-risk patients with heart failure, ischemic heart disease, and new-onset ventricular arrhythmia: an effectiveness study. *J Am Coll Cardiol*. May 03 2005; 45(9): 1474-81. PMID 15862422
55. Persson R, Earley A, Garlitski AC, et al. Adverse events following implantable cardioverter defibrillator implantation: a systematic review. *J Interv Card Electrophysiol*. Aug 2014; 40(2): 191-205. PMID 24948126
56. Ezzat VA, Lee V, Ahsan S, et al. A systematic review of ICD complications in randomised controlled trials versus registries: is our 'real-world' data an underestimation?. *Open Heart*. 2015; 2(1): e000198. PMID 25745566
57. Kirkfeldt RE, Johansen JB, Nohr EA, et al. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. *Eur Heart J*. May 2014; 35(18): 1186-94. PMID 24347317
58. van Rees JB, de Bie MK, Thijssen J, et al. Implantation-related complications of implantable cardioverter-defibrillators and cardiac resynchronization therapy devices: a systematic review of randomized clinical trials. *J Am Coll Cardiol*. Aug 30 2011; 58(10): 995-1000. PMID 21867832
59. Olde Nordkamp LR, Postema PG, Knops RE, et al. Implantable cardioverter-defibrillator harm in young patients with inherited arrhythmia syndromes: A systematic review and meta-analysis of inappropriate shocks and complications. *Heart Rhythm*. Feb 2016; 13(2): 443-54. PMID 26385533
60. Food and Drug Administration. Premature Insulation Failure in Recalled Riata Implantable Cardioverter Defibrillator (ICD) Leads Manufactured by St. Jude Medical, Inc.: FDA Safety Communication. 2014; <https://wayback.archive-it.org/7993/20170722215745/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm314930.htm>. Accessed April 1, 2024.
61. Hauser RG, Katsiyannis WT, Gornick CC, et al. Deaths and cardiovascular injuries due to device-assisted implantable cardioverter-defibrillator and pacemaker lead extraction. *Europace*. Mar 2010; 12(3): 395-401. PMID 19946113
62. Providência R, Kramer DB, Pimenta D, et al. Transvenous Implantable Cardioverter-Defibrillator (ICD) Lead Performance: A Meta-Analysis of Observational Studies. *J Am Heart Assoc*. Oct 30 2015; 4(11). PMID 26518666
63. Birnie DH, Parkash R, Exner DV, et al. Clinical predictors of Fidelis lead failure: report from the Canadian Heart Rhythm Society Device Committee. *Circulation*. Mar 13 2012; 125(10): 1217-25. PMID 22311781
64. Hauser RG, Maisel WH, Friedman PA, et al. Longevity of Sprint Fidelis implantable cardioverter-defibrillator leads and risk factors for failure: implications for patient management. *Circulation*. Feb 01 2011; 123(4): 358-63. PMID 21242478
65. Poole JE, Gleva MJ, Mela T, et al. Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: results from the REPLACE registry. *Circulation*. Oct 19 2010; 122(16): 1553-61. PMID 20921437
66. Ricci RP, Pignalberi C, Magris B, et al. Can we predict and prevent adverse events related to high-voltage implantable cardioverter defibrillator lead failure?. *J Interv Card Electrophysiol*. Jan 2012; 33(1): 113-21. PMID 21882010
67. Cheng A, Wang Y, Curtis JP, et al. Acute lead dislodgements and in-hospital mortality in patients enrolled in the national cardiovascular data registry implantable cardioverter defibrillator registry. *J Am Coll Cardiol*. Nov 09 2010; 56(20): 1651-6. PMID 21050975
68. Faulknier BA, Traub DM, Aktas MK, et al. Time-dependent risk of Fidelis lead failure. *Am J Cardiol*. Jan 01 2010; 105(1): 95-9. PMID 20102898
69. Smit J, Korup E, Schønheyder HC. Infections associated with permanent pacemakers and implanted cardioverter-defibrillator devices. A 10-year regional study in Denmark. *Scand J Infect Dis*. Sep 2010; 42(9): 658-64. PMID 20465488
70. Nery PB, Fernandes R, Nair GM, et al. Device-related infection among patients with pacemakers and implantable defibrillators: incidence, risk factors, and consequences. *J Cardiovasc Electrophysiol*. Jul 2010; 21(7): 786-90. PMID 20102431

71. Sohail MR, Hussain S, Le KY, et al. Risk factors associated with early- versus late-onset implantable cardioverter-defibrillator infections. *J Interv Card Electrophysiol.* Aug 2011; 31(2): 171-83. PMID 21365264
72. Borleffs CJ, Thijssen J, de Bie MK, et al. Recurrent implantable cardioverter-defibrillator replacement is associated with an increasing risk of pocket-related complications. *Pacing Clin Electrophysiol.* Aug 2010; 33(8): 1013-9. PMID 20456647
73. Daubert JP, Zareba W, Cannom DS, et al. Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. *J Am Coll Cardiol.* Apr 08 2008; 51(14): 1357-65. PMID 18387436
74. Tan VH, Wilton SB, Kuriachan V, et al. Impact of programming strategies aimed at reducing nonessential implantable cardioverter defibrillator therapies on mortality: a systematic review and meta-analysis. *Circ Arrhythm Electrophysiol.* Feb 2014; 7(1): 164-70. PMID 24446023
75. Sterns LD, Meine M, Kurita T, et al. Extended detection time to reduce shocks is safe in secondary prevention patients: The secondary prevention substudy of PainFree SST. *Heart Rhythm.* Jul 2016; 13(7): 1489-96. PMID 26988379
76. Auricchio A, Schloss EJ, Kurita T, et al. Low inappropriate shock rates in patients with single- and dual/triple-chamber implantable cardioverter-defibrillators using a novel suite of detection algorithms: PainFree SST trial primary results. *Heart Rhythm.* May 2015; 12(5): 926-36. PMID 25637563
77. Lee DS, Krahn AD, Healey JS, et al. Evaluation of early complications related to De Novo cardioverter defibrillator implantation insights from the Ontario ICD database. *J Am Coll Cardiol.* Feb 23 2010; 55(8): 774-82. PMID 20170816
78. Furniss G, Shi B, Jimenez A, et al. Cardiac troponin levels following implantable cardioverter defibrillation implantation and testing. *Europace.* Feb 2015; 17(2): 262-6. PMID 25414480
79. Healey JS, Krahn AD, Bashir J, et al. Perioperative Safety and Early Patient and Device Outcomes Among Subcutaneous Versus Transvenous Implantable Cardioverter Defibrillator Implantations : A Randomized, Multicenter Trial. *Ann Intern Med.* Dec 2022; 175(12): 1658-1665. PMID 36343346
80. 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 01 2014; 35(25): 1657-65. 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: 126-33. 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): 944-53. 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): 157-64. 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): 1159-63. 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): 1933-9. PMID 23062537
92. 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
93. 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
94. 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
95. Köbe J, Hucklenbroich K, Geisendörfer N, et al. Posttraumatic stress and quality of life with the totally subcutaneous compared to conventional cardioverter-defibrillator systems. *Clin Res Cardiol*. May 2017; 106(5): 317-321. PMID 27878381
96. Pedersen SS, Mastenbroek MH, Carter N, et al. A Comparison of the Quality of Life of Patients With an Entirely Subcutaneous Implantable Defibrillator System Versus a Transvenous System (from the EFFORTLESS S-ICD Quality of Life Substudy). *Am J Cardiol*. Aug 15 2016; 118(4): 520-6. PMID 27353211
97. 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
98. 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
99. 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
100. 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
101. 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
102. Ommen SR, Mital S, Burke MA, et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. Dec 22 2020; 142(25): e533-e557. PMID 33215938
103. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Oct 02 2018; 72(14): 1677-1749. PMID 29097294
104. 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
105. Epstein AE, DiMarco JP, Ellenbogen KA, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Jan 22 2013; 61(3): e6-75. PMID 23265327

106. 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
107. 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
108. 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
109. Priori SG, Wilde AA, Horie M, et al. HRS/EHRA/APHRs expert consensus statement on the diagnosis and management of patients with inherited primary arrhythmia syndromes: document endorsed by HRS, EHRA, and APHRs in May 2013 and by ACCF, AHA, PACES, and AEPC in June 2013. *Heart Rhythm*. Dec 2013; 10(12): 1932-63. PMID 24011539
110. 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
111. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4). 2018; <https://www.cms.gov/Medicare-Coverage-Database/view/ncacal-decision-memo.aspx?proposed=N&NCAlid=288>. Accessed April 1, 2024.