FEP Medical Policy Manual

FEP 7.01.44 Implantable Cardioverter Defibrillators

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Related Policies:

2.02.10 - Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure
2.02.15 - Wearable Cardioverter Defibrillators

Implantable Cardioverter Defibrillators

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.

OBJECTIVE

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

POLICY STATEMENT

Adults

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

Primary Prevention

- Ischemic cardiomyopathy with New York Heart Association (NYHA) functional class II or 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 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
- Nonischemic dilated cardiomyopathy and left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; or
- 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 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 patients with HCM.
- 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):
  - 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 (see Policy Guidelines section)

The use of the ICD is considered **investigational** in primary prevention patients who:

- have had an acute myocardial infarction (ie, <40 days before ICD treatment);
- have NYHA class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy ICD device);
- have had a cardiac revascularization procedure in past 3 months (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) or are candidates for a cardiac revascularization procedure; or
- have noncardiac disease that would be associated with life expectancy less than 1 year.

Secondary Prevention

- Patients with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes (eg, acute ischemia) have been excluded.

The use of the ICD for secondary prevention is considered **investigational** for patients who do not meet the criteria for secondary prevention.

Pediatrics

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

- survivors of cardiac arrest, after reversible causes have been excluded;
- symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; or
- congenital heart disease with recurrent syncope of undetermined origin in the presence of ventricular dysfunction or inducible ventricular arrhythmias.
- HCM with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in ≥1 first-degree relatives <50 years; massive left ventricular hypertrophy based on age-specific norms; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with HCM.
- diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death (see Policy Guidelines):
    - congenital long QT syndrome; OR
    - Brugada syndrome; OR
    - short QT syndrome; OR
    - catecholaminergic polymorphic ventricular tachycardia.

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 adults or children who have an indication for ICD implantation for primary or secondary prevention for any of the above reasons and meet all of the following criteria:

- Have a contraindication to a transvenous ICD due to 1 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 patient 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 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.

POLICY GUIDELINES

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

Indications for pediatric ICD use are based on American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (HRS) guidelines published in 2008 (updated in 2012), which acknowledged the lack of primary research on pediatric patients in this field (see Rationale section). These indications derive from nonrandomized studies, extrapolation from adult clinical trials, and expert consensus.

Criteria for Implantable Cardioverter Defibrillator Implantation in Patients 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 patients 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 patients 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):
    - Patients with a diagnosis of LQTS who are survivors of cardiac arrest
    - Patients with a diagnosis of LQTS who experience recurrent syncopal events while on β-blocker therapy.

- Brugada syndrome (BrS):
    - Patients with a diagnosis of BrS who are survivors of cardiac arrest
    - Patients with a diagnosis of BrS who have documented spontaneous sustained ventricular tachycardia (VT) with or without syncope
    - Patients with a spontaneous diagnostic type 1 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)
    - Patients with a diagnosis of BrS who develop ventricular fibrillation during programmed electrical stimulation.
- Catecholaminergic polymorphic ventricular tachycardia (CPVT):
    - Patients with a diagnosis of CPVT who are survivors of cardiac arrest
    - Patients with a diagnosis of CPVT who experience recurrent syncope or polymorphic/bidirectional VT despite optimal medical management, and/or left cardiac sympathetic denervation.
- Short QT syndrome (SQTS):

Patients with a diagnosis of SQTS who are survivors of cardiac arrest

Patients with a diagnosis of SQTS who are symptomatic and have documented spontaneous VT with or without syncope

Patients with a diagnosis of SQTS or are asymptomatic or symptomatic and have a family history of sudden cardiac death.

NOTE: For congenital LQTS, patients may have 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 patients with a family history of sudden cardiac death due to LQTS, infants with a diagnosis of LQTS with functional 2:1 atrioventricular block, patients with a diagnosis of LQTS in conjunction with a diagnosis of Jervell and Lange-Nielsen syndrome or Timothy syndrome, and patients with a diagnosis of LQTS with profound QT prolongation (>550 ms). These factors should be evaluated on an individualized basis by a clinician with expertise in LQTS when considering the need for ICD placement.

Criteria for Implantable Cardioverter Defibrillator Implantation in Patients With Cardiac Sarcoid

Criteria for ICD placement in patients 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 patients 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 MRI or positron emission tomographic (PET) scan OR
- Inducible sustained ventricular arrhythmias (>30 seconds of monomorphic VT or polymorphic VT) or clinically relevant VF

- An indication for permanent pacemaker implantation.

Please see the Codes table for details.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

Medicare has specified a "desire to ensure that defibrillator implantation only occurs in those patients who are most likely to benefit and that the procedures are done only by competent providers in facilities with a history of good outcomes and a quality assessment/improvement program to identify providers with poor outcomes and other areas for improvement." Medicare has noted it is "concerned that the available evidence does not allow providers to target these devices to patients who will clearly derive benefit." Therefore, Medicare "will require that reimbursement for ICDs [implantable cardioverter defibrillators] for primary prevention of sudden cardiac death occur only if the beneficiary receiving the defibrillator implantation is enrolled in either an FDA-approved category B Investigational Device Exemption clinical trial or a qualifying national database (registry)" (see Rationale section).

Because of Medicare reimbursement policy, implantable cardioverter defibrillator placement may require an out-of-network referral. Plans may decide whether to encourage non-Medicare member participation in qualifying registries.

FDA REGULATORY STATUS

Transvenous Implantable Cardioverter Defibrillators

A large number of ICDs have been approved by the FDA through the premarket approval (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.[1] Many originally approved ICDs have received multiple supplemental applications. A selective summary of some currently available ICDs is provided in Table 1.

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 (see 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.

Table 1. Implantable Cardioverter Defibrillators with FDA 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

FDA: Food and Drug Administration; PMA: premarket application.
NOTE: ICDs may be combined with other pacing devices, such as pacemakers for atrial fibrillation, or biventricular pacemakers designed to treat heart failure. This evidence review addresses ICDs alone when used solely to treat patients at risk for ventricular arrhythmias.

RATIONALE

Summary of Evidence

Transvenous Implantable Cardioverter Defibrillators

For individuals who have a high-risk of sudden cardiac death (SCD) due to ischemic or to nonischemic cardiomyopathy in adulthood who receive transvenous implantable cardioverter defibrillator (ICD) (TV-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. RCTs assessing early ICD use following recent myocardial infarction did not support a benefit for immediate vs delayed implantation for at least 40 days. For nonischemic cardiomyopathy, there is less clinical trial data, but pooled estimates of available evidence from RCTs enrolling patients with nonischemic cardiomyopathy and from subgroup analyses of RCTs with mixed populations have supported a survival benefit for this group. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a high-risk of SCD due to hypertrophic cardiomyopathy (HCM) in adulthood who receive TV-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 rates are considered adequate evidence to support the use of ICDs in patients with HCM. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

For individuals who have a high-risk of SCD due to cardiac sarcoid who receive TV-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 sarcoiditis), 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 TV-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 a meaningful improvement in the net health outcome.

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

Subcutaneous Implantable Cardioverter Defibrillators

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

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

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Heart Association et al

Heart Failure

The AHA, American College of Cardiology, and Heart Rhythm Society (HRS) (2017) published joint guidelines on the management of heart failure, which updated their 2012 guidelines.[90,91,] These guidelines made the following recommendations on the use of ICD devices (see Tables1-8). The recommendations for the use of an ICD apply only if meaningful survival is expected to be greater than one year.

Table 1. Guidelines on Device-Based Therapy of Cardiac Rhythm Abnormalities

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

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

Table 2. Guidelines on Use of ICDs as a Primary Prevention of Ischemic Heart Disease

Recommendation	COR	LOE
"In patients with LVEF of 35% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days postrevascularization, and with NYHA class II or III HF despite GDMT..."	I	A
" In patients with LVEF of 30% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days postrevascularization, and with NYHA class I HF despite GDMT..."	I	A
"A transvenous ICD provides high value in the primary prevention of SCD particularly when the patient's risk of death due to a VA is deemed high and the risk of nonarrhythmic death (either cardiac or noncardiac) is deemed low based on the patient's burden of comorbidities and functional status..."		B-R
"In patients with NSVT due to prior MI, LVEF of 40% or less and inducible sustained VT or VF at electrophysiological study..."	I	B-R
"In nonhospitalized patients with NYHA class IV symptoms who are candidates for cardiac transplantation or an LVAD..."	IIa	B-NR
"An ICD is not indicated for NYHA class IV patients with medication-refractory HF who are not also candidates for cardiac transplantation, an LVAD, or a CRT defibrillator that incorporates both pacing and defibrillation capabilities."	III[a]	C-EO

CRT: cardiac resynchronization therapy; COR: class of recommendation; ICD: implantable cardioverter defibrillator; GDMT: guideline-directed management and therapy; HF: heart failure; LOE: level of evidence; LVAD: left ventricular assist device; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NSVT: nonsustained ventricular tachycardia; NYHA: New York Heart Association; SCD: sudden cardiac death; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.
a No benefit.

Table 3. Guidelines on Use of ICDs for Nonischemic Cardiomyopathy

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

COR: class of recommendation; CRT: cardia resynchronization therapy; GDMT: guideline-directed management and therapy; HF: heart failure; ICD: implantable cardioverter defibrillator: LOE: level of evidence; LVAD: left ventricular assist device; LVEF: left ventricular ejection fraction; NICM: nonischemic cardiomyopathy; NYHA: New York Heart Association; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.
a No benefit.

Table 4. Guidelines on Use of ICDs for HCM

Recommendation	COR	LOE
"In patients with HCM who have survived an SCA due to VT or VF, or have spontaneous sustained VT causing syncope or hemodynamic compromise..."	I	B-NR
"In patients with HCM and 1 or more of the following risk factors... • 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..."	IIa	B-NR C-LD
"In patients with HCM who have NSVT (LOE: B-NR) or an abnormal blood pressure response with exercise (LOE: B-NR) but do not have any other SCD risk modifiers, an ICD may be considered, but its benefit is uncertain."	IIB	B-NR B-NR
"In patients with an identified HCM genotype in the absence of SCD risk factors, an ICD should not be implanted"	III[a]	B-NR

COR: class of recommendation; HCM: hypertrophic cardiomyopathy; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LV: left ventricular; NSVT: nonsustained ventricular tachycardia; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VF: ventricular fibrillation; VT: ventricular tachycardia.
a No benefit.

Table 5. Guidelines on Use of Subcutaneous ICDs for Cardiac Sarcoiditis

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

ICD: implantable cardioverter defibrillator; COR: class of recommendation; LOE: level of evidence;VT: ventricular tachycardia; SCA: sudden cardiac arrest; LVEF: left ventricular ejection fraction; MRI: magnetic resonance imaging; VA: ventricular arrhythmia

Table 6. Guidelines on Use of ICDs for Other Conditions

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

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

Table 7. Guidelines on Use of Subcutaneous ICDs

Recommendation	COR	LOE
"In patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended."	I	B-NR
"In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated."	IIa	B-NR
"In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted."	III[a]	B-NR

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

a Harm.

The 2013 update made the following recommendations on ICD therapy for children (see Table 19).[90,]

Table 8. Guidelines on ICD Therapy for Children

Recommendation	COR	LOE
ICD implantation is indicated in the survivor of cardiac arrest after evaluation to define the cause of the event and to exclude any reversible causes.	I	B
ICD implantation is indicated for patients with symptomatic sustained VT in association with congenital heart disease who have undergone hemodynamic and electrophysiological evaluation. Catheter ablation or surgical repair may offer possible alternatives in carefully selected patients.	I	C
ICD implantation is reasonable for patients with congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study.	IIa	B
ICD implantation may be considered for patients with recurrent syncope associated with complex congenital heart disease and advanced systemic ventricular dysfunction when thorough invasive and noninvasive investigations have failed to define a cause.	IIb	C
All class III recommendations found in Section 3, "Indications for Implantable Cardioverter-Defibrillator Therapy," apply to pediatric patients and patients with congenital heart disease, and ICD implantation is not indicated in these patient populations.	III[a]	C

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

ICD Therapy in Patients Not Well Represented in Clinical Trials

The HRS, the American College of Cardiology, and AHA (2014) published an expert consensus statement on the use of ICD therapy for patients not included or poorly represented in ICD clinical trials.[92,] The statement presented a number of consensus-based guidelines on the use of ICDs in select patient populations.

American Heart Association

AHA (2010) issued a scientific statement, endorsed by HRS, on cardiovascular implantable electronic device infections and their management.[93.] This statement made the following recommendations on the removal of device-related infections (see Table 9).

Table 9. Guidelines on the Management of CIED Infections

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

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

Heart Rhythm Society- Arrhythmogenic Cardiomyopathy

In 2019, the HRS published a consensus statement on evaluation, risk stratification, and management of arrhythmogenic cardiomyopathy.[94.] Recommendations related to ICD risk stratification and placement decisions are shown in Table 10.

Table 10. Guidelines on Risk Stratification and ICD 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

ICD: Implantable cardioverter defibrillator; ACM: arrhythmogenic cardiomyopathy; ARVC: arrhythmogenic right ventricular cardiomyopathy; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; NSVT: nonsustained ventricular tachycardia; VT: ventricular tachycardia; FLNC: filamin-C; COR: Class of Recommendation; LOE: Level of Evidence

[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

The HRS, the European Heart Rhythm Association, and the Asia-Pacific Heart Rhythm Society (2013) issued a consensus statement on the diagnosis and management of patients with inherited primary arrhythmia syndromes, which included recommendations on ICD use in patients with long QT syndrome, Brugada syndrome, catecholaminergic polymorphic ventricular tachycardia, and short QT syndrome (see Table 11).[95,]

Table 11. Guidelines on the Diagnosis and Management of Inherited Primary Arrhythmia Syndromes

Recommendation	COR
Long QT syndrome	
ICD implantation is recommended for patients with a diagnosis of LQTS who are survivors of a cardiac arrest	I
ICD implantation can be useful in patients with a diagnosis of LQTS who experience recurrent 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 standalone therapy is not indicated in an asymptomatic patient with a diagnosis of CPVT	III[a]
Short QT syndrome	
ICD implantation is recommended in symptomatic patients with a diagnosis of SQTS who:Are survivors of cardiac arrest and/orHave documented spontaneous VT with or without syncope.	I
ICD implantation may be considered in asymptomatic patients with a diagnosis of SQTS and a family history of sudden cardiac death.	IIb

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

tachycardia.
a Not recommended.

ICD implantation may be considered in patients with LVEF in the range of 36% - 49% and/or RV ejection fraction <40%, despite optimal medical therapy and a period of immunosuppression (if indicated).

Heart Rhythm Society - Cardiac Sarcoid

In 2014, the HRS published a consensus statement on the diagnosis and management of arrhythias associated with cardiac sarcoiditis, including recommendations for ICD implantation in patients with cardiac sarcoid (Table 12).[29.] The writing group concluded that although there are few data specific to ICD use in patients with cardiac sarcoid, data from the major primary and secondary prevention ICD trials were relevant to this population and recommendations from the general device guideline documents apply to this population.

Table 12. Recommendations for ICD Implantation in Patients with Cardiac Sarcoid

Recommendation	COR[1]
ICD implantation **is recommended** in patients with cardiac sarcoid 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 sarcoid, 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

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

Pediatric and Congenital Electrophysiology Society and Heart Rhythm Society

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

therapy in adults with congenital heart disease (see Table 13).[96,]

Table 13. Guidelines on the Management of CHD

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

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

In February 2018, Medicare issued an update with minor changes to its 2005 national coverage guideline for the use of ICDs.[97,] The Centers for Medicare & Medicaid Services determined that the evidence is adequate to conclude that an ICD is reasonable and necessary for the following:

1. "Patients with ischemic dilated cardiomyopathy (IDCM), documented prior MI [myocardial infarction], NYHA [New York Heart Association] Class II and III heart failure, and measured LVEF [left ventricular ejection fraction] of ≤ 35%;
2. Patients with non-ischemic dilated cardiomyopathy (NIDCM) >9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%;
3. Patients who meet all current Centers for Medicare & Medicaid Services (CMS) coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA class IV heart failure;"

For each group, patients must not have:

- "Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
- Had a CABG [coronary artery bypass graft] or PTCA [percutaneous transluminal coronary angioplasty] within the past 3 months;
- Had an acute MI within the past 40 days;
- Clinical symptoms or findings that would make them a candidate for coronary revascularization;
- Irreversible brain damage from preexisting cerebral disease;
- Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year;"

Also, the Centers for Medicare & Medicaid Services specified that the beneficiary receiving an ICD for primary prevention must be enrolled in an approved clinical trial or a qualifying data collection system.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2013	Replace policy	Policy updated with literature review, with references added. Information about FDA approval of the subcutaneous ICD added. ACCF/AHA guidelines on management of patients with HCM added. Policy statement revised to include clarification for the indications in ischemic cardiomyopathy and the use of subcutaneous ICD considered not medically necessary for all indications
March 2014	Replace policy	Policy updated with literature review, with references 13, 25, 27 and 29 added and re-ordered. Policy statement regarding secondary prevention was revised to include medically necessary after reversible causes (e.g., acute ischemia) have been excluded.
March 2015	Replace policy	Policy updated with literature review through September 7, 2014. References 1. 16, 17, 23, 31, 33 and 35-39 added. Rationale section reorganized. Policy statements unchanged.

Date	Action	Description
December 2015	Replace policy	Policy updated with literature review through September 1, 2015; references 5, 12, 18-23, 29-32, 34-40, 43, 48-50, 52, 54, 57, 60, 63, 64, 67, 69-70, 72, and 78-81 added. Clinical input reviewed. ICD medically necessary for patients with cardiac ion channelopathies with conditions; S-ICD medically necessary in limited situations.
September 2016	Replace policy	Policy updated with literature review; references 23, 35, 53, 68, 74 and 83 added. Policy guideline section and the investigational policy statement revised to provide clarifications to policy intent.
September 2018	Archive policy	Policy updated with literature review through March 5, 2018; references 14-19, 22-23, 25, 31-40, 69, 71-75, 81 and 88 added; reference 95 updated; some references removed. Policy statements unchanged. Policy Archived.
December 2020	Reinstate active policy	Policy updated with literature review through April 13, 2020; references added. Indication for cardiac sarcoid added. Implantable cardioverter defibrillator (ICD) is medically necessary for patients with cardiac sarcoid with conditions. Policy statements otherwise unchanged. Policy reinstated as a resource for use with related policies (eg., 2.02.10 and 2.02.15)
March 2021	Administrative update	Policy edited grouping adult primary prevention statements. No change to policy statements.