Medical Coverage Policy

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Cardioverter-Defibrillator Devices

Table of Contents

Related Coverage Resources

Biventricular Pacing/Cardiac Resynchronization Therapy (CRT)
Cardiac Electrophysiological (EP) Studies

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses the use of implantable transvenous, subcutaneous cardioverter-defibrillators and substernal cardioverter-defibrillators.

This Coverage Policy also addresses wearable cardioverter-defibrillators and automatic external defibrillators in the home.

These devices are used to monitor heart rhythm and/or deliver an electrical shock when a life-threatening ventricular arrhythmia is detected.

Coverage Policy

Transvenous Implantable Cardioverter Defibrillator (ICD)

Secondary Prevention of Sudden Cardiac Death (SCD)

A transvenous implantable cardioverter defibrillator (ICD) is considered medically necessary for the secondary prevention of sudden cardiac death for EITHER of the following indications:

- **Individual with cardiac arrest due to ventricular fibrillation (VF) or hemodynamically unstable sustained ventricular tachycardia (VT) after reversable causes (e.g., myocardial ischemia (MI), electrolyte disorder) have been excluded.**

- **Individual with structural heart disease (e.g., prior MI, cardiomyopathy, valvular heart disease, adult congenital heart disease) and spontaneous sustained VT, whether hemodynamically stable or unstable.**

- **Individual with genetic conditions associated with sustained VT/VF (i.e., congenital long QT, short QT, catecholaminergic polymorphic VT, Brugada syndrome, arrhythmogenic right ventricular cardiomyopathy, hypertrophic cardiomyopathy).**

- **Individual without structural heart disease (left ventricular ejection fraction [LVEF] > 50%) or known genetic causes of sustained VT/VF and EITHER of the following:**
  - Bradycardia dependent VT/VF
  - Idiopathic VF/VT with normal ventricular function

- **Individual with unexplained syncope due to ANY of the following:**
  - Cardiac sarcoidosis with documented spontaneous sustained ventricular tachycardia
  - Ischemic heart disease with inducible sustained monomorphic VT on electrophysiological study.

- Left ventricular non-compaction
- Nonischemic dilated cardiomyopathy, LVEF ≤ 49%
- Structural heart disease (e.g. prior MI) with LVEF ≤ 35%
- Structural heart disease (e.g. prior MI) with LVEF 36%–49% and inducible sustained VT/VF on electrophysiological study.
- Tetralogy of Fallot with prior corrective surgery

- **Individual with syncope of suspected arrhythmic cause and ANY of the following:**
  - Arrhythmogenic right ventricular cardiomyopathy (ARVC)
  - Brugada ECG pattern
  - Cardiac amyloidosis
  - Catecholaminergic polymorphic VT (CPVT)
  - Hypertrophic Cardiomyopathy (HCM)
  - Long QT Syndrome (LQTS) and EITHER of the following:
    - syncope while receiving beta-blockers
    - beta-blockers are contraindicated

Primary Prevention of Sudden Cardiac Death

A transvenous implantable cardioverter defibrillator (ICD) is considered medically necessary for the primary prevention of sudden cardiac death for ANY of the following indications:

- **In an individual that is post-acute myocardial infarction (MI) (> 48 hours and < 40 days) and/or revascularization (< 90 days), with LVEF ≤ 40% and BOTH of the following:**
  - **Nonsustained ventricular tachycardia (NSVT)**
  - **Inducible sustained VT at electrophysiological (EP) study**

- **In an individual that is post-MI (≤ 40 Days) and need guideline-directed pacemaker therapy post-MI (e.g., sick sinus syndrome (SSS), complete heart block (CHB), or other indications for permanent pacemaker), with LVEF ≤ 40%**

- **In an individual that is post-MI (≥ 40 days) with ischemic cardiomyopathy, no recent percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) (≥ 90 days) and ANY of the following:**
  - LVEF ≤ 30% NYHA class I (despite guideline-directed medical therapy)
  - LVEF ≤ 35% NYHA class II or III (despite guideline-directed medical therapy)
  - LVEF ≤ 40% NSVT with EPS showing inducible sustained VT/VF

- **Individual with nonischemic cardiomyopathy, at least 3 months on guideline-directed medical therapy, with LVEF ≤ 35%, NYHA Class II-III**

- **Individual with cardiac sarcoidosis and ANY of the following:**
  - Sustained VT
  - Survivors of SCA
  - LVEF ≤ 35%
  - LVEF > 35% with syncope and/or evidence of myocardial scar by cardiac MRI or positron emission tomographic (PET) scan
  - LVEF > 35%, with inducible sustained VA

- **Individual with ANY of the following conditions:**

- Myotonic dystrophy
- Chagas disease
- Acute lymphocytic myocarditis, newly diagnosed (< 3 months)
- Giant cell myocarditis
- Peripartum cardiomyopathy, persists > 3 months postpartum, LVEF ≤ 35%

- **Individual with ANY of the following genetic conditions (excludes syncope and sustained VT, addressed above)**
  - Hypertrophic cardiomyopathy (HCM) with 1 or more risk factors:
    - Prior cardiac arrest or spontaneous nonsustained VT
    - Family history of SCD from HCM
    - LV thickness greater than or equal to 30 mm by echocardiography or cardiovascular magnetic resonance (CMR) imaging
    - abnormal blood pressure response to exercise
    - NSVT episodes on continuous ambulatory electrocardiographic monitoring
    - LV apical aneurysm, independent of size
    - LV systolic dysfunction (EF < 50%) by echocardiography or CMR imaging.
    - Extensive late gadolinium enhancement (LGE) on CMR imaging.
  - Arrhythmogenic right ventricular dysplasia/cardiomyopathy with no symptoms due to arrhythmia
  - Congenital long QT Syndrome with 1 or more risk factors (e.g., sudden cardiac arrest, family history of SCD, compliance/intolerance to drugs is a concern)
  - Catecholaminergic polymorphic VT with nonsustained VT (without syncope)
  - Incidentally discovered Brugada by ECG (type I ECG pattern) in the absence of symptoms or family history of sudden cardiac death, with inducible VT or VF at EPS
  - Familial dilated nonischemic cardiomyopathy (RV/LV) associated with sudden cardiac death, and ANY of the following:
    - Evidence of structural cardiac disease, but LVEF > 35%
    - Normal ECG and echo, but carrying the implicated gene
    - LV non-compaction with LVEF > 35%
  - Nonischemic cardiomyopathy (NICM) due to a Lamin A/C mutation with 2 or more risk factors (e.g., NSVT, LVEF <45%, non-missense mutation, male sex)

A transvenous ICD is considered medically necessary in a child who is receiving optimal medical therapy and has survived cardiac arrest when evaluation fails to identify a reversible cause.

A transvenous ICD is considered medically necessary in a child with hypertrophic cardiomyopathy and unexplained syncope, massive left ventricular hypertrophy, or family history of sudden cardiac death.

Replacement of a transvenous ICD pulse generator and/or leads is considered medically necessary.

A transvenous ICD is considered not medically necessary for ANY other indication.

<u>Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)</u>

A subcutaneous implantable cardioverter defibrillator (S-ICD) system is considered medically necessary when an individual has met the criteria for a transvenous ICD and has NONE of the following:

- symptomatic bradycardia
- incessant ventricular tachycardia (VT)
- spontaneous frequent recurring VT reliably terminated with anti-tachycardia pacing

A subcutaneous implantable cardioverter defibrillator (S-ICD) system is considered not medically necessary for ANY other indication.

Substernal Implantable Cardioverter Defibrillator

A substernal implantable cardioverter-defibrillator is considered experimental, investigational or unproven for ANY indication.

Wearable Cardioverter-Defibrillator

Coverage for a wearable cardioverter defibrillator varies across plans. Refer to the customer's benefit plan document for coverage details.

If coverage for a wearable cardioverter defibrillator is available, the following conditions of coverage apply.

A U.S. Food and Drug Administration (FDA)-approved wearable cardioverter defibrillator (e.g., ASSURE System, LifeVest™) is considered medically necessary when ANY of the following criteria is met:

- The individual is at high risk for sudden cardiac death and meets criteria for implantable cardioverter defibrillator (ICD) placement but is not currently a suitable candidate for ICD placement because of one of the following:
  - awaiting heart transplantation
  - awaiting ICD reimplantation following infection-related explantation
  - systemic infectious process or other temporary medical condition precludes implantation

- As a bridge to ICD risk stratification and possible implantation for patients immediately following myocardial infarction (MI) for EITHER of the following:
  - history of ventricular tachycardia or ventricular fibrillation after the first 48 hours
  - left ventricular ejection fraction (LVEF) ≤ 35%

- For primary prevention, as a bridge to ICD risk stratification and possible implantation for newly diagnosed dilated cardiomyopathy (ischemic or nonischemic) with LVEF ≤ 35%
- The pediatric individual meets criteria for ICD however implantation of an ICD is contraindicated and ALL of the following criteria are met:
  - Chest circumference of 26 inches (66 centimeters) or greater
  - Weight of 41.3 pounds (18.75 kilograms) or greater

A wearable cardioverter-defibrillator (e.g., ASSURE System, LifeVest) is considered not medically necessary for any other indication.

Automatic External Defibrillator (AED)

Effective 12/15/2024

A U.S. Food and Drug Administration (FDA)-approved pediatric nonwearable automatic external defibrillator (AED) is considered medically necessary for an individual who weighs less than 55 pounds (25 kilograms) and BOTH of the following criteria are met:

- individual meets criteria for implantable cardioverter defibrillator (ICD) however implantation of a permanent defibrillator is contraindicated
- Individual does not meet criteria for a wearable cardioverter-defibrillator

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

In the United States, SCD is responsible for an estimated 350,000 cardiac deaths per year. Epidemiologic studies suggest that men, Blacks and individuals from socioeconomically disadvantaged backgrounds experience higher rates of cardiac arrest. The incidence of SCD increases with age in both men and women; however, at any level of multivariate risk, women are less likely to experience sudden death than men and a higher fraction of sudden deaths in women occur without prior overt CHD (Podrid, 2024b). Banerjee et al. (2021) reported that Blacks and Hispanics tend to reside in neighborhoods that have lower rates of bystander cardiopulmonary resuscitation and automatic external defibrillator (AED) use and, should they happen to survive a cardiac arrest, are less likely to subsequently receive an implantable cardioverter-defibrillator (ICD).

Patel et al. (2016) reported on the gender, racial and health insurance differences in implantable cardioverter-defibrillator (ICD) utilization. The study used a hospitalization database to determine the trend of ICD utilization over the last decade and if disparities in gender, race, and insurance-payer changed over the last decade. The majority of ICDs were implanted in men age ≥ 65 years. Implantation of ICDs was 2.5x more common in men than in women (402 per million vs 163 per million). Approximately 95% of the ICDs were implanted in insured patients, and 5% were used in the uninsured population.

Several reviews have reported on the gender and racial disparities in clinical presentation, management, and outcome of hypertrophic cardiomyopathy (HCM) and heart failure. Black patients with HCM are more likely to present with heart failure but are less commonly referred for symptom management, sudden cardiac death stratification, surgical septal myectomy, or for implantable cardioverter-defibrillators. However, there were no significant differences in clinical outcome between Black and White patient groups for rate of adverse HCM events (including SCD, HCM mortality, heart transplant, and all-cause mortality). Prevalence of bystander cardiopulmonary resuscitation is lower for Black patients than for White patients. Finally, Black patients with HCM have decreased survival after hospital discharge following out-of-hospital cardiac arrest. Women presented with more comorbidities and more severe HF and more frequently non-ischemic cardiomyopathies but they were less likely to be referred for ICD therapy despite current guideline recommendations. ICD devices are underused in women and racial

minorities independent of demographics, hospital characteristics, and comorbidities. Women and racial minorities also had higher rates of complications and greater resource use compared with men and those belonging to the White race (Chahine, et al., 2022; Patlolla, et al., 2022; Banerjee, et al., 2021; Ntusi and Sliwa, 2021; Regitz-Zagrosek, 2020; Zhao, et al., 2019; Patel, et al., 2016).

General Background

Sudden cardiac arrest (SCA) and sudden cardiac death (SCD) refer to the sudden stopping of cardiac activity with hemodynamic collapse which is frequently due to sustained ventricular tachycardia/ventricular fibrillation. These events frequently occur in patients with structural heart disease (that may not have been previously diagnosed), particularly coronary heart disease (CHD). Additionally, there is a high incidence of sudden cardiac death (SCD) in patients with heart failure and diminished left ventricular ejection fraction (LVEF) and in patients who are recovering from acute myocardial infarction (MI). Although the risk of SCD increases in proportion to the severity of cardiac disease in an individual patient, most events occur in patients with no known cardiac history and with few or no risk factors. The risk factors for CHD are also risk factors for SCA. These include dyslipidemia, hypertension, cigarette smoking, physical inactivity, obesity, diabetes mellitus, and a family history of premature CHD or myocardial infarction. (Podrid, 2024a; Podrid, 2024b; Kusmirek and Gold, 2007; Zipes, et al., 2006).

Although a number of studies have investigated the electrophysiologic (EP) mechanisms responsible for the onset of ventricular tachycardia and ventricular fibrillation, antiarrhythmic agents have not been shown to be effective in preventing SCD. Rather, it is the drugs that have no direct EP actions on cardiac muscle or specialized conducting tissue that have been demonstrated to be effective in preventing SCD. Such drugs include beta blockers, ACE inhibitors, angiotensin receptor-blocking agents, lipid-lowering agents, spironolactone, and fibrinolytic and anti-thrombotic agents (Al-Khatib et al., 2017; Zipes, et al., 2006).

Transvenous Implantable Cardioverter Defibrillator (ICD)

The implantable cardioverter defibrillator (ICD) is a surgically implanted device designed to constantly monitor an individual's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT) and deliver an electric shock to terminate these arrhythmias in order to reduce the risk of sudden death. The device is connected to leads positioned inside the heart or on its surface. These leads sense the cardiac rhythm, deliver electrical shocks, and sometimes pace the heart, as needed. The leads are tunneled to a pulse generator, which is implanted in a pouch beneath the skin of the chest or abdomen. Progressive improvements in design and miniaturization have allowed transvenous placement of ICDs to become routine. An epicardial rather than transvenous approach may be required in children, and less commonly in adults. In this surgical procedure one end of the lead is attached to the heart and the other end of the lead is attached to the pulse generator and placed in a pocket created under the skin of the abdomen.

ICDs have been demonstrated to be effective in the prevention of sudden death in patients who have experienced a life-threatening clinical event associated with sustained ventricular tachyarrhythmia, patients who have had a prior MI and reduced left ventricular ejection fraction (LVEF), and patients who have cardiac risk factors that place them at increased risk for sudden cardiac death.

Procedural complication rates range from three to ten percent, with up to on-half of these considered serious. Complications include bleeding infections, lead dislodgement, pneumothorax, cardiac perforation, and rarely death. Perioperative mortality with transvenous ICD implantation

has ranged from 0.2 to 0.4 percent. Lead-related complications, in addition to infection and dislodgement, include fracture and insulation defects. Most lead dislodgements and infections occur in the first three months following implantation, while lead fractures continue to occur during follow-up. Reported lead failure rates vary from one to nine percent at two years, two to fifteen percent and five years and five to forty percent at eight to ten years. Deaths related to lead failure have been reported but are exceedingly rare. The overall complication rate has decreased over the period from 2006 to 2010, a period that correlates with the introduction of an ICD registry in the US. In an observational study of 367,153 ICD recipients between April 2006 and March 2010, in-hospital complications and mortality significantly decreased from 3.7% during year one to 2.8% during year four (Kwaku, 2023).

Additional problems associated with ICDs include inappropriate shock discharge, defibrillator storm with appropriate recurrent ICD discharge for recurrent ventricular tachyarrhythmias, inappropriate discharge for multiple reasons, infections related to implantation and exacerbation of heart failure when a high percentage of the heartbeats are paced from the right ventricle apex and ventricular function is already compromised.

When an ICD nears the end of battery life it is replaced. A pulse generator will last for five or more years in most patients. One study suggested that devices implanted after 2002 have significantly longer battery lives (5.6 versus 4.9 years), and single chamber ICDs implanted since 2002 had the longest battery life (mean 6.7 years).

Two categories of trials have investigated the use of ICDs for prevention of SCD. ICDs have been evaluated for primary (i.e., prophylactic) prevention of SCD in patients who have not experienced a life-threatening ventricular arrhythmia (or a symptomatic equivalent). Secondary prevention trials have evaluated the use of ICDs in patients who have had an abortive cardiac arrest, a life-threatening VT, or unexplained syncope with high probability that a ventricular tachyarrhythmia was the cause (Priori, et al., 2015; Zipes, et al., 2006).

U.S. Food and Drug Administration (FDA): Multiple ICD devices have been approved by the FDA through the Premarket Approval (PMA) process. Manufacturers of ICD devices include Biotronik (Lake Oswego, OR), Boston Scientific (Natick, MA), Sorin Group (Arvada, CO), Medtronic (Minneapolis, MN), and St. Jude Medical (St. Paul, MN).

Professional Societies/Organizations:
American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Failure Society of America (HFSA) Guideline for the Management of Heart Failure: The updated AHA/ACC/HFSA guidelines for the management of heart failure (HF) were published in 2022 (Heidenreich, et al., 2022). To develop the guidelines, the committee used the 2019 ACC/AHA evidence-based methodologies to assign each recommendation a Class of Recommendation and a Level of Evidence:

Class (Strength) of Recommendation:

- Class 1 (Strong)
  - Benefit >>>Risk
  - Intervention is recommended; is indicated/useful/effective/beneficial.
- Class 2a (Moderate)
  - Benefit>>Risk
  - Intervention is reasonable; can be useful/effective/beneficial.
- Class 2b (Weak)
  - Benefit ≥ Risk

  - Intervention may be reasonable; may be considered; its usefulness/ effectiveness is unknown/unclear/uncertain or not well-established.
- Class 3 No Benefit (Moderate)
  - Benefit=Risk
  - Intervention is not recommended/indicated/useful/effective/beneficial; it should not be performed/administered.
- Class 3 Harm (Strong)
  - Risk > Benefit
  - Intervention is not recommended/indicated/useful/effective/beneficial; it should not be performed/ administered.

Level (Quality) of Evidence:

- Level A
  - High-quality evidence from more than one RCT.
  - Meta-analyses of high-quality RCTs.
  - One or more RCTs corroborated by high-quality registry studies.
- Level B-R (Randomized)
  - Moderate-quality evidence from one or more RCTs.
  - Meta-analyses of moderate-quality RCTs.
- Level B-NR (Nonrandomized)
  - Moderate-quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies.
  - Meta-analyses of such studies
- Level C-LD (Limited Data)
  - Randomized or nonrandomized observational or registry studies with design or execution limitations.
  - Meta-analyses of such studies
  - Physiological or mechanistic studies in human subjects
- Level C-EO (Expert Opinion)
  - Consensus of expert opinion based on clinical experience.

The guideline stated that reevaluation of EF (> 40 days after MI, > 90 days after revascularization, > 90 days after GDMT) is useful to determine candidacy for implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT). For the primary prevention of SCD in patients who have heart failure with reduced ejection fraction (HFrEF) the guidelines made the following recommendations concerning ICD's:

- In patients with nonischemic DCM or ischemic heart disease who are at least 40 days post-MI with LVEF ≤ 35% and a NYHA class II or III symptoms on chronic GDMT, who have reasonable expectation of meaningful survival for >1 year, ICD therapy is recommended for primary prevention of SCD to reduce total mortality (Class of Recommendation: 1; Level of Evidence: A).
- In patients at least 40 days post-MI with LVEF ≤ 30% and NYHA class I symptoms while receiving GDMT, who have reasonable expectation of meaningful survival for >1 year, ICD therapy is recommended for primary prevention of SCD to reduce total mortality (Class of Recommendation: 1; Level of Evidence: B-R)

Heart Rhythm Society (HRS): In 2022 the HRS published an expert consensus statement on evaluation and management of arrhythmic risk in neuromuscular disorders (NMD's). The cardiovascular presentation and management of patients with NMDs is dependent on the specific disorder. This consensus statement focused on the muscular dystrophies exhibiting prominent cardiac and arrhythmic manifestations, including Duchenne muscular dystrophy (DMD), Becker

muscular dystrophy (BMD), limb-girdle muscular dystrophy type 2 (LGMD2) and limb-girdle muscular dystrophy type 1B (LGMD1B), myotonic dystrophy type 1 (DM1) and myotonic dystrophy type 2 (DM2), Emery-Dreifuss muscular dystrophy (EDMD), facioscapulohumeral muscular dystrophy (FSHD), and mitochondrial myopathies including Friedreich ataxia (FA) and Kearns-Sayre syndrome (Groh, et al., 2022).

The HRS recommended the following for the use of ICDs to manage arrhythmic risk in neuromuscular disorders (NMD's) using the 2019 ACC/AHA evidence-based methodologies:

Indication	Recommendation for ICD placement	COR/LOE*
Emery-Dreifuss and limb-girdle type 1B muscular dystrophies	In patients with DM1 or DM2 in whom ICD therapy is planned, an ICD system with permanent pacing capability is recommended.	1/B-NR
	In patients with DM1 or DM2 who are survivors of spontaneously occurring hemodynamically significant sustained VT or VF, ICD therapy is indicated if concordant with the patient's goals of care and clinical status.	1/B-NR
	In patients with DM1 or DM2 and an LVEF ≤ 35% despite guideline-directed medical therapy, ICD therapy is indicated if concordant with the patient's goals of care and clinical status.	1/B-NR
	In patients with DM1 or DM2 in whom clinically relevant ventricular arrhythmias are induced during electrophysiological study, ICD therapy is recommended if concordant with the patient's goals of care and clinical status.	1/B-NR
	In patients with DM1 or DM2 in whom permanent pacemaker implantation is indicated, ICD therapy may be considered if concordant with the patient's goals of care and clinical status.	2b/B-NR
Emery-Dreifuss and limb-girdle type 1B muscular dystrophies	In patients with EDMD or LGMD1B in whom ICD therapy is planned, an ICD system with permanent pacing capability is recommended.	1/B-NR
	In patients with EDMD or LGMD1B who are survivors of spontaneously occurring hemodynamically significant sustained VT or VF, ICD therapy is indicated if concordant with the patient's goals of care and clinical status.	1/B-NR
	In patients with EDMD or LGMD1B with at least one of the following: second-degree or third-degree AV block, PR interval ≥ 230 ms, or spontaneous HV ≥ 70 ms, ICD therapy is recommended if concordant with the patient's goals of care and clinical status.	1/B-NR
	In patients with EDMD or LGMD1B with an LVEF ≤ 35% despite guideline-directed medical therapy, ICD therapy is indicated if concordant with the patient's goals of care and clinical status.	1/B-NR
	In patients with EDMD or LGMD1B in whom clinically relevant ventricular arrhythmias are induced during electrophysiological study, ICD therapy is recommended if concordant with the patient's goals of care and clinical status.	1/B-NR

Indication	Recommendation for ICD placement	COR/LOE*
	In patients with EDMD or LGMD1B with LVEF < 45% and nonsustained VT, an ICD is reasonable if concordant with the patient's goals of care and clinical status.	2a/B-NR
	In patients with EDMD or LGMD1B with at least one of the following: LBBB, right bundle branch block (RBBB), or AF or AFL with slow ventricular response (ventricular rate < 50 bpm), ICD therapy is reasonable if concordant with the patient's goals of care and clinical status.	2a/C-LD
	In patients with EDMD or LGMD1B with symptomatic sinus node dysfunction or sinus bradycardia with heart rate < 40 bpm, ICD therapy may be considered if concordant with the patient's goals of care and clinical status	2b/C-LD
Mitochondrial myopathies including Friedreich ataxia	In patients with mitochondrial myopathies including FA with spontaneously occurring VF or sustained hemodynamically significant VT, ICD therapy is indicated if concordant with the patient's goals of care and clinical status.	1/B-NR
	In patients with mitochondrial myopathies including FA with an LVEF ≤ 35% despite guideline-directed medical therapy, ICD therapy is reasonable if concordant with the patient's goals of care and clinical status.	2a/B-NR

American College of Cardiology Foundation (ACCF)/American Heart Association (AHA): Additional recommendations for patient selection for ICDs in those with hypertrophic cardiomyopathy are included in guidelines for the diagnosis and treatment of hypertrophic cardiomyopathy (Ommen, et al., 2020).

The ACCF/AHA recommended the following for the use of ICDs using the 2019 ACC/AHA evidence-based methodologies that are referenced under: Heidenreich, et al., 2022:

Class I

- The decision to place an ICD in patients with HCM should include application of individual clinical judgment, as well as a thorough discussion of the strength of evidence, benefits, and risks to allow the informed patient's active participation in decision making *(Level of Evidence: C)*

- ICD placement is recommended for patients with HCM with prior documented cardiac arrest, ventricular fibrillation, or hemodynamically significant ventricular tachycardia (VT) *(Level of evidence: B)*

Class IIa

- It is reasonable to recommend an ICD for patients with HCM with:
  - Sudden death presumably caused by HCM in one or more first-degree relatives who are ≤ 50 years of age; *(Level of Evidence: B)*
  - LV wall thickness greater than or equal to 30 mm *(Level of Evidence: B)*
  - One or more recent unexplained syncopal episodes *(Level of Evidence: B)*
  - Any size left ventricular apical aneurysm *(Level of Evidence: B)*
  - Left ventricular systolic dysfunction EF < 50 *(Level of Evidence: B)*

- It is reasonable to recommend an ICD for children with HCM and ≥ 1 conventional risk factor (e.g., unexplained syncope, massive LVH, NSVT, family history of early HCM-related SCD) after considering the relatively high complication rates of long-term ICD placement. *(Level of Evidence: B)*

- It is reasonable to recommend an ICD for patients ≥ 16 years of age with HCM and with ≥ 1 major SCD risk factor after a discussion of the estimated 5-year sudden death risk and mortality rates. (Level of Evidence: B)

Class IIb

- The usefulness of an ICD is uncertain in patients with HCM and no major SCD risk factors *(Level of Evidence: B)*

- ICD may be considered in patients with extensive LGE by contrast-enhanced CMR imaging or NSVT present on ambulatory monitoring. (*Level of Evidence: B)*

- The usefulness of an ICD is uncertain in select pediatric patients with HCM in whom risk stratification is otherwise less certain and it may be useful to consider additional factors such as extensive LGE on contrast-enhanced CMR imaging and systolic dysfunction in risk stratification. (Level of Evidence: C)

Class III: Harm

- ICD placement as a routine strategy in patients with HCM without an indication of increased risk is potentially harmful. *(Level of Evidence: B)*

- ICD placement as a strategy to permit patients with HCM to participate in competitive athletics is potentially harmful. *(Level of Evidence: B)*

As stated above, the guideline includes a recommendation for ICD use in high-risk children with HCM, based on unexplained syncope, massive LV hypertrophy, or family history of SCD, after taking into account the relatively high complication rate of long-term ICD implantation. Although not defined in the guideline, massive LV hypertrophy is generally considered to be a maximal wall thickness approximately three times greater than normal. The authors note that the rate of inappropriate shocks and lead fractures appears to be higher in children than in adults, primarily because their activity level and body growth places continued strain on the leads, which are the weakest link in the system. This is of particular concern, considering the long period of time young patients will have prophylactically implanted devices. Other treatment options that may be considered for children with HCM include pharmacological management and surgical septal myectomy.

Heart Rhythm Society (HRS): In 2019, the HRS published an expert consensus statement on evaluation, risk stratification, and management of arrhythmogenic cardiomyopathy. Arrhythmogenic cardiomyopathy (ACM) incorporates a broad spectrum of genetic, systemic, infectious, and inflammatory disorders. This designation includes, but is not limited to, arrhythmogenic right/left ventricular cardiomyopathy, cardiac amyloidosis, sarcoidosis, Chagas disease, and left ventricular noncompaction. To develop the guidelines, the committee used the 2016 ACC/AHA evidence-based methodologies to assign each recommendation a Class of Recommendation and a Level of Evidence (Towbin, et al., 2019):

Guideline Class of Recommendation (COR) and Level of Evidence (LOE) are described as follows:

- Class (Strength) of Recommendation:
- Class I (Strong) Benefit >>>Risk

- Class IIa (Moderate) Benefit>>Risk
- Class IIb (Weak) Benefit ≥ Risk
- Class III No Benefit (Moderate) Benefit=Risk
- Class III Harm (Strong) Risk>Benefit

Level (Quality) of Evidence:

- Level A if the data were derived from high-quality evidence from more than one randomized clinical trial(RCT), meta-analyses of high-quality RCTs, or one or more RCTs corroborated by high-quality registry.
- Level B-R when data were derived from moderate quality evidence from one or more RCTs, or meta-analyses of moderate-quality RCTs.
- Level B-NR was used to denote moderate-quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies. This designation was also used to denote moderate-quality evidence from meta-analyses of such studies.
- Level C-LD when the primary source of the recommendation was randomized or nonrandomized observational or registry studies with limitations of design or execution, meta-analyses of such studies, or physiological or mechanistic studies of human subjects.
- Level C-EO was defined as expert opinion based on the clinical

The consensus statement issued the following recommendations for ICD placement (Towbin, et al., 2019):

Indication	Recommendation for ICD placement	COR/LOE
Arrhythmogenic Cardiomyopathy ACM	In individuals with arrhythmogenic cardiomyopathy ACM who have suffered a cardiac arrest with VT or VF, an ICD is recommended.	I/B-NR
	In individuals with ACM who have sustained VT not hemodynamically tolerated, an ICD is recommended.	I/B-NR
	In individuals with ACM and syncope suspected to be due to a ventricular arrhythmia, an ICD is reasonable.	IIa/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
Arrhythmogenic Right Ventricular Cardiomyopathy	In individuals with arrhythmogenic right ventricular cardiomyopathy (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
Phospholamban Cardiomyopathy	In individuals with phospholamban cardiomyopathy and LVEF 45%, or NSVT, an ICD is reasonable.	IIa/B-NR

Indication	Recommendation for ICD placement	COR/LOE
Lamin A/C ACM	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 lamin A/C ACM and an indication for pacing, an ICD with pacing capabilities is reasonable.	IIa C-LD
Secondary Prevention: Cardiac Amyloidosis	In individuals with cardiac amyloidosis who have survived a cardiac arrest, an ICD is recommended if meaningful survival greater than 1 year is expected.	I/C-EO
Primary Prevention: Cardiac Amyloidosis	In individuals with AL-type cardiac amyloidosis with nonsustained ventricular arrhythmias, a prophylactic ICD may be considered if meaningful survival greater than 1 year is expected. Guideline noted: Primary prevention ICD implantation remains controversial, and there are conflicting data on the prevention of SCD in cardiac Amyloidosis	IIb/B-NR
Left Ventricular Non-Compaction (LVNC)	ICD implantation is recommended in individuals with LVNC and evidence of ventricular tachyarrhythmias associated with syncope or resuscitated sudden death if meaningful survival greater than 1 year is expected.	I/B-NR
	ICD implantation is reasonable in individuals with LVNC and evidence of nonsustained VT associated with a reduced ejection fraction.	IIa/B-NR

American Heart Association (AHA)/American College of Cardiology (ACC)/Health Rhythm Society (HRS): The AHA/ACC/HRS 2017 guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death recommended the following for ICD placement using the Class of Recommendation (COR) and LOE system mentioned above by Towbin, et al. (2019) (Al-Khatib, et al., 2017):

Indication	Recommendation for ICD placement	COR/LOE
Adult Congenital Heart Disease	In patients with adult congenital heart disease and hemodynamically unstable VT, an ICD is recommended after evaluation and appropriate treatment for residual lesions/ventricular dysfunction if meaningful survival of greater than 1 year is expected.	I/B-NR
	In patients with adult congenital heart disease with SCA due to VT or VF in the absence of reversible causes, an ICD is recommended if meaningful survival of greater than 1 year is expected.	I/B-NR
	In adults with repaired tetralogy of Fallot physiology and inducible VT/VF or spontaneous sustained VT, implantation of an ICD is reasonable if meaningful survival greater than 1 year is expected.	IIa/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	IIa/B-NR

Indication	Recommendation for ICD placement	COR/LOE
	inducible sustained VA is reasonable if meaningful survival of greater than 1 year is expected.	
	In patients with adult congenital heart disease and severe ventricular dysfunction (LVEF <35%) and symptoms of heart failure despite GDMT or additional risk factors, ICD implantation may be considered if meaningful survival of greater than 1 year is expected.	IIb/B-NR
Arrhythmogenic Right Ventricular Cardiomyopathy	In patients with arrhythmogenic right ventricular cardiomyopathy and an additional marker of increased risk of SCD (resuscitated SCA, sustained VT, significant ventricular dysfunction with RVEF or LVEF ≤35%), an ICD is recommended if meaningful survival greater than 1 year is expected.	I/B-NR
	In patients with arrhythmogenic right ventricular cardiomyopathy and syncope presumed due to VA, an ICD can be useful if meaningful survival greater than 1 year is expected.	IIa/B-NR
Brugada Syndrome	In patients with Brugada syndrome with spontaneous type 1 Brugada electrocardiographic pattern and cardiac arrest, sustained VA or a recent history of syncope presumed due to VA, an ICD is recommended if meaningful survival of greater than 1 year is expected.	I/B-NR
Cardiac Channelopathies	In patients with a cardiac channelopathy and SCA, an ICD is recommended if meaningful survival of greater than 1 year is expected.	I/B-NR
Cardiac Sarcoidosis	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
Catecholaminergic Polymorphic Ventricular Tachycardia	In patients with catecholaminergic polymorphic ventricular tachycardia and recurrent sustained VT or syncope, while receiving adequate or maximally tolerated beta blocker, treatment intensification with either combination medication therapy (eg, beta blocker, flecainide), left	I/B-NR

Indication	Recommendation for ICD placement	COR/LOE
	cardiac sympathetic denervation, and/or an ICD is recommended.	
Congenital Long QT Syndrome	In high-risk patients with symptomatic long QT syndrome in whom a beta blocker is ineffective or not tolerated, intensification of therapy with additional medications (guided by consideration of the particular long QT syndrome type), left cardiac sympathetic denervation, and/or an ICD is recommended.	I/B-NR
	In asymptomatic patients with long QT syndrome and a resting QTc greater than 500 ms while receiving a beta blocker, intensification of therapy with medications (guided by consideration of the particular long QT syndrome type), left cardiac sympathetic denervation or an ICD may be considered.	IIb/B-NR
Coronary Artery Spasm	In patients resuscitated from SCA due to coronary artery spasm in whom medical therapy is ineffective or not tolerated, an ICD is reasonable if meaningful survival of greater than 1 year is expected.	IIa/B-NR
	In patients resuscitated from SCA due to coronary artery spasm, an ICD in addition to medical therapy may be reasonable if meaningful survival of greater than 1 year is expected.	IIb/B-NR
Early Repolarization "J-wave" Syndrome	In patients with early repolarization pattern on ECG and cardiac arrest or sustained VA, an ICD is recommended if meaningful survival greater than 1 year is expected.	I/B-NR
Heart Failure	In patients with HFrEF who are awaiting heart transplant and who otherwise would not qualify for an ICD (eg, NYHA class IV and/or use of inotropes) with a plan to discharge home, an ICD is reasonable.	IIa/B-NR
Heart Transplant	In patients with a heart transplant and severe allograft vasculopathy with LV dysfunction, an ICD may be reasonable if meaningful survival of greater than 1 year is expected.	IIb/B-NR
Hypertrophic Cardiomyopathy (HCM)	In patients with HCM who have survived an SCA due to VT or VF, or have spontaneous sustained VT causing syncope or hemodynamic compromise, an ICD is recommended if meaningful survival greater than 1 year is expected.	I/B-NR
	In patients with HCM and 1 or more of the following risk factors, an ICD is reasonable if meaningful survival of greater than 1 year is expected: a. Maximum LV wall thickness ≥30 mm	IIa/B=NR
	b. SCD in 1 or more first-degree relatives presumably caused by HCM	IIa/C-LD
	c. 1 or more episodes of unexplained syncope within the preceding 6 months	IIa/C-LD

Effective 12/15/2024

Indication	Recommendation for ICD placement	COR/LOE
	In patients with HCM who have spontaneous NSVT or an abnormal blood pressure response with exercise (LOE: B-NR), who also have additional SCD risk modifiers or high-risk features, an ICD is reasonable if meaningful survival greater than 1 year is expected.	IIa/B-NR IIa/C-LD
	In patients with HCM who have NSVT or an abnormal blood pressure response with exercise but do not have any other SCD risk modifiers, an ICD may be considered, but its benefit is uncertain.	IIb/B-NR IIb/B-NR
	In patients with an identified HCM genotype in the absence of SCD risk factors, an ICD should not be implanted	III/B-NR
Idiopathic Polymorphic VT/VF	In patients resuscitated from SCA due to idiopathic polymorphic VT or VF, an ICD is recommended if meaningful survival greater than 1 year is expected.	I/B-NR
Left Ventricular Assist Device	In patients with an LVAD and sustained VA, an ICD can be beneficial.	IIa/C-LD
Myocarditis	In patients with giant cell myocarditis with VF or hemodynamically unstable VT treated according to GDMT, an ICD and/or an antiarrhythmic medication may be considered if meaningful survival of greater than 1 year is expected.	IIb/C-LD
Neuromuscular Disorders	In patients with neuromuscular disorders, primary and secondary prevention ICDs are recommended for the same indications as for patients with NICM if meaningful survival of greater than 1 year is expected.	I/B-NR
	In patients with Emery-Dreifuss and limbgirdle type IB muscular dystrophies with progressive cardiac involvement, an ICD is reasonable if meaningful survival of greater than 1 year is expected.	IIa/B-NR
	In patients with myotonic dystrophy type 1 with an indication for a permanent pacemaker, an ICD may be considered to minimize the risk of SCA from VT if meaningful survival of greater than 1 year is expected.	IIb/B-NR
Pregnancy	In pregnant patients needing an ICD or VT ablation, it is reasonable to undergo these procedures during pregnancy, preferably after the first trimester.	IIa/B-NR
Primary Prevention of SCD in Patients with Ischemic Heart Disease	In patients with LVEF of 35% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days postrevascularization, and with NYHA class II or III HF despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected.	I/A
	In patients with LVEF of 30% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days postrevascularization, and with NYHA class I HF despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected.	I/A

Effective 12/15/2024

Indication	Recommendation for ICD placement	COR/LOE
	In patients with NSVT due to prior MI, LVEF of 40% or less and inducible sustained VT or VF at electrophysiological study, an ICD is recommended if meaningful survival of greater than 1 year is expected.	I/B-R
	In nonhospitalized patients with NYHA class IV symptoms who are candidates for cardiac transplantation or an LVAD, an ICD is reasonable if meaningful survival of greater than 1 year is expected.	IIa/B-NR
	An ICD is not indicated for NYHA class IV patients with medication-refractory HF who are not also candidates for cardiac transplantation, an LVAD, or a CRT defibrillator that incorporates both pacing and defibrillation capabilities.	III/C-EO
Primary Prevention of SCD in Patients with Nonischemic Cardiomyopathy (NICM)	In patients with NICM, HF with NYHA class II–III symptoms and an LVEF of 35% or less, despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected.	I/A
	In patients with NICM due to a Lamin A/C mutation who have 2 or more risk factors (NSVT, LVEF <45%, nonmissense mutation, and male sex), an ICD can be beneficial if meaningful survival of greater than 1 year is expected.	Ia/B-NR
	In patients with NICM, HF with NYHA classI symptoms and an LVEF of 35% or less, despite GDMT, an ICD may be considered if meaningful survival of greater than 1 year is expected.	IIb/B-R
	In patients with medication-refractory NYHA class IV HF who are not also candidates for cardiac transplantation, an LVAD, or a CRT defibrillator that incorporates both pacing and defibrillation capabilities, an ICD should not be implanted.	III/C-EO
Secondary Prevention of SCD in Patients with Ischemic Heart Disease	In patients with ischemic heart disease, who either survive SCA due to VT/VF or experience hemodynamically unstable VT or stable sustained VT not due to reversible causes, an ICD is recommended if meaningful survival greater than 1 year is expected.	I/B-R I/B-NR
	In patients with ischemic heart disease and unexplained syncope who have inducible sustained monomorphic VT on electrophysiological study, an ICD is recommended if meaningful survival of greater than 1 year is expected.	I/B-NR
Secondary Prevention of SCD in Patients with Nonischemic Cardiomyopathy (NICM)	In patients with NICM who either survive SCA due to VT/VF or experience hemodynamically unstable VT or stable sustained VT not due to reversible causes, an ICD is recommended if meaningful survival greater than 1 year is expected.	I/B-R I/B-NR

Indication	Recommendation for ICD placement	COR/LOE
	In patients with NICM who experience syncope presumed to be due to VA and who do not meet indications for a primary prevention ICD, an ICD or an electrophysiological study for risk stratification for SCD can be beneficial if meaningful survival greater than 1 year is expected.	IIa/B-NR
Short QT Syndrome	In patients with short QT syndrome who have a cardiac arrest or sustained VA, an ICD is recommended if meaningful survival greater than 1 year is expected.	I/B-NR
Ventricular Arrhythmias (VA)	In patients with ischemic cardiomyopathy, NICM, or adult congenital heart disease who have syncope or other VA symptoms and who do not meet indications for a primary prevention ICD, an electrophysiological study can be useful for assessing the risk of sustained VT.	IIa/B-R

American Heart Association (AHA)/American College of Cardiology (ACC)/Health Rhythm Society (HRS): Using the same 2016 evidence guidelines for class of recommendation (COR) and level of evidence (LOE) mentioned by Towbin, et al., (2019) the AHA/ACC/HRS 2017 guideline for the evaluation and management of patients with syncope recommended the following for ICD placement (Shen, et al., 2017):

Indication	Recommendation for ICD placement	COR/LOE
Syncope	ICD implantation is recommended in patients with arrhythmogenic right ventricular cardiomyopathy (ARVC) who present with syncope and have a documented sustained VA.	I/B-NR
	ICD implantation is recommended in patients with cardiac sarcoidosis presenting with syncope and documented spontaneous sustained VA.	I/B-NR
Unexplained Syncope	An ICD is recommended in patients with syncope of undetermined origin with clinically relevant and significant VA induced at the time of an EPS.	NA
	ICD therapy is reasonable for patients with unexplained syncope and nonischemic dilated cardiomyopathy with significant LV dysfunction.	NA
Syncope of suspected arrhythmic cause	ICD implantation is reasonable in patients with HCM presenting with ≥ 1 recent episodes of syncope suspected to be of arrhythmic nature.	NA
	ICD implantation is reasonable in patients with ARVC who present with syncope of suspected arrhythmic etiology.	IIa/B-NR
	ICD implantation is reasonable in patients with cardiac sarcoidosis and syncope of suspected arrhythmic origin, particularly with LV dysfunction or pacing indication.	IIa/B-NR
	ICD implantation is reasonable in patients with Brugada ECG pattern and syncope of suspected arrhythmic etiology.	IIa/B-NR
	ICD implantation may be considered in patients with short-QT pattern and syncope of suspected arrhythmic etiology.	IIb/C-EO

Indication	Recommendation for ICD placement	COR/LOE
	ICD implantation is reasonable in patients with LQTS and suspected arrhythmic syncope who are on beta-blocker therapy or are intolerant to beta-blocker therapy.	IIa/B-NR
	ICD implantation may be considered in patients with early repolarization pattern and suspected arrhythmic syncope in the presence of a family history of early repolarization pattern with cardiac arrest.	IIb/C-EO
Exercise or stress-induced syncope	ICD therapy is reasonable in patients with catecholaminergic polymorphic ventricular tachycardia (CPVT) and a history of exercise- or stress-induced syncope despite use of optimal medical therapy or left cardiac sympathetic denervation (LCSD).	IIa/B-NR

American College of Cardiology Foundation (ACCF)/Heart Rhythm Society (HRS)/American Heart Association (AHA)/American Society of Echocardiography (ASE)/Heart Failure Society of America (HFSA)/Society for Cardiovascular Angiography and Interventions (SCAI)/Society of Cardiovascular Computed Tomography (SCCT)/Society for Cardiovascular Magnetic Resonance (SCMR): The 2013 appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy described the appropriate use of these devices for selected patient populations (Russo, et al., 2013). The authors stated that the appropriate use criteria should be used in conjunction with the ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (Epstein et al., 2008) and the 2012 focused update of that guideline (Tracy, et al., 2012).

The appropriateness scores for each indication reflect the median score of the 17 technical panel members. The authors state that "The relationship of these criteria to existing guidelines was provided to the technical panel. In addition, extensive links to clinical trials and other literature regarding the role of ICD and CRT in each clinical scenario were provided to technical panel members. This document represents the current understanding of the clinical utility of ICD and CRT implantation in clinical practice as measured by physicians with a variety of backgrounds and areas of expertise. It is the goal that these criteria will help provide a guide to inform medical decisions and help clinicians and stakeholders understand areas of consensus as well as uncertainty, while identifying areas where there are gaps in knowledge that warrant additional investigation".

Recommendations are provided based on the following scoring method:

- **Median score 7–9:** Appropriate care: An appropriate option for management of patients in this population due to benefits generally outweighing risks; effective option for individual care plans, although not always necessary, depending on physician judgment and patient-specific preferences (i.e., procedure is generally acceptable and is generally reasonable for the indication).
- **Median score 4–6:** May be appropriate for care: At times an appropriate option for management of patients in this population due to variable evidence or agreement regarding the benefit/risk ratio, potential benefit based on practice experience in the absence of evidence, and/or variability in the population; effectiveness for individual care must be determined by a patient's physician in consultation with the patient based on additional clinical variables and judgment along with patient preferences (i.e., procedure may be acceptable and may be reasonable for the indication).

- **Median score 1–3:** Rarely appropriate care: Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e., procedure is not generally acceptable and is not generally reasonable for the indication).

Generally, criteria that have been deemed Appropriate or May Be Appropriate in these scenarios often meet Class I, IIa, or IIb criteria in guideline documents, are supported by a critical mass of existing data, or were deemed by the technical panel to meet sufficient clinical judgment to be reasonable and appropriate.

Indications rated as Appropriate are detailed below; indications rated as May be Appropriate and Rarely Appropriate are outlined in the appropriate use criteria document described above.

The following indications were rated as Appropriate Care (median score 7-9):
Secondary Prevention
Coronary artery disease (CAD): ventricular fibrillation (VF) or hemodynamically unstable ventricular tachycardia (VT) associated with acute (< 48 hours) myocardial infarction (MI) (newly diagnosed, no prior assessment of left ventricular ejection fraction (LVEF)

- Total Revascularization Completed After Cardiac Arrest
  - VF or polymorphic VT during acute (< 48 hours) MI, NSVT 4 days post MI, Inducible VT/VF at EPS ≥ 4 days after revascularization, LVEF 36–49% (7)
  - VF or polymorphic VT during acute (< 48 hours) MI, LVEF ≤ 35% (8)
- Obstructive CAD with coronary anatomy not amenable to revascularization
  - VF or polymorphic VT during acute (< 48 hours) MI, no electrophysiologic study (EPS) done (7)

CAD: VF or Hemodynamically Unstable VT < 48 h (Acute) Post-Elective Revascularization

- No evidence for acute coronary occlusion, restenosis, preceding infarct, or other clearly reversible cause, LVEF ≤ 35% (7)

CAD: VF or Hemodynamically Unstable VT (No Recent MI [< 40 Days] Prior to VF/VT and/or No Recent Revascularization [3 Months] Prior to VF/VT)

- No identifiable transient and completely reversible causes. No need for revascularization identified by catheterization performed following VF/VT (9)
- No revascularization performed (significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization (9)
- Significant CAD identified at catheterization performed following VF/VT. Complete revascularization performed after cardiac arrest. LVEF ≤ 49% (7)
- Significant CAD identified at catheterization performed following VF/VT. Incomplete revascularization performed after cardiac arrest LVEF ≥ 50% (7)
- Significant CAD identified at catheterization performed following VF/VT. Incomplete revascularization performed after cardiac arrest. LVEF 36–49% (8)
- Significant CAD identified at catheterization performed following VF/VT. Incomplete revascularization performed after cardiac arrest. LVEF ≤ 35% (9)

CAD: VF or Hemodynamically Unstable VT During Exercise Testing Associated with Significant CAD

- No revascularization performed (significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization) (9)
- Significant CAD identified at catheterization performed following VF/VT. Complete revascularization performed after cardiac arrest. LVEF ≤ 35% (7)

- Significant CAD identified at catheterization performed following VF/VT. Incomplete revascularization performed after cardiac arrest LVEF ≥ 36% (7)
- Significant CAD identified at catheterization performed following VF/VT. Incomplete revascularization performed after cardiac arrest LVEF ≤ 35% (8)

No CAD, VF or Hemodynamically Unstable VT
- Dilated nonischemic cardiomyopathy (9)
- VF/Hemodynamically Unstable VT Associated With Other Structural Heart Disease
    - Myocardial Sarcoidosis (9)
    - Giant cell myocarditis (8)

Genetic Diseases with Sustained VT, VF
- Congenital long QT (9)
- Short QT (9)
- Catecholaminergic polymorphic VT (9)
- Brugada Syndrome (9)
- ARVC with successful ablation of all inducible monomorphic VTs (9)
- ARVC with unsuccessful attempt to ablate an inducible VT (9)
- ARVC without attempted ablation (9)
- Hypertrophic cardiomyopathy (9)

No Structural Heart Disease (LVEF > 50%) or Known Genetic Causes of Sustained VT/VF
- Idiopathic VF With Normal Ventricular Function
    - No family history of sudden cardiac death (9)
    - First degree relative with sudden cardiac death (9)

Syncope in Patients without Structural Heart Disease
- Unexplained Syncope in a Patient With Long QT Syndrome
    - While on treatment with beta blockers (9)
    - Not being treated with beta blockers (7)
- Unexplained Syncope in a Patient with Brugada ECG Pattern
    - No EPS performed (8)
    - EPS performed. No ventricular arrhythmia induced (8)
    - EPS performed. Sustained VT/VF induced (9)
- Unexplained Syncope in a Patient with Catecholaminergic Polymorphic VT
    - While on treatment with beta blockers (8)
    - Not being treated with beta blockers (8)

Syncope in Patients with Coronary Artery Disease
- Unexplained Syncope With Prior MI and No Acute MI, LVEF 36%–49%
    - EPS revealed inducible sustained VT/VF (9)

Unexplained Syncope with Prior MI and no Acute MI. LVEF ≤ 35%
- EPS not performed (9)
- Inducible VT/VF on EPS (9)
- Not inducible at EPS (8)

Syncope in Patients with Nonischemic Structural Heart Disease
- Unexplained Syncope in a Patient with Left Ventricular Hypertrophy, Without Criteria for Hypertrophic Cardiomyopathy
    - Left ventricular hypertrophy/hypertensive heart disease, LVEF ≤ 35% (8)
- Unexplained Syncope in a Patient with Nonischemic Cardiomyopathy

  - Nonischemic dilated cardiomyopathy, LVEF ≤ 35% (8)
  - Left ventricular non-compaction, LVEF 36%–49% (7)
  - Left ventricular non-compaction, ≤ 35% (8)
  - Hypertrophic cardiomyopathy (8)
  - Tetralogy of Fallot with prior corrective surgery (7)
- Unexplained syncope in a Patient With Arrhythmogenic Right Ventricular Cardiomyopathy
  - No EPS performed (7)
  - No induction of VT/VF at EPS (7)
  - Inducible VT/VF at EPS. All inducible VTs successfully ablated (7)
  - Inducible VT/VF at EPS. Ablation unsuccessful (8)

Sustained Hemodynamically Stable Monomorphic VT Associated with Structural Heart Disease

- CAD and prior MI
  - LVEF ≥ 36% (7)
  - LVEF ≤ 35% (9)
- CAD and prior MI. All inducible VTs successfully ablated. LVEF ≤ 35% (9)
- CAD and prior MI. Troponin elevation thought to be secondary to VT. All inducible VTs successfully ablated. LVEF 36%–49% (7)
- CAD and prior MI. Troponin elevation thought to be secondary to VT. All inducible VTs successfully ablated. LVEF ≤ 35% (8)
- Nonischemic dilated cardiomyopathy. LVEF ≥ 50% (7)
- Nonischemic dilated cardiomyopathy. LVEF 36%–49% (7)
- Nonischemic dilated cardiomyopathy LVEF ≤ 35% (9)
- Nonischemic dilated cardiomyopathy. All inducible VTs successfully ablated. LVEF 36%–49% (7)
- Nonischemic dilated cardiomyopathy. All inducible VTs successfully ablated. LVEF ≤ 35% (8)
- Bundle branch re-entry successfully ablated in a patient with nonischemic cardiomyopathy. LVEF 36%–49% (7)
- Bundle branch re-entry successfully ablated in a patient with nonischemic cardiomyopathy. LVEF ≤ 35% (8)

Primary Prevention

Post-Acute Myocardial Infarction (MI) (< 40 days) LVEF ≤ 30%

- Revascularized after Acute MI
  - Asymptomatic nonsustained ventricular tachycardia (NSVT) (> 4 days post MI). EPS with inducible sustained VT (EPS performed after revascularization, within 30 days of MI) (7)
  - Asymptomatic NSVT (> 4 days post MI). EPS with inducible sustained VT (EPS performed after revascularization, between 30 and 40 days after MI) (8)

- Not Revascularized. Obstructive CAD With Coronary Anatomy Not Amenable to Revascularization
  - Asymptomatic NSVT (> 4 days post MI). EPS with inducible sustained VT (EPS performed within 30 days of MI) (7)
  - Asymptomatic NSVT (> 4 days post MI) EPS with inducible sustained VT (EPS performed between 30 and 40 days after MI) (8)

Post-Acute MI (≤ 40 days) LVEF 31%–40%

- Revascularized for acute MI
  - Asymptomatic NSVT (> 4 days post MI). EPS with inducible sustained VT (EPS performed after revascularization, within 30 days of MI) (7)

- Asymptomatic NSVT (> 4 days post MI) EPS with inducible sustained VT (EPS performed after revascularization, between 30 and 40 days after MI) (7)

Post-Acute MI (≤ 40 days) and Pre-Existing Chronic Cardiomyopathy (≥ 3 Months)
- LVEF < 30% due to old infarction. NYHA class I (8)
- LVEF < 35% due to old infarction. NYHA class II–III (9)
- LVEF < 35% due to nonischemic causes. NYHA class II–III (8)

Post-MI (≤ 40 Days) and Need for Guideline-Directed Pacemaker Therapy Post-MI (e.g., Sick Sinus Syndrome (SSS), Complete Heart Block (CHB), or Other Indications for Permanent Pacemaker)
- LVEF ≤ 35% (7)

Post-Myocardial Infarction (> 40 Days) With Ischemic Cardiomyopathy
- No Recent Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Graft (CABG)
  - LVEF < 30%, New York Heart Association (NYHA) Class I (8)
  - LVEF < 30%, New York Heart Association (NYHA) Class II or III (9)
  - LVEF 31%–35%. NYHA Class I (7)
  - LVEF 31%–35%. NYHA Class II or III (9)
  - LVEF 36%–40%. Asymptomatic NSVT. EPS with inducible sustained VT/VF (8)
- Recent PCI or CABG (≤ 3 months)
  - Pre-existing documented cardiomyopathy. LVEF ≤ 35% on guideline-directed medical therapy > 3 months before PCI/CABG (8)
  - LVEF ≤ 35%. Need for permanent pacemaker post-revascularization (e.g., SSS, CHB, or other guideline-directed indications for permanent pacemaker) (8)

Duration of Guideline-Directed Medical Therapy for Ischemic Cardiomyopathy without Recent MI (Revascularization Not Indicated)
- LVEF ≤ 35%. On guideline-directed medical therapy for < 3 months, NSVT, EPS with inducible sustained VT (8)
- LVEF ≤ 35%. On guideline-directed medical therapy ≥ 3 months (9)

Nonischemic Cardiomyopathy
- At Least 3 Months on Guideline-Directed Medical Therapy
  - LVEF < 30%, NYHA Class I (7)
  - LVEF < 30%, NYHA Class II or III (9)
  - LVEF 31%–35%, NYHA Class I (7)
  - LVEF 31–35%, NYHA Class II or III (9)

Specific Etiologies
- Sarcoid heart disease, myotonic dystrophy, or Chagas disease, with LVEF ≤ 35% (8)
- Giant cell myocarditis, LVEF ≤ 35% (8)
- Giant cell myocarditis, LVEF > 35% (7)
- Peripartum cardiomyopathy, persists > 3 months postpartum (8)

Genetic Conditions (Excludes Syncope and Sustained VT, addressed above)
- Hypertrophic cardiomyopathy with 1 or more risk factors (7)
  - Major risk factors:
    - prior cardiac arrest, spontaneous nonsustained VT, family history of SCD, LV thickness greater than or equal to 30 mm, and an abnormal blood pressure response to exercise

    - Possible risk factors
        - AF, myocardial ischemia, LV outflow obstruction, high-risk mutations, and intense (competitive) physical exertion
- Arrhythmogenic right ventricular dysplasia/cardiomyopathy with no symptoms due to arrhythmia (7)
- Congenital long QT Syndrome with 1 or more risk factors, receiving guideline-directed medical therapy (7)
    - Risk factors:
        - sudden cardiac arrest, strong family history of SCD or when compliance or intolerance to drugs is a concern
- Catacholiminergic polymorphic VT with nonsustained VT (without syncope)
    - Not receiving beta-blockers, flecainide, or propafenone (7)
    - Receiving beta-blockers (7)
    - Not tolerating or breakthrough nonsustained ventricular arrhythmias on beta-blockers (8)
- Incidentally discovered Brugada by ECG (type I ECG pattern) in the absence of symptoms or family history of sudden cardiac death, with inducible VT or VF at EPS (7)
- Familial dilated nonischemic cardiomyopathy (RV/LV) associated with sudden cardiac death
    - Evidence of structural cardiac disease, but LVEF > 35% (7)
    - LV non-compaction with LVEF > 35% (7)

Other Indications: Transvenous Implantable Cardioverter Defibrillator (ICD):
ICDs are indicated for primary and secondary prophylaxis of sudden cardiac death in selected patients which has been described above. There is insufficient evidence in the published peer-reviewed scientific literature to support the use of an ICD for any other indication, including but not limited to mitral annulus disjunction (MAD).

Mitral annular disjunction (MAD) is a structural abnormality where there is a separation between the mitral valve annulus and the left atrial wall which is not well understood. Mitral annular disjunction appears to be common in myxomatous mitral valve disease and mitral valve prolapse which can be detected on cardiac imaging. It is proposed that MAD can cause ventricular arrhythmias and sudden cardiac death. Treatment options have not been established.

Literature Review - Transvenous Implantable Cardioverter Defibrillator (ICD):
There is a paucity of well-designed evidence evaluating the standard defined work-up or defined treatment options for MAD. Well-designed studies are needed to assess the role of implantable cardioverter defibrillators (ICDs) in treating arrhythmias associated with MAD.

Subcutaneous ICD
The subcutaneous ICD (S-ICD) is an alternative to transvenous ICDs for selected patients. To implant the device, an incision is made in the left chest along the rib cage to create a pouch beneath the skin. A subcutaneous electrode is connected to the pulse generator, and the system is adjusted using an external programmer prior to closing the incisions. Since no electrodes are placed in or on the heart, investigators expect fewer perioperative and long-term vascular complications, problems with obtaining venous access, and lead complications. Avoiding the intravascular space has inherent limitations; however. The S-ICD cannot provide antitachycardia pacing, advanced diagnostics, or radiofrequency interrogation with remote monitoring. The S-ICD therefore would not be considered for patients with symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

The median longevity of the first-generation S-ICD system is reported as five years. The majority of devices were replaced because of battery depletion (Theuns, et al., 2015).

In the EFFORTLESS Registry, discussed below Lambiase et al. (2014), the rate of complications requiring reintervention within 360 days was 6.4%. Complication rates among various publications on the S-ICD range from 1.3 to 19%. Inappropriate shocks are one of the most common and concerning complications, with most studies reporting an incidence of 4-16%. The most common cause is over sensing of T-waves. Inappropriate shocks are more likely to occur in younger, physically active patients. Pocket infections have been reported in 1–10% of implantations, and complicated infections requiring device explantation have been reported in 1–4% of patients. Lead dislodgement or migration has been reported in 3–11% of patients and is thought to result from vigorous physical activity without adequate fixation of the parasternal lead. Suture sleeves are currently used to anchor the parasternal lead in order to eliminate lead dislodgement and migration. Less common complications that may require reintervention include skin erosion, premature battery depletion, or explantation due to the need for antitachycardia/bradycardia pacing or a new indication for resynchronization therapy.

U.S. Food and Drug Administration (FDA): The Subcutaneous Implantable Cardioverter Defibrillator (S-ICD™) System (Cameron Health, Inc., San Clemente, CA) (P110042) received FDA approval through the PMA process on September 28, 2012. Cameron Health was subsequently acquired by Boston Scientific. The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Literature Review - Subcutaneous ICD: Existing, peer-reviewed literature consists of prospective registry studies and case series, non-comparative observational studies, and retrospective studies (n=118-1637) supporting the safety and effectiveness of subcutaneous ICDs for individuals who meet criteria for ICD placement but who are not appropriate candidates for transvenous ICD placement. Studies report inappropriate shock free rates of up to 95.9%, inappropriate shock rates of 3.1%-16.9%, complication free rates at 30-days of 96.2% and 92.5% at 1-year; and efficacy rates between 90% and 100% for the 1st and final shock (i.e., up to 5) (Gold, et al., 2022; Gold, et al., 2021; Burke, et al., 2020; Gold, et al., 2017; Weiss, et al., 2013; Lambiase, et al., 2022; Boersma, et al., 2017; Burke, et al., 2015; Lambiase, et al., 2014; Olde Nordkamp, et al., 2021).

Professional Societies/Organizations
American Heart Association (AHA)/American College of Cardiology (ACC): The 2020 AHA/ACC guideline for the diagnosis and treatment of patients with hypertrophic cardiomyopathy issued the following recommendation for a subcutaneous ICD using using the 2019 ACC/AHA evidence-based methodologies previously mentioned by Heidenreich, et al., 2022 (Ommen, et al., 2022).

- In patients with HCM who are receiving an ICD, either a single chamber transvenous ICD or a subcutaneous ICD is recommended after a shared decision-making discussion that takes into consideration patient preferences, lifestyle, and expected potential need for pacing for bradycardia or VT termination (Class of Recommendation (COR): 1; Level of Evidence: B-NR)

The subtest of the guideline discussed the advantages and disadvantages of the subcutaneous ICD. The advantages included the lack of a transvenous lead, potentially fewer lead failures, and ease of removal. Disadvantages included the larger size of the device, the shorter battery

longevity, potentially increased inappropriate shocks because of T-wave oversensing and myopotentials, and shorter history of use.

American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Rhythm Society (HRS): The 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Al-Khatib et al.) provided the following recommendations using the Class of Recommendation (COR) and LOE system mentioned previously by Towbin, et al. (2019) for a subcutaneous implantable cardioverter-defibrillator:

Class 1

- 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 (Burke, et al., 2015; El-Chami, et al., 2015; Lambiase, et al., 2014; Weiss, et al., 2013; Bardy, et al., 2010). (Level of Evidence: B-NR).

The recommendation supportive text in the guideline states that difficulties in achieving venous access can prolong the implantation procedure and occasionally result in failed ICD implantation. These difficulties are likely to be encountered in patients with limited venous access such as patients with ESRD. The risk of infection appears to be lower with subcutaneous implantable cardioverter-defibrillators than with transvenous ICDs. Therefore, a subcutaneous implantable cardioverter-defibrillator may be preferred in patients who are at high risk of infection, such as those with a prior device infection, ESRD, diabetes mellitus, or who are chronically immunosuppressed.

Class IIa

- 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 (Burke, et al., 2015; Lambiase, et al., 2014; Weiss, et al., 2013; Bardy, et al., 2010). (Level of Evidence: B-NR).

The recommendation supportive text in the guideline states that nonrandomized studies show that the subcutaneous implantable cardioverter-defibrillator reliably detects and converts VF during defibrillation threshold testing and successfully terminates spontaneous sustained VT that occurs during follow-up. An ongoing trial will compare the effect of the subcutaneous implantable cardioverter-defibrillator with that of the transvenous ICD on the outcomes of inappropriate shocks, complications, shock efficacy, and mortality (Olde Nordkamp, et al., 2012).

Class III: Harm

- 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.

The recommendation supportive text in the guideline states that the subcutaneous implantable cardioverter-defibrillator is incapable of bradycardia pacing, biventricular pacing, or anti-tachycardia pacing. Patients who need any of these types of pacing from an ICD should not be offered a subcutaneous implantable cardioverter-defibrillator. Some clinical scenarios may come up in which a transvenous pacemaker for bradycardia pacing in a patient with a subcutaneous implantable cardioverter-defibrillator- which is needed; this can be performed as long as the pacing is not unipolar. Leadless pacing devices for patients who require bradycardia pacing will be evaluated with the subcutaneous implantable cardioverter-defibrillator in the near future.

Effective 12/15/2024

Substernal implantable cardioverter-defibrillator
The substernal ICD system, also known as extravascular ICD (EV ICD) with substernal lead placement, provides defibrillation and pacing therapies and has been proposed as an alternative to the available ICD systems. The substernal ICD system is an investigational device and not currently available. Evidence published to date evaluating the substernal ICD system is limited and studies that further evaluate safety and efficacy are currently in progress.

U.S. Food and Drug Administration (FDA): The FDA issued a PMA (P220012) approval order in October, 2023 for the Aurora EV-ICD System (Medtronic, Inc., Mounds View, MN). The device is used with the Epsila EV™ MRI SureScan Model EV2401 extravascular lead which is indicated "for use in the anterior mediastinum for pacing therapies, cardioversion, and defibrillation when an extravascular implantable cardioverter defibrillator is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias." Results from the Extravascular ICD Pivotal Study (EV ICD) (NCT04060680) that served as the bases for the PMA approval have not yet been published.

Literature Review: Friedman et al. (2022) conducted a prospective, single-group, nonrandomized, premarket global clinical study that evaluated the safety and efficacy of the extravascular ICD system. The study included patients (n=316) with a class I or IIa indication for an ICD for primary or secondary prevention. The primary efficacy outcome measured the successful defibrillation at implantation. This outcome would be met if the lower boundary of the one-sided 97.5% confidence interval for the percentage of patients with successful defibrillation was greater than 88%. The primary safety outcome measured the freedom from major system- or procedure-related complications at six months. The safety outcome would be met if the lower boundary of the one-sided 97.5% confidence interval for the percentage of patients free from such complications was greater than 79%. Of the 356 patients were enrolled, 316 had an implantation attempt. Among the 302 patients in whom ventricular arrhythmia could be induced and who completed the defibrillation testing protocol, the percentage of patients with successful defibrillation was 98.7% (lower boundary of the one-sided 97.5% confidence interval [CI], 96.6%; $p<0.001$ for the comparison to the performance goal of 88%); 299 of 316 patients (94.6%) were discharged with a working ICD system. The estimate of the percentage of patients free from major system- or procedure-related complications at six months was 92.6% (lower boundary of the one-sided 97.5% CI, 89.0%; $p<0.001$ for the comparison to the performance goal of 79%). There were no major intraprocedural complications were reported. At six months, 25 major complications were observed, in 23 of 316 patients (7.3%). The success rate of anti-tachycardia pacing, as assessed with generalized estimating equations, was 50.8% (95% CI, 23.3 to 77.8). A total of 29 patients received 118 inappropriate shocks for 81 arrhythmic episodes. Eight systems were explanted without extravascular ICD replacement over the 10.6-month mean follow-up period. Limitations of the study included the lack of a comparison group and implantation was performed at expert centers, with a prespecified follow-up and testing plan. Additionally, the number of episodes of spontaneous arrhythmia was modest, and defibrillation testing may not be a good indicator of clinical shock efficacy. The authors reported that the study population was younger than typical ICD recipients and had a high frequency of hypertrophic cardiomyopathy, and may not be applicable to an older, sicker population and should be performed with caution. Testing at 6 months was performed in a subgroup of patients and was designed to assess maintained shock efficacy for ventricular arrhythmia and not the defibrillation threshold. Therefore, these data do not provide information on threshold changes over time. Observations regarding pause-prevention pacing are limited. The authors noted that women may have been slightly underrepresented in the trial, comprising 25.3% of enrolled patients compared to the estimate that women represent 30-40% of sudden cardiac deaths. No information on gender identity was collected in our study. For geographical representation, patients were enrolled at 46 sites in 17 countries across Australia, New Zealand, Canada, Europe, the Middle East, Hong Kong,

and the United States in the Extravascular ICD Pivotal Study. Additional long term randomized control trials with large patient populations are needed to validate the outcomes of this study and establish the efficacy and safety of the extravascular ICD system.

Crozier et al. (2020) conducted a prospective, nonrandomized, pilot study at four centers in Australia and New Zealand that evaluated the safety and performance of a substernal implantable cardioverter-defibrillator (ICD). Eligible patients (n=21) were referred for ICD implantation with a Class I or IIa indication on the basis of current clinical practice guidelines. Among the 21 patients undergoing attempted implantation, 81% were men aged 22–77 years and 86% had primary ICD indications. Patients (n=21) received a substernal ICD system but one patient had to have the device explanted. The primary efficacy outcome measured the success of defibrillation testing during implantation. Ventricular fibrillation (VF) was induced via the device at implantation and defibrillation efficacy was tested by inducing, detecting, and converting VF episodes. Implantation required termination of VF with either a single 20-J shock or on two consecutive episodes with a 30-J shock. If the patient was successfully defibrillated at 20 J, defibrillation efficacy was assessed at 15 J. The primary safety outcome measured any complication related to the substernal ICD system or procedure that resulted in death, system revision, hospitalization, prolongation of a hospitalization, or permanent loss of defibrillation function due to device dysfunction. Patients received follow-up at two weeks, 4–6 weeks and three months after implantation. At the three-month follow-up, devices were interrogated, sensing and pacing tolerability testing performed, and chest radiography (day one, week two, weeks 4–6, and three months) and chest computed tomography (three months) performed. Among the 20 patients who completed defibrillation testing, 18 (90%) were able to be converted to sinus rhythm with 15 J (n=11), 20 J (n=4), or 30 J in two consecutive terminations (n=3) as required per protocol. The two patients who were successfully defibrillated at 15 J were tested at 10 J, and both were successful at 10 J. The two patients who did not pass defibrillation testing underwent explantation, with subsequent implantation of transvenous defibrillators. Among 20 patients who underwent successful implantation, the median defibrillation threshold was 15 J, and pacing was successful in 95% at ≥ 10 J. There were no intraprocedural complications. There were six adverse events that occurred within three months. One patient experienced an inappropriate shock 78 days post-implantation because of P-wave oversensing that occurred when the lead tip deflected toward the right atrial appendage. The system was subsequently explanted at 85 days post-implantation. The 90-day rate of freedom from systemic or procedural major complication was 94.1%. In addition to the single instance of inappropriate shock, two patients reported inspiratory discomfort post-operatively, and three had minor wound issues (two with swelling or impaired healing and one with superficial wound infection at the xiphoid incision site with minor purulent discharge, which resolved with an antibiotic course and a change of dressing), all of which resolved without sequelae. Fifteen patients remain under follow-up to date. Author noted limitations included short-term follow-up and the small patient cohort of predominantly male patients from a single geographic region. The study concluded that larger, longer-term evaluation will be needed to address the long-term sensing performance of the system and detection algorithms, whether predictors exist to ascertain probable defibrillation efficacy prior to implantation, how effectively ATP from a lead in this configuration performs relative to transvenous systems, and the extractability of the EV ICD system.

Boersma et al (2019) conducted the Acute Extravascular Defibrillation, Pacing, and Electrogram (ASD2) study which was a prospective multicenter, worldwide, nonrandomized, acute, proof-of-concept clinical trial. The study evaluated the feasibility of sensing, pacing, and defibrillation from an investigational lead designed specifically for the substernal space. An investigational lead was inserted into the substernal space via a minimally invasive subxiphoid access, and a cutaneous defibrillation patch or subcutaneous active can emulator was placed on the left mid-axillary line. Pacing thresholds and extracardiac stimulation were evaluated. Up to two episodes of ventricular

fibrillation were induced to test defibrillation efficacy. Eighty-seven patients were enrolled across 16 sites in Europe (n=54), the United States (n=19), New Zealand (n=10), Hong Kong (n=3), and Australia (n=1). Following data collection, the ASD2 research system was removed before the planned procedure of the patient. The investigational lead was placed in 79 patients. The investigational lead deployed successfully during the first insertion attempt in 66 patients (83.5%) and was redeployed (in 1–4 attempts) to achieve the preferred orientation in all remaining patients. Ventricular pacing was successful in at least one vector in 76 of 78 patients (97.4%), and 72 of 78 (92.3%) patients had capture in ≥ 1 vector with no extracardiac stimulation. A 30-J shock successfully terminated 104 of 128 episodes (81.3%) of ventricular fibrillation in 69 patients. Of the 79 patients who underwent the ASD2 study, there were seven adverse events in six patients adjudicated as causally (n=5) or as possibly (n=2) related to the ASD2 procedure. Four of the five adverse events adjudicated as being causally related to the ASD2 procedure resolved with no lasting effect on the patient; these included bleeding at the incision site, mild erythema at the incision, an episode of transient atrial fibrillation that occurred during VF induction, and reaction to anesthesia that resulted in low oxygen saturation. The fifth event was a pericardial effusion with tamponade. The authors concluded that the study demonstrated the ability to pace, sense, and defibrillate using a lead designed specifically for the substernal space. However, further evaluation is needed to assess the impacts of pacing and defibrillation on lead stability, patient movement or posture, and chronic tissue encapsulation, as well as long-term system management issues related to infection, system modification, or extraction.

Professional Societies/Organizations
Clinical guidelines that recommend use of a substernal implantable cardioverter-defibrillator are lacking.

Wearable Cardioverter Defibrillator (WCD)
The WCD is an external device capable of automatic detection and defibrillation of VT or VF. The approved devices do not have pacing capabilities and therefore are unable to provide therapy for bradycardic events or antitachycardic pacing (Chung, 2023). WCDs have been proposed as an option for patients who are at risk for sudden cardiac arrest and who are not candidates for or refuse an ICD. The device has also been proposed as a bridge to ICD risk stratification and possible implantation for high-risk patients following acute myocardial infarction (MI), patients diagnosed with cardiomyopathy, and those who have undergone coronary artery bypass graft (CABG) surgery or percutaneous coronary angioplasty (PTCA).

The WCD is composed of four dry, non-adhesive monitoring electrodes, three defibrillation electrodes incorporated into a chest strap assembly, and a defibrillation unit carried on a waist belt. The monitoring electrodes are positioned circumferentially around the chest, held in place by tension from an elastic belt, and provide two surface electrocardiogram leads. The defibrillation electrodes are positioned in a vest assembly for apex-posterior defibrillation. Proper fitting is required to achieve adequate skin contact to avoid noise and frequent alarms (Chung, 2023).

Arrhythmia detection by the WCD is programmed using electrocardiogram (ECG) rate and morphology criteria. The WCD system is programmed to define ventricular arrhythmias when the ventricular heart rate exceeds a preprogrammed rate threshold with an ECG morphology that does not match a baseline electrocardiographic template. If an arrhythmia is detected, an escalating alarm sequence occurs, including a vibration against the skin and audible tones. A voice cautions the patient and bystanders to the impending shock. Patients are trained to hold a pair of response buttons during these alarms to avoid receiving a shock while awake. A patient's response serves as a test of consciousness; if no response occurs and a shock is indicated, the device charges, extrudes gel from the defibrillation electrodes, and delivers up to five biphasic shocks at preprogrammed energy levels. The device includes a default sleep time from 11 p.m. to 6 a.m.,

programmable in one-hour increments, which allows additional time for deep sleepers, if they awaken, to abort shocks (Chung, 2023).

Shock efficacy with the WCD is reported to be similar to that reported with an implantable cardioverter-defibrillator (ICD). Patient education, and promotion of compliance while using the WCD, is important. Sudden cardiac death may still occur in those not wearing the device, those with improper positioning of the device, due to bystander interference, due to the inability of the WCD to detect the electrocardiogram signal, or due to bradyarrhythmias. The WCD stores data regarding patient compliance with the device, arrhythmias and noise or interference with its proper functioning. Arrhythmia recordings from the WCD are available for clinician review once stored data are transmitted via a modem to the manufacturer's network (Chung, 2023).

There are reported limitations with a WCD system. The device must be fitted to each patient. Some patients may not have a good fit due to body habitus. It may not be an option for morbidly obese patients. There are also limited data on WCD use in children, in whom the device may not fit properly if the child is small. The external design of the WCD does not allow for pacemaker functionality and introduces a component of patient interaction and compliance as well as the potential for external noise leading to inappropriate shocks. The device must be removed for bathing with no protection while the device is off. It is recommended that caregivers or other persons be nearby during these periods when the WCD is not worn. Comfort may be an issue for some patients due to the weight and size of the device (Chung, 2023).

Both the WCD and an ICD may inappropriately deliver shocks due to device malfunction, electronic noise, or detection of supraventricular tachycardia (SVT) above the preprogrammed rate criteria. Studies of ICDs have reported an incidence of inappropriate shock of 0.2%–2.3% of patients per month. Comparable rates of inappropriate shocks have been reported among users of the WCD, with rates ranging from 0.5%–1.4% per month. Inappropriate shocks with a WCD can be potentially reduced due to the ability to abort shocks while awake by pressing response buttons. Patients may not comply with wearing a WCD for a many reasons including device size and weight, itching, skin rash, and problems sleeping. Efficacy of the WCD in the prevention of sudden cardiac death is dependent on patient compliance and appropriate use of the device. Improved compliance and acceptance of the WCD may be seen with newer devices, which are 40 percent smaller in size and weight (Chung, 2023).

Goldenberg et al. (2021) assessed the sex differences in atrial and ventricular arrhythmias during WCD use, as well as in compliance with the WCD, and evaluated improvement in cardiac function at the end of WCD use through a substudy analysis of the Prospective Registry of Patients Using the Wearable Cardioverter Defibrillator (WEARIT-II Registry). The study stratified 2000 patients by sex into women (n=598) and men (n=1402). It was concluded that there is a higher burden of ventricular and atrial arrhythmic events in women than in men. WCD wear time was similar in women and men, with longer daily use in women. ICD implantation rates at the end of WCD use were similar.

U.S. Food and Drug Administration (FDA): The LIFECOR Wearable Cardioverter Defibrillator (WCD®) 2000 System (Zoll® Medical Corp., formerly Lifecor, Inc., Pittsburgh, PA) was approved by the U.S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) process (P010030) on December 18, 2001. According to the FDA approval letter, the WCD 2000 System is indicated for adult patients who are at risk for sudden cardiac arrest and who are not candidates for or refuse an ICD. The device is contraindicated in patients with an active ICD and should not be used in patients who:

- need an ICD or already have an operating ICD

- are under age 18
- have a vision or hearing problem that may interfere with reading or hearing the WCD messages
- are taking medication that would interfere with pushing the response buttons on the WCD alarm module
- are unwilling or unable to wear the device continuously, except when bathing or showering
- are pregnant or breastfeeding
- are of childbearing age and not attempting to prevent pregnancy
- are exposed to excessive electromagnetic interference (EMI) from machinery such as powerful electric motors, radio transmitters, power lines, or electronic security scanners, as EMI can prevent the WCD from detecting an abnormal heart rhythm

The trade name of the WCD 2000 System was changed to LifeVest™ in 2002. The LifeVest is a microprocessor-based and programmable patient-worn device that is designed to sense cardiac function and automatically deliver electrical therapy to treat ventricular arrhythmias. The device is intended to be worn continuously, since the purpose of the device is to constantly monitor the patient's electrocardiogram (ECG) and detect life-threatening ventricular tachyarrhythmias (i.e., VT or VF). If the device detects VT or VF above a programmable preset rate, it is capable of delivering a defibrillating pulse to the heart through the electrodes in an attempt to restore an effective rhythm. The wearable components include a monitor, battery pack, alarm module, electrode belt, garment and holster. The nonwearable components include a battery charger, modem, mode cable, computer cable, diagnostic tester, and the WCDNET. The WCDNET is a web-based data storage and retrieval system that allows physicians to access patient data using a web browser and internet connection. An authorized physician or operator can view and print electrocardiogram events and generate reports related to patient wear-time and overall WCD 2000 monitoring performance.

On December 17, 2015, the LifeVest Wearable Cardioverter Defibrillator models 3000, 3100 and 4000 received FDA PMA approval. The FDA supplemental approval order statement states that "the LifeVest System is indicated for patients under 18 years of age who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator. Patients must have a chest circumference of 26 inches (66 centimeters) or greater and a weight of 18.75 kilograms (41.3 pounds) or greater". No modifications to the currently approved LifeVest devices are proposed for their use with pediatric patients. The chest circumference limit stated in the FDA indications for use is based on the garments sizes currently marketed with the LifeVest device. The pediatric users being included in the indications under the FDA submission are generally capable of using the primary safety feature of the device. By pressing a button on the device control unit, the patients can prevent treatment in the unusual case when the device intends to deliver a shock when no shock is necessary as determined by the patient being conscious when the device enters the mode preparing for shock treatment (FDA, 2015).

The 2015 FDA Summary of Safety and Effectiveness Data (SSED) mentions other proposed alternatives for the treatment of life-threatening arrhythmias in pediatric patients who are at risk for sudden cardiac arrest including: emergency medical services (EMS) or calling 911, automatic external defibrillators (AEDs) in the community or home, implantable cardioverter defibrillators (ICDs), antiarrhythmic medication, and telemetry monitoring within a hospital environment.

The SSED states that as of November 8, 2012 publications in the literature have reported the use of the LifeVest in 248 pediatric patients, aged 3–17, and 510 young adults, aged 18–21. The total duration of use for patients age 3 to 21 is 65,247 days, with an exposure mean of 3.2 months (range: < 1 day to 39.0 months). The average daily wear time for patients age 3 to 21 is 16.6 +/- 6.2 hours. Data provided by Zoll Manufacturing Corporation has shown the ability of the LifeVest

to successfully convert a sudden cardiac arrest to a life-sustaining rhythm in patients as young as thirteen. Four patients in the 3–17 age group (indications for use: Wolf-Parkinson-White syndrome, cardiomyopathy, Tetralogy of Fallot, and congenital heart disease) and five in the 18–21 age group (indications for use: cardiomyopathy for all five) experienced sudden cardiac arrest during LifeVest use that was successfully converted to a life sustaining rhythm.

The FDA final conditions of approval citied in the FDA approval order state that a PMA post approval study, LifeVest in those under 18 years of age, will be conducted. The study will consist of a serial, prospective data collection of patients under 18 years of age utilizing the LifeVest Wearable Cardioverter Defibrillator who meet the proposed indication for the treatment of life-threatening arrhythmias. Performance information will include daily compliance with use, duration of use, appropriate therapy delivery, ECG recordings during appropriate therapy delivery, and any available description of the circumstances found within the Call Report Database. Safety data to be included are inappropriate defibrillation therapy delivery, ECG recordings during inappropriate therapy delivery and any available description of the circumstances found within the Call Report Database, and adverse events reported to ZOLL through the customer support or technical support departments. The data on the first 150 patients who meet the proposed indication will be collected and data will be obtained from the returned device.

On February 24, 2017, the Hospital Wearable Defibrillator (HWD) model 1000 received FDA PMA supplemental approval (P010030/S067). This is a wearable defibrillation for hospital use that is based on the previously approved LifeVest Wearable Cardioverter (WCD) 4000 design as a platform and incorporates design features from the previously approved WCD 3000S.

On July 27, 2021, the ASSURE Wearable Cardioverter Defibrillator (WCD) System (ASSURE system) received FDA PMA approval. The ASSURE system is a non-invasive, external, patient-worn device which is designed to automatically evaluate an electrocardiogram (ECG) for life-threatening ventricular arrhythmias and deliver a shock (defibrillation) to the heart to restore an effective rhythm. The approval order statement states that the ASSURE System "is indicated for adult patients who are at risk for sudden cardiac arrest and are not candidates for, or refuse, an implantable defibrillator". The FDA approval requires an Annual Report that must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device. As part of the annual report, the number of devices returned to the applicant for normal end-of-life and alleged failures or malfunctions must be provided. A summary of information should be provided that includes defibrillation success and the number of shocks required for success, identification of any error codes or malfunctions during use and their related MDR number. Lastly, a listing of any safety alerts, technical service bulletins, user communications, or recalls for devices should be included.

In addition to the Annual Report requirements, the following data is required in post-approval study (PAS) reports for the PAS listed below.

The ASSURE WCD Clinical Evaluation (ACE-PAS), will be conducted. The study will consist of active surveillance using real-world data collected in the ASSURE Registry. A total of 271 appropriate shock episodes for VT/VF is required to provide the required level of statistical precision for the primary effectiveness outcome. It is estimated that a total of 5,179 patients will be required to provide data on 271 appropriate shock episodes. The device will be used temporarily (days of use), and the data will be obtained from that period of use. No additional patient follow-up is required. The primary safety outcome measures the inappropriate shocks per patient-month of use (total inappropriate shocks/cumulative months of device use for all patients) ≤ 0.0075. The

FDA requires the first report to be provided after 500 patients. Following the initial report, subsequent reports will be provided every six months until the required sample size is achieved, and a final report is generated. PAS Progress Reports must be submitted every six months until subject enrollment has been completed, and annually thereafter. If milestones are not met, quarterly enrollment status reports (i.e., every 3 months) must be submitted in addition to your periodic (6-months) PAS Progress Reports, until FDA states otherwise (FDA, 2021).

Literature Review - Wearable Cardioverter Defibrillator (WCD)
Poole et al. (2022) conducted a multicenter prospective, nonrandomized trial (ACE-DETECT) that evaluated the ASSURE WCD (A-WCD) (Kestra Medical Technologies) false alarm rate, wear compliance, and adverse events (AEs) in ambulatory patients. The aim of the study was to test the A-WCD which is designed for reduced false shock alarms and improved comfort. Included patients (n=130) had a left ventricular ejection fraction ≤ 40% and an active implantable cardioverter defibrillator (ICD). Patients completed training on the use of the A-WCD and were successfully fitted with a garment. Detection was enabled on the A-WCD and shock alarm markers were recorded, but shocks and shock alarms were disabled. All WCD episodes and ICD ventricular tachycardia/ventricular fibrillation (VT/VF) episodes were adjudicated. The primary outcome measured the false positive shock alarm rate with a performance goal of one every 3.4 days (0.29 per patient-day). Additional outcomes measured included a summary of A-WCD and ICD detected episodes, patient-reported outcomes including perceived comfort, adverse events determined to be possibly related to use of the A-WCD and patient wear compliance. Patients were followed for 30 days with clinical follow-up weekly by phone. Patients returned for final follow-up at the end of the 30-day participation period. Both the A-WCD and ICD were interrogated to collect all stored arrhythmia episodes. A-WCD data also included minutes of wear per day. Patients reported their perceived discomfort using for each of eight anatomical regions on the torso at baseline and final follow-up. One-hundred and twenty-one patients (93.1%) completed the study. The majority were male (69%) and predominantly white (64%). Black/African Americans represented 27%. Of 163 WCD episodes, four were ventricular tachycardia/ventricular fibrillation (VT/VF) and 159 non-VT/VF. Three false-positive shock alarm markers were recorded; one false-positive shock alarm every 1333 patient-days ($p<0.001$). No ICD recorded VT/VF episodes meeting WCD detection criteria (≥ 170 bpm for ≥ 20 s) were missed by the WCD during 3501 patient days of use. Median wear was 31.0 days. Adverse events were mostly mild: skin irritation (19.4%) and musculoskeletal discomfort (8.5%). Limitations noted by the authors included the small sample size and short-term follow-up which limited the generalizability of the results. Furthermore, since the auditory/vibratory alarms and shocks were disabled, the reported wear compliance may not reflect clinical use when this functionality is enabled. An additional limitation is that the study included a high proportion of white men and the results may not be applicable to other races or ethnic groups. Further prospective large studies will enable assessment of overall A-WCD performance and patient compliance. The study concluded that the ASSURE WCD demonstrated a low false-positive shock alarm rate, low patient-reported discomfort and no serious adverse events.

In a systematic review of 14 clinical studies (n=22908), Kovacs et al. (2018) reported that prolonged use of wearable cardioverter-defibrillators (WCD) is not uncommon. The majority of the studies were retrospective based on registries. Median wear times ranged from 16 to 394 days. The median wear time was especially long for patients suffering from nonischemic cardiomyopathy (NICM) (range: 50–71 days) and specifically peripartum cardiomyopathy (PPCM) (120 days) and for heart transplant candidates. There was a large variation of appropriate shocks according to indication for WCD use. In contrast to NICM in general, the number of appropriate shocks was particularly high in patients with PPCM (0 in 254 patients and 5 in 49 patients, respectively). The median and maximal time periods to the first appropriate shock were longest in patients with PPCM (median time to the first appropriate shock: 68 days). The authors report that careful

patient selection for prolonged use may decrease the need for ICD implantation in the future; however, prospective data are needed to confirm this hypothesis. The heterogeneity of clinical studies, which resulted in missing data on the time of appropriate shocks, is a limitation of this study. Eleven of the 14 studies reported the database kept by ZOLL. It is therefore possible that patients fulfilling inclusion criteria for more than one of the studies were reported more than once.

Epstein et al. (2013) published observational data from the manufacturer's database of WCD use in patients considered to be at high risk for sudden cardiac arrest following acute MI. Between September 2008 and July 2011, a WCD was prescribed for 8,678 patients post-MI who met the study criteria, i.e. coded as having had a recent MI with ejection fraction ≤ 35%, or given an ICD-9 diagnosis of acute MI. Of these patients, 225 were not fitted with the device or did not wear it for various reasons, leaving 8,453 patients. A total of 133 patients (1.6%) received 309 appropriate shocks during 146 shock events, 252 successfully terminated VT/VF, 9 led to asystole, 41 were unsuccessful, one resulted in nonsustained VT, one resulted in supraventricular tachycardia, and in five patients rhythm outcomes were unknown. The survival rate per patient of those who received appropriate shocks was 91%; of these initial survivors, three died within two days, and 41 died ≥ three days after shock delivery. Actuarial survival analysis of patients treated with appropriate shocks demonstrated cumulative survival at 3, 6, and 12 months of 73%, 70%, and 65%, respectively. Thirty-four additional deaths occurred while wearing the device due to bradycardia or asystole events not associated with VT/VF. There were 114 inappropriate shocks in 99 patients.

A retrospective review by Saltzberg et al. (2012) evaluated characteristics and outcomes of peripartum vs. non-peripartum cardiomyopathy in women using a WCD. WCD medical orders from 2003 to 2009 and death index searches were used to identify women with peripartum cardiomyopathy (PPCM) (n=107) and matched non-pregnant women with nonischemic dilated cardiomyopathy (NIDCM) (n=159). WCD use averaged 124 ± 123 days for PPCM patients and 96 ± 83 days among NIDCM patients. No PPCM patients received an appropriate shock for ventricular tachycardia/ventricular fibrillation. Twenty-eight PPCM patients (26%) had improvement in EF from baseline to ≥35%, and WCD use was discontinued, while 21 patients (20%) were implanted with an ICD due to persistent ventricular dysfunction. In the NIDCM group, one patient with an ejection fraction of 15%, New York Heart Association Class IV Heart Failure, received two successful shocks and subsequently received an ICD. Twenty patients (13%) discontinued WCD use due to improvement in EF, and 64 (40%) underwent ICD implantation due to persistent ventricular dysfunction. Fourteen (9%) patients ended WCD use early due to non-adherence, discomfort or skin irritation. Eleven of the NIDCM patients died during WCD usage; seven deaths were reported as cardiac related, and the cause was unknown in the remaining four patients. Ten of the eleven patients who died were not wearing the device at the time of death; details on the 11th patient were not available. Thirteen patients in the NIDCM group died after WCD usage at an average of 10.9 (± 7.8 months) after use), while 3 patients in the NIDCM group died after WCD use; one at 30 months, one at 40 months, and one was lost to follow-up. Adherence was an issue with both groups; the WCD was only worn an average of 17 to 18 hours per day (median 19–20) The authors noted that the implications are compelling, since sudden cardiac death is an unpredictable event, and these women were unprotected 25–30% of each day. The fact that the WCD can be removed by the user compromises overall compliance and effectiveness.

Rao et al. (2011) conducted an analysis of registry data to evaluate the short-and long-term outcomes of patients with congenital structural heart disease (CSHD) (n=43) and inherited arrhythmias (IA) (n=119) at risk for ventricular tachyarrhythmias and sudden cardiac death who received a wearable cardioverter defibrillator (WCD). The most frequent indication for WCD was pending genetic testing in the IA group and transplant listing in the CSHD group. Compliance was 91% in both groups. Three ventricular tachyarrhythmias were successfully terminated in IA

patients during a median follow-up of 29 days of therapy. No arrhythmias occurred in the patients with CSHD during a median follow-up of 27 days. No patients died while actively wearing the WCD.

Chung et al. (2010) published aggregate experience with the LifeVest from 2002 to 2006, with data obtained from the manufacturer's database. The mean duration of use was 52.6 ± 69.6 days, and mean daily use was 19.9 ± 4.7 hours. Of 2169 patients with recorded data, 307 (14.2%) stopped wearing the WCD prematurely due to comfort issues or adverse reactions (primarily the size and weight of the monitor). Eighty sustained ventricular tachycardia (VT)/ventricular fibrillation (VF) events occurred in 59 patients (1.7%), and the first shock was successful in 79 of 80 patients. Eight patients died after successful conversion of unconscious VT/VF. Four patients died due to recurrent arrhythmias after initially recovering consciousness. Not all cardiac arrests were secondary to arrhythmias; asystole occurred in 23 patients resulting in 17 deaths; and three additional patients died due to pulseless electrical activity (2) and respiratory arrest (1), representing 24.5% of cardiac arrests.

The prospective nonrandomized multicenter trial submitted as part of the FDA PMA for the WCD 2000 System was published in 2004 (Feldman, et al., 2004 for the WEARIT/BIROAD Investigators). The WEARIT and BIROAD studies were designed to assess the safety and efficacy of a wearable cardioverter defibrillator in treating ventricular tachyarrhythmias in patients who were at high risk for SCD but did not meet eligibility criteria for ICD placement or who would not receive an ICD for several months. After a combined total of 289 patients had been enrolled in the two studies, prespecified safety and effectiveness guidelines had been met. Two populations of patients were selected. The WEARIT study (n=177) enrolled MYHA class III or IV patients with an ejection fraction (EF) of < 30%. The BIROAD study (n=112) enrolled patients in whom a wearable device could be used to bridge patients for a four-month period to possible ICD implantation, including those with complications associated with high risk of sudden death after an MI or bypass surgery. Six of eight defibrillator attempts were successful. Six inappropriate shock episodes occurred during 901 months of patient use. Of six sudden deaths that occurred during the study, five were in patients not wearing the device, and one occurred in a patient wearing the device incorrectly. The authors concluded that the results of these studies suggest that a wearable defibrillator is beneficial in detecting and effectively treating ventricular tachyarrhythmias in patients at high risk for sudden death who are not clear candidates for an ICD and may be useful as a bridge to transplantation or ICD in some patients. The authors acknowledged several limitations of the WEARIT/BIROAD study, including the fact that 46 patients received an ICD during the course of the study, raising the possibility that these individuals might have been less likely to have survived a defibrillation by the wearable device, and thus their early exit from the study may have biased the results. A second limitation was the fact that this study did not have a control group of patients not receiving the wearable device.

The risk of sudden death following acute myocardial infarction (MI) is highest early after the event, and declines progressively over the next six to twelve months. Following an acute MI, the estimate of left ventricular ejection is not reliable and may improve during the subsequent weeks. According to current guidelines and standard practice, it is recommended that a decision regarding ICD implantation be deferred for at least a month to allow accurate estimation of LVEF and reliable determination of whether an ICD is indicated. The WCD has been proposed as a bridge to ICD risk stratification and possible implantation.

Evidence published to date from several randomized controlled trials has failed to show a survival benefit for ICD implantation early after MI. The reasons for this acute MI-sudden cardiac death paradox are not yet clear. The pathophysiology of sudden cardiac death in the early post-MI period may differ from that which occurs in the later post-MI period. Since sudden cardiac death is

not synonymous with an arrhythmic event, it is possible that the increased incidence of sudden death after acute MI is largely not caused by a lethal ventricular arrhythmia. Neither an ICD nor a WCD, therefore, would be expected to have an impact on this type of sudden death. In addition, high-voltage ICD shocks have been associated with several deleterious effects, including transient myocardial dysfunction and troponin release/elevation, and whether these effects occur more frequently in the setting of a healing vs. healed MI requires further study (Goldberger and Passman, 2009).

There is limited evidence in the published medical literature on the safety and efficacy of wearable defibrillators. The literature indicates that these devices be limited to the small subset of patients at high risk for SCD who meet criteria for ICD placement but in whom the procedure is currently not indicated, such as those awaiting heart transplantation, awaiting ICD reimplantation following infection-related explantation, or patients with a systemic infectious process or other temporary condition that precludes implantation The WCD may also be appropriate as a bridge to ICD risk stratification and possible implantation for patients in the immediate post-MI period who have either a history of ventricular tachycardia or ventricular fibrillation at least 48 hours after the acute MI, or a left ventricular ejection fraction ≤ 35%. In addition, the WCD may be reasonable as a bridge to ICD risk stratification in patients with newly diagnosed ischemic or nonischemic dilated cardiomyopathy. A percentage of such patients may demonstrate an improvement in LVEF after a period of guideline-directed medical therapy to a degree that an ICD is not required.

A rental period of up to three months is reasonable for an individual with newly diagnosed dilated cardiomyopathy, and for a period of up to 40 days immediately following MI, when used as a bridge to ICD risk stratification (as described above), An initial rental period of up to two months is indicated for patients who are awaiting ICD reimplantation and those with a systemic infection or temporary condition that precludes implantation, For patients awaiting cardiac transplantation, an initial rental period of three months is generally indicated, with continued coverage for ongoing rental until transplantation, provided that it is determined upon review that the patient is fully compliant with use of the device.

Literature Review WCD Use in Children/Pediatrics

In a discussion of the WCD, Chung (UpToDate, 2023) noted that the WCD in children requires special attention to assure compliance and correct fitting for optimal use. A variety of device harness sizes are available, but the smallest option may still be too large for smaller children. Additional data on clinical efficacy, compliance, and complications should be collected in children as WCD use increases.

Spar et al. (2018) conducted a retrospective review that assessed the effectiveness, safety, and compliance of the WCD in the identification and treatment of life-threatening ventricular arrhythmias in pediatric patients. Included patients (n=455) were < age 18 years who had a WCD prescribed by their physician. Patients were divided into two groups: patients who had the WCD placed because of an ICD problem (n=63) (ICD problem) group and patients with any other indication for the WCD (n=392) (non-ICD problem) group. Appropriate therapies delivered for ventricular tachycardia (VT) or ventricular fibrillation (VF). Therapy provided for any rhythm besides VT or VF was considered inappropriate. Successful therapies were defined as terminating the VT or VF. The wear duration in days was significantly shorter in the ICD problem group compared with the non-ICD problem group, 26 days versus 35 days ($p<0.05$). There were eight patients (1.8% of the total study population) that received therapy from WCD. There were six patients with appropriate therapies (1.3% of the study population). The median age for patients with appropriate therapies was 15.5 years (12–17). There were two inappropriate therapies (0.4% of the study population). The inappropriate therapies were secondary to oversensing of artifact during asystole (n=1) and noise/artifact during sinus rhythm (n=1). There were seven deaths (1.5

percent); none were wearing the WCD at the time of death. The authors concluded that the WCD is safe and effective in treating ventricular arrhythmias that can lead to sudden cardiac death in pediatric patients. No health disparities were identified by the investigators.

In a retrospective study of the WCD manufacturer's clinical database (2002-2009), Collins et al. (2010) compared the use of the wearable defibrillator in patients ≤ 18 years of age to those aged 19–21 years. There were 81 patients ≤ 18 years of age (median age=16.5 years [9-18] and 52% male). There were 103 patients aged 19–21 years (median age=20 years [19–21] and 47% male). Cardiomyopathy and primary arrhythmia were the most common underlying diagnosis in both groups. A larger proportion of patients ≤ 18 years old had congenital heart disease compared with the older patients. Reasons for a wearable defibrillator versus implanting an ICD were varied. The largest groupings were of patients awaiting further testing or treatment, expected recovery of ventricular function, a bridge to an ICD, and evaluation of cardiac transplantation. Other important groupings were ICD malfunction or infection. There was no difference between groups in average hours/day or in total number of days the patients wore the defibrillator. In patients ≤ 18 years of age, there was one inappropriate therapy due to sinus tachycardia and artifact and one withholding of therapy due to a device-device interaction with a unipolar pacemaker. There were no appropriate shocks administered in the ≤ 18 years of age group thus the true efficacy of the wearable external defibrillator cannot be assessed. In patients aged 19–21 years, there were five appropriate discharges in two patients and one inappropriate discharge in a single patient. The largest category for discontinuation of the wearable defibrillator was that the patients received a permanent ICD. Noncompliance or reports of the device being uncomfortable occurred in 6/81 (7%) of the pediatric patients and in 11/103 (11%) of the young adult patients. Within the time period of the study, there were nine (11%) deaths in patients ≤ 18 years and nine (9%) deaths in patients aged 19–21 years. The wearable defibrillator was still prescribed in five of the deaths in patients ≤ 18 years and in four deaths in patients aged 19–21 years. Two patients in each group died when they were not wearing the defibrillator, even though it was still prescribed. The authors report that noncompliance with the device is an important consideration when prescribing the wearable defibrillator.

One retrospective, single center case series study reported on the utility of WCD use in four children aged 9 to 17 years with anthracycline-induced cardiomyopathy (Everitt, et al., 2010). No inappropriate shocks were delivered however, one child experienced cardiac arrest due to ventricular fibrillation with the vest unfastened and required external cardioversion. Two children, aged 15 and 17 years, required adjustment of the WCD with downsizing or refitting of the vest to achieve better electrode contact and reduction in noise.

Professional Societies/Organizations
American Heart Association (AHA): The 2016 AHA science advisory on wearable cardioverter-defibrillator therapy for the prevention of sudden cardiac death (Piccini, et al., 2016) included the following recommendations for wearable cardioverter-defibrillator therapy:

Class IIa
- Use of wearable defibrillators is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care such as infection. (*Level of Evidence: C)*
- Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation. (*Level of Evidence: C*)

A Class IIa, Level of Evidence C recommendation indicates it is reasonable to perform the procedure/administer the treatment. The benefit outweighs the risk, but additional studies with

focused objectives are needed. The recommendation is in favor of the treatment or procedure being useful/effective. Only diverging expert opinion, case studies, or standard of care.

Class IIb

- WCDs may be appropriate as bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 days of MI. (*Level of Evidence: C*)

- Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time or treatment of left ventricular dysfunction, for example, in ischemic heart disease with recent revascularization, newly diagnosed nonischemic dilated cardiomyopathy in a patient starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc) in which the underlying cause is potentially treatable. (*Level of Evidence: C*)

A Class IIb, Level of evidence C recommendation indicates additional studies with broad objectives needed; additional registry data would be helpful. The recommendation is in favor of the treatment or procedure being useful/effective. Only diverging expert opinion, case studies, or standard of care.

Class III

- WCDs should not be used when nonarrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive > 6 months. (*Level of Evidence: C*)

A Class III, Level of evidence C recommendation indicates no proven benefit or harmful to patients. The recommendation is in favor of the treatment or procedure being useful/effective. Only diverging expert opinion, case studies, or standard of care.

The authors noted that since there is a paucity of prospective data supporting the use of the WCD, particularly the absence of any published, randomized, clinical trials, the recommendations provided in this advisory are not intended to be prescriptive or to suggest an evidence-based approach to the management of patients with FDA-approved indications for use. The recommendations are offered to provide clinicians direction when discussing this therapy with patients (Piccini, et al., 2016).

American College of Cardiology Foundation (ACCF)/American Heart Association (AHA): The 2013 ACCF and AHA Guideline for the Management of ST-Elevation Myocardial Infarction (O'Gara, et al., 2013) does not include a recommendation for WCD use. In a background discussion of assessment of risks of sudden cardiac death, the authors stated that the utility of a wearable cardioverter-defibrillator in high-risk patients during the first four to six weeks after STEMI is under investigation.

American College of Cardiology Foundation (ACCF)/Heart Rhythm Society (HRS)/American Heart Association (AHA)/American Society of Echocardiography (ASE)/Heart Failure Society of America (HFSA)/Society for Cardiovascular Angiography and Interventions (SCAI)/Society of Cardiovascular Computed Tomography (SCCT)/Society for Cardiovascular Magnetic Resonance (SCMR): The use of a wearable cardioverter defibrillator is not mentioned in the ACCF, HRS, AHA, ASE, HFSA, SCAI, SCCT, and SCMR 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy (Russo, et al., 2013).

American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Rhythm Society (HRS): The ACC, AHA, HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (Epstein, et al.) does not address use of a WCD, nor does a 2012 focused update of this guideline (Tracy, et al., 2012).

American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Rhythm Society (HRS): The 2017 AHA, ACC, HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Al-Khatib, et al.) provides the following recommendations for a wearable cardioverter-defibrillator:

Class IIa
- In patients with an implantable cardioverter-defibrillator (ICD) and a history of sudden cardiac arrest (SCA) or sustained ventricular arrhythmia (VA) in whom removal of the ICD is required (as with infection), the wearable cardioverter defibrillator is reasonable for the prevention of sudden cardiac death (SCD) (Level of Evidence: B-NR).

Class IIb
- In patients at an increased risk of SCD but who are not ineligible for an ICD, such as awaiting cardiac transplant, having an left ventricular ejection fraction (LVEF) of 35% or less and are within 40 days from an myocardial infarction (MI), or have newly diagnosed nonischemic cardiomyopathy (NICM), revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, wearable cardioverter-defibrillator may be reasonable (Level of Evidence: B-NR).

Class (Strength) of Recommendation:
- Class I (Strong) Benefit >>>> Risk
- Class IIa (Moderate) Benefit >> Risk
- Class IIb (Weak) Benefit > Risk
- Class III No Benefit (Moderate) Benefit = Risk
- Class III Harm (Strong) Benefit > Risk

Level (Quality) of Evidence:
- Level A if the data were derived from high-quality evidence from more than one randomized clinical trial, meta-analyses of high-quality randomized clinical trials, or one or more randomized clinical trials corroborated by high-quality registry.
- Level B-R when data were derived from moderate quality evidence from one or more randomized clinical trials, or meta-analyses of moderate-quality randomized clinical trials.
- Level B-NR was used to denote moderate-quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies. This designation was also used to denote moderate-quality evidence from meta-analyses of such studies.
- Level C-LD when the primary source of the recommendation was randomized or nonrandomized observational or registry studies with limitations of design or execution, meta-analyses of such studies, or physiological or mechanistic studies of human subjects.
- Level C-EO was defined as expert opinion based on the clinical experience of the writing group.

<u>Automatic External Defibrillator (AED)</u>
Early defibrillation has been shown to be a critical factor in improving survival after out-of-hospital cardiac arrest. The use of automatic external defibrillators (AEDs) has become an important component of emergency medical services (EMS), and advances in technology have permitted

expansion of AED use to minimally trained first responders and trained laypersons who witness an arrest.

U.S. Food and Drug Administration (FDA): The FDA requires premarket approval for all AEDs and AED accessories. After a PMA decision is made, only FDA-approved accessories can continue to be marketed. Once the AEDs and AED accessories are on the market, the FDA proactively monitors their safety and reliability by reviewing the manufacturers' manufacturing and design changes, performance reports, and medical device reports (MDRs) (FDA, 2023)

The HeartStart Home Defibrillator (Model M5068A; Philips Medical Systems, Bothell, WA) received PMA FDA approval (P160029) on June 6, 2019. The HeartStart Home (Model M5068A) is indicated for use on potential victims of cardiac arrest with the following symptoms:

- unconsciousness; and
- absence of normal breathing

The HeartStart Home (Model M5068A) is indicated for adults over 55 pounds (25 kg). The HeartStart Home is also indicated for infants and children under 55 lbs (25 kg) or 8 years old when used with the optional infant/child SMART pads (Model M5072A). If Infant/Child SMART pads are not available, or you are uncertain of the child's age or weight, proceed with treatment using adult SMART pads (Model M5071A).

The HeartStart Home is an over-the-counter (OTC) home-use defibrillator and has been commercially available since 2004, when it was first cleared by FDA under K040904.

Literature Review - Automatic External Defibrillator (AED)
McLeod et al. (2017) conducted a retrospective review that reviewed their experience of prescribing automated external defibrillators to families with children at potential increased risk of arrhythmic sudden death. Over a period of 10.5 years, 36 automated external defibrillators were issued to 36 families for 44 children. The age of the children at the time the automated external defibrillator was issued ranged from 1 day to 15 years (mean 8.8 years). Follow-up ranged from 12 to 138 months, with a median of 50 months (4.1 years) and a mean of 75.5 months (6.2 years). Of the 44 children, 35 (79%) were issued an automated external defibrillator on recommendation of the physician. This group included six children for whom an implantable cardioverter defibrillator had been recommended, but implant was delayed on account of small patient size (n=3), chronic infection (n=2), and parental uncertainty about implantable cardioverter defibrillator placement (n=1). For nine (20%) patients, the automated external defibrillator was issued because of parental request and anxiety, even though not recommended by the physician. Of the 44 children, 19 (43%) had symptoms or events after the automated external defibrillator was issued that included syncopal events, dizziness and palpitations. Three children (7%) had a cardiac arrest, and 11/19 patients with symptoms or events had an implantable loop recorder. During the study period, the AED was used in four (9%) children, and in all four the automated external defibrillator correctly discriminated between a shockable rhythm, polymorphic ventricular tachycardia/ventricular fibrillation (n=3) and non-shockable rhythm (n=1). Of the three children, two of them who received one or more shocks for ventricular fibrillation/polymorphic ventricular tachycardia survived, but one died as a result of recurrent torsades de pointes. There were no other deaths. The study concluded that parents can be taught to recognize cardiac arrest, apply resuscitation skills, and use an automated external defibrillator. A limitation of the study included that the population only included children from the Scottish Pediatric Cardiac Electrophysiology Service and results may not be applicable to other races or ethnic groups.

The Home Automatic External Defibrillator Trial (HAT), an international, multicenter trial sponsored by the National Heart, Lung, and Blood Institute (NHLBI), was designed to test whether an AED in the home of patients with intermediate risk of sudden cardiac arrest could improve survival (Bardy, et al., 2008). A total of 7001 patients at 178 clinical sites in seven countries were randomized between 2003 and 2005. Patients in stable medical condition who had a previous anterior-wall Q-wave or non-Q-wave MI were randomized to receive one of two responses after a cardiac arrest occurring at home: either the control response that included calling emergency medical services (EMS) and performing cardiopulmonary resuscitation (CPR) (n=3506), or the use of an AED, followed by calling EMS and performing CPR (n=3495). The primary outcome was death from any cause. Patients who were candidates for an ICD were excluded from the study. Evidence-based drug therapy was encouraged for all patients. Participants were required to have a spouse or companion willing and able to call for assistance from emergency medical services (EMS), perform CPR, and use an AED. The median follow-up was 37.3 months. A total of 450 patients died; 228 of 3506 (6.5%) in the control group and 222 of 3495 patients (6.4%) in the AED group (p=0.77). Only 160 deaths (35.6%) were from sudden cardiac arrest from tachyarrhythmia. Of these deaths, 117 of occurred at home and 58 events were witnessed. AEDs were used in 32 patients; 14 received an appropriate shock, and four survived to hospital discharge. No inappropriate shocks were documented. Access to a home AED did not significantly improve overall survival in this intermediate risk population, compared to reliance on conventional resuscitation methods. However, AEDs resulted in long-term survival for 6 (33%). The authors stated that the high proportion of unwitnessed events, the underuse of the AEDs in emergencies, rather than a lack of device efficacy, appear to explain these results. Using an AED in the home by laypeople with minimal training is feasible and terminates ventricular fibrillation (VF).

There is little published information on the efficacy of AED use in the home. The Public Access Defibrillation (PAD) Trial, a community-based prospective multicenter trial, was designed to determine whether the rate of survival would increase if laypersons are trained to attempt defibrillation with the use of AEDs. A diverse group of community facilities (e.g., shopping malls, recreation centers, hotels and apartment complexes) was recruited to participate. Each facility had to have a pool of potential volunteer responders and the ability to deliver an AED within three minutes to a person in cardiac arrest. The number of patients who survived to discharge after out-of-hospital cardiac arrest where volunteers recognized the event, telephoned EMS, and performed cardiopulmonary resuscitation (CPR) was compared to the number who survived to discharge when volunteers could also provide early defibrillation with an on-site AED. There were more survivors to hospital discharge in units assigned to have responders trained in CPR plus the use of AEDs (30 survivors/128 arrests) than in the group assigned to have volunteers trained only in CPR (15 survivors/107 arrests). When the data for arrests that occurred in residential units and public units are examined separately, however, there is no demonstrated survival benefit of CPR plus AED in residential patients. There were 37 arrests/one survivor in residential units and 70 arrests/14 survivors in public units in the group treated by CPR only, compared to 33 arrests/one survivor in the residential units and 95 arrests/29 survivors in the public units in the group treated with CPR and AED. The authors concluded that training and equipping volunteers to attempt early defibrillation within a structured response system can increase the number of survivors to hospital discharge after out-of-hospital cardiac arrest. This study, however, does not provide evidence that AEDs in residences improve survival beyond what is achieved with standard EMS response (Hallstrom, et al., 2004).

Professional Societies/Organizations
American College of Cardiology Foundation (ACCF)/American Heart Association American (AHA): The ACC, AHA Guideline for Management of Patients with ST-Elevation Myocardial Infarction (O'Gara, et al., 2013) recommendations do not include AED use in the home.

Effective 12/15/2024

American College of Cardiology (ACC)/American Heart Association (AHA): The ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (Epstein, et al.) does not address use of an AED, nor does a 2012 focused update of this guideline (Tracy, et al., 2012).

American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Rhythm Society (HRS): The 2017 AHA, ACC, HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Al-Khatib, et al., 2017) does not provide recommendations for an AED in the home.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Implantable Automatic Defibrillators (20.4)	3/26/2019
LCD	CGS Administrators, LLC & Noridian Healthcare Solutions, LLC	Automatic External Defibrillators (L33690)	1/1/2022

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Transvenous Implantable Cardioverter Defibrillator (ICD)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
33202	Insertion of epicardial electrode(s); open incision (eg, thoracotomy, median sternotomy, subxiphoid approach)
33203	Insertion of epicardial electrode(s); endoscopic approach (eg, thoracoscopy, pericardioscopy)
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion and/or replacement of existing generator)

CPT®* Codes	Description
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only, with existing multiple leads
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead
33241	Removal of implantable defibrillator pulse generator only
33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy
33244	Removal of single or dual chamber implantable defibrillator electrodes(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system

HCPCS Codes	Description
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
G0448	Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
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

Effective 12/15/2024

CPT®* Codes	Description
33272	Removal of subcutaneous implantable defibrillator electrode
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode
33999†	Unlisted procedure, cardiac surgery
93260	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system
93261	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

†**Note: Considered medically necessary when used to report implantation of subcutaneous implantable cardioverter defibrillator (S-ICD).**

Substernal Implantable Cardioverter-Defibrillator

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
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
0575T	Programming device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional
0576T	Interrogation device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter
0577T	Electrophysiological evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

CPT®* Codes	Description
0578T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
0579T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results
0580T	Removal of substernal implantable defibrillator pulse generator only
0614T	Removal and replacement of a substernal implantable defibrillator pulse generator

Wearable Cardioverter-Defibrillator

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
93745	Initial set-up and programming by a physician or other qualified health care professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events

HCPCS Codes	Description
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement battery for automated external defibrillator, garment type only, each
K0608	Replacement garment for use with automated external defibrillator, each
K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each

Automatic External Defibrillator (AED)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
E0617	External defibrillator with integrated electrocardiogram analysis

References

1. Al-Khatib SM, Stevenson WG, Ackerman MJ, Bryant WJ, Callans DJ, Curtis AB, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of

Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2017 Oct 30.

2. Banerjee S, Aaysha Cader F, Gulati M, Capers Q 4th. Racism and Cardiology: A Global Call to Action. CJC Open. 2021 Sep 24;3(12 Suppl):S165-S173.

3. Bardy GH, Lee KL, Mark DB, Poole JE, Toff WD, Tonkin AM, et al., for the HAT Investigators. Home use of automated external defibrillators for sudden cardiac arrest. N Engl J Med. 2008 Apr 24;358(17):1793-804.

4. Boersma L, Barr C, Knops R, Theuns D, Eckardt L, Neuzil P, et al; EFFORTLESS Investigator Group. Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. J Am Coll Cardiol. 2017 Aug 15;70(7):830-841.

5. Boersma LVA, Merkely B, Neuzil P, Crozier IG, Akula DN, Timmers L, et al. Therapy From a Novel Substernal Lead: The ASD2 Study. JACC Clin Electrophysiol. 2019 Feb;5(2):186-196.

6. Burke MC, Aasbo JD, El-Chami MF, Weiss R, Dinerman J, Hanon S, Kalahasty G, et al. 1-Year Prospective Evaluation of Clinical Outcomes and Shocks: The Subcutaneous ICD Post Approval Study. JACC Clin Electrophysiol. 2020 Nov;6(12):1537-1550.

7. Burke MC, Gold MR, Knight BP, Barr CS, Theuns DA, Boersma LV, 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. 2015 Apr 28;65(16):1605-15.

8. Chahine M, Fontaine JM, Boutjdir M. Racial Disparities in Ion Channelopathies and Inherited Cardiovascular Diseases Associated With Sudden Cardiac Death. J Am Heart Assoc. 2022 Mar 15;11(6):e023446.

9. Chung MK, Szymkiewicz SJ, Shao M, Zishiri E, Niebauer MJ, Lindsay BD, Tchou PJ. Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. J Am Coll Cardiol. 2010 Jul 13;56(3):194-203.

10. Chung MK. Wearable cardioverter-defibrillator. In: UpToDate; Page RL (Ed). UpToDate, Waltham, MA. Literature review current through: Apr 2024. Topic last updated: February 22, 2023. Accessed May 22, 2024.

11. ClinicalTrials.gov. Accessed May 23, 2024. Available at URL address: https://www.clinicaltrials.gov/

12. Collins KK, Silva JN, Rhee EK, Schaffer MS. Use of a wearable automated defibrillator in children compared to young adults. Pacing Clin Electrophysiol. 2010 Sep;33(9):1119-24.

13. Crozier I, Haqqani H, Kotschet E, Shaw D, Prabhu A, Roubos N, et al. First-in-Human Chronic Implant Experience of the Substernal Extravascular Implantable Cardioverter-Defibrillator. JACC Clin Electrophysiol. 2020 Nov;6(12):1525-1536.

14. Epstein AE, Abraham WT, Bianco NR, Kern KB, Mirro M, Rao SV, et al. Wearable cardioverter-defibrillator use in patients perceived to be at high risk early post-myocardial infarction. J Am Coll Cardiol. 2013 Nov 19;62(21):2000-7.

15. Epstein AE, DiMarco JP, Ellenbogen KA, Estes NA 3rd, Freedman RA, Gettes LS,et al. 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); American Association for Thoracic Surgery; Society of Thoracic Surgeons. 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. Am Coll Cardiol. 2008 May 27;51(21):e1-62.

16. Everitt MD, Saarel EV. Use of the wearable external cardiac defibrillator in children. Pacing Clin Electrophysiol. 2010 Jun 1;33(6):742-6.

17. Feldman AM, Klein H, Tchou P, Murali S, Hall WJ, Mancini D, et al. Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD. Pacing & Clinical Electrophysiology. 2004 Jan;27(1):4-9.

18. Friedman P, Murgatroyd F, Boersma LVA, Manlucu J, O'Donnell D, Knight BP, et al. Efficacy and Safety of an Extravascular Implantable Cardioverter-Defibrillator. N Engl J Med. 2022 Oct 6;387(14):1292-1302.

19. Friedman DJ, Parzynski CS, Varosy PD, Prutkin JM, Patton KK, Mithani A, Russo et al. Trends and In-Hospital Outcomes Associated With Adoption of the Subcutaneous Implantable Cardioverter Defibrillator in the United States. JAMA Cardiol. 2016 Nov 1;1(8):900-911.

20. Goetz G, Wernly B, Wild C. Wearable cardioverter defibrillator for preventing sudden cardiac death in patients at risk: An updated systematic review of comparative effectiveness and safety. Int J Cardiol Heart Vasc. 2023 Mar 28;45:101189.

21. Gold MR, Aasbo JD, El-Chami MF, Niebauer M, Herre J, Prutkin JM, et al. Subcutaneous implantable cardioverter-defibrillator Post-Approval Study: Clinical characteristics and perioperative results. Heart Rhythm. 2017 Oct;14(10):1456-1463.

22. Gold MR, Aasbo JD, Weiss R, Burke MC, Gleva MJ, Knight BP, et al. Infection in patients with subcutaneous implantable cardioverter-defibrillator: Results of the S-ICD Post Approval Study. Heart Rhythm. 2022 Dec;19(12):1993-2001.

23. Gold MR, Lambiase PD, El-Chami MF, Knops RE, Aasbo JD, Bongiorni MG, et al. Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial. Circulation. 2021 Jan 5;143(1):7-17.

24. Goldberger JJ, Passman R. Implantable cardioverter-defibrillator therapy after acute myocardial infarction: the results are not shocking. J Am Coll Cardiol. 2009 Nov 24;54(22):2001-5.

25. Goldenberg I, Erath JW, Russo AM, Burch AE, Assmus B, Bonderman D, et al. Sex differences in arrhythmic burden with the wearable cardioverter-defibrillator. Heart Rhythm. 2021 Mar;18(3):404-410.

26. Groh WJ, Bhakta D, Tomaselli GF, Aleong RG, Teixeira RA, Amato A, et al. 2022 HRS expert consensus statement on evaluation and management of arrhythmic risk in neuromuscular disorders. Heart Rhythm. 2022 Oct;19(10):e61-e120.

27. Hallstrom AP, Ornato JP, Weisfeldt M, Travers A, Christenson J, McBurnie MA, et al. Public-access defibrillation and survival after out-of-hospital cardiac arrest. N Engl J Med. 2004 Aug 12;351(7):637-46.

28. Heidenreich PA, Bozkurt B, Aguilar D, Allen LA, Byun JJ, Colvin MM, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2022 May 3;79(17):e263-e421.

29. Kovacs B, Reek S, Krasniqi N, Eriksson U, Duru F. Extended Use of the Wearable Cardioverter-Defibrillator: Which Patients Are Most Likely to Benefit? Cardiol Res Pract. 2018 Nov 29;2018:7373610.

30. Kwaku KF. Cardiac implantable electronic devices: Peri-procedural complications. In: UpToDate; Dardas TF (Ed). UpToDate, Waltham, MA. Literature review current through: Apr 2024. Topic last updated: Mar 2023. Accessed May 22, 2024.

31. Lambiase PD, Barr C, Theuns DA, Knops R, Neuzil P, Johansen, et al.; EFFORTLESS Investigators. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. Eur Heart J. 2014 Jul 1;35(25):1657-65.

32. Lambiase PD, Theuns DA, Murgatroyd F, Barr C, Eckardt L, Neuzil P, et al. Subcutaneous implantable cardioverter-defibrillators: long-term results of the EFFORTLESS study. Eur Heart J. 2022 Jan 28:ehab921.

33. McLeod KA, Fern E, Clements F, McGowan R. Prescribing an automated external defibrillator for children at increased risk of sudden arrhythmic death. Cardiol Young. 2017 Sep;27(7):1271-1279.

34. Ntusi NAB, Sliwa K. Associations of Race and Ethnicity With Presentation and Outcomes of Hypertrophic Cardiomyopathy: JACC Focus Seminar 6/9. J Am Coll Cardiol. 2021 Dec 21;78(25):2573-2579.

35. O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the American College of Emergency Physicians and Society for Cardiovascular Angiography and Interventions. Catheter Cardiovasc Interv. 2013 Jul 1;82(1):E1-27.

36. Olde Nordkamp LR, Dabiri Abkenari L, Boersma LV, Maass AH, de Groot JR, van Oostrom AJ, et al. The entirely subcutaneous implantable cardioverter-defibrillator: initial clinical experience in a large dutch cohort. J Am Coll Cardiol 2012 Nov 6;60(19):1933-9.

37. Olde Nordkamp LR, Knops RE, Bardy GH, Blaauw Y, Boersma LV, Bos JS, et al. Rationale and design of the PRAETORIAN trial: a Prospective, Randomized comparison of

subcutaneous and transvenous implantable cardioverter-defibrillator therapy. Am Heart J. 2012 May;163(5):753-760.e2.

38. Ommen SR, Mital S, Burke MA, Day SM, Deswal A, Elliott P, et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2020 Dec 22;76(25):e159-e240.

39. Patel NJ, Edla S, Deshmukh A, Nalluri N, Patel N, Agnihotri K, et al. Gender, Racial, and Health Insurance Differences in the Trend of Implantable Cardioverter-Defibrillator (ICD) Utilization: A United States Experience Over the Last Decade. Clin Cardiol. 2016 Feb;39(2):63-71.

40. Patlolla SH, Schaff HV, Nishimura RA, Geske JB, Dunlay SM, Ommen SR. Sex and Race Disparities in Hypertrophic Cardiomyopathy: Unequal Implantable Cardioverter-Defibrillator Use During Hospitalization. Mayo Clin Proc. 2022 Mar;97(3):507-518.

41. Piccini JP Sr, Allen LA, Kudenchuk PJ, Page RL, Patel MR, Turakhia MP; American Heart Association Electrocardiography and Arrhythmias Committee of the Council on Clinical Cardiology and Council on Cardiovascular and Stroke Nursing. Wearable Cardioverter-Defibrillator Therapy for the Prevention of Sudden Cardiac Death: A Science Advisory from the American Heart Association. Circulation. 2016 Apr 26;133(17):1715-27.

42. Podrid PJ. Overview of sudden cardiac arrest and sudden cardiac death. In: UpToDate; Olshansky B (Ed). UpToDate, Waltham, MA. Literature review current through: Apr 2024. Topic last updated: May 2024a. Accessed April 14, 2023.

43. Podrid PJ. Pathophysiology and etiology of sudden cardiac arrest. In: UpToDate; Olshansky B, Manaker S (Eds). UpToDate, Waltham, MA. Literature review current through: Apr 2024. Topic last updated: May 2024b. Accessed April 14, 2023.

44. Poole JE, Gleva MJ, Birgersdotter-Green U, Branch KRH, Doshi RN, Salam T, et al. A wearable cardioverter defibrillator with a low false alarm rate. J Cardiovasc Electrophysiol. 2022 Feb 16.

45. Priori SG, Blomström-Lundqvist C, Mazzanti A, Blom N, Borggrefe M, Camm J, et al; Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC)Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). Europace. 2015 Nov;17(11):1601-87.

46. Rao M, Goldenberg I, Moss AJ, Klein H, Huang DT, Bianco NR, et al. Wearable defibrillator in congenital structural heart disease and inherited arrhythmias. Am J Cardiol. 2011 Dec 1;108(11):1632-8.

47. Regitz-Zagrosek V. Sex and Gender Differences in Heart Failure. Int J Heart Fail. 2020 Jul;2(3):157-181.

48. Russo AM, Stainback RF, Bailey SR, Epstein AE, Heidenreich PA, Jessup M, Kapa et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy: a report of the American College of Cardiology Foundation appropriate use criteria task force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. Heart Rhythm. 2013 Apr;10(4):e11-58.

49. Saltzberg MT, Szymkiewick S, Bianco NR. Characteristics and outcomes of peripartum versus nonperipartum cardiomyopathy in women using a wearable cardiac defibrillator. J Card Fail. 2012 Jan;18(1):21-7.

50. Shen WK, Sheldon RS, Benditt DG, Cohen MI, Forman DE, Goldberger ZD, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm. 2017 Aug;14(8):e155-e217.

51. Spar DS, Bianco NR, Knilans TK, Czosek RJ, Anderson JB. The US Experience of the Wearable Cardioverter-Defibrillator in Pediatric Patients. Circ Arrhythm Electrophysiol. 2018 Jul;11(7):e006163.

52. Theuns DA, Crozier IG, Barr CS, Hood MA, Cappato R, Knops RE, et al. Longevity of the Subcutaneous Implantable Defibrillator: Long-Term Follow-Up of the European Regulatory Trial Cohort. Circ Arrhythm Electrophysiol. 2015 Oct;8(5):1159-63.

53. Towbin JA, McKenna WJ, Abrams DJ, Ackerman MJ, Calkins H, Darrieux FCC, et al. 2019 HRS expert consensus statement on evaluation, risk stratification, and management of arrhythmogenic cardiomyopathy. Heart Rhythm. 2019 Nov;16(11):e301-e372.

54. Tracy CM, Epstein AE, Darbar D, Dimarco JP, Dunbar SB, Mark Estes NA 3rd, et al. 2012 ACCF/AHA/HRS focused update of the 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. J Thorac Cardiovasc Surg. 2012 Dec;144(6):e127-45.

55. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. 510(k) Premarket Notification. Databases. Classification Product Code: NSA, FTL. Page Last Updated: May 20, 2024. Accessed May 23, 2024. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K040904

56. U.S. Food and Drug Administration (FDA). Automatic External Defibrillators (AEDs). Content current as of Jul 6, 2023. Accessed May 23, 2024. Available at URL address: https://www.fda.gov/medical-devices/cardiovascular-devices/automated-external-defibrillators-aeds

57. U.S. Food and Drug Administration (FDA). Letter on AEDs and Accessories. September 26, 2019. Accessed May 23, 2024. Available at URL address: https://www.fda.gov/media/131108/download

58. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Premarket Approval (PMA). Databases. Product Code: LWS, NVY, MVK, MKJ, NSA. Page Last Updated: May 13, 2024. Accessed May 23, 2024. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

59. Weiss R, Knight BP, Gold MR, Leon AR, Herre JM, Hood M, Rashtian M, Kremers M, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation. 2013 Aug 27;128(9):944-53.

60. Zhao D, Post WS, Blasco-Colmenares E, Cheng A, Zhang Y, Deo R, et al. Racial Differences in Sudden Cardiac Death. Circulation. 2019 Apr 2;139(14):1688-1697.

61. Zipes DP, Camm AJ, Borgrefe M, Buxton AE, Chaitman B, Fromer M, et al. American College of Cardiology; American Heart Association Task Force; European Society of Cardiology Committee for Practice Guidelines. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). J Am Coll Cardiol. 2006 Sep 5;48(5):e247-346.

Revision Details

Type of Revision	Summary of Changes	Date
Focused Review	• Added policy statement for pediatric wearable cardioverter-defibrillators. • Revised policy statement for Automatic external defibrillators.	12/15/2024
Annual Review	• Combined with content from CP 0181 Implantable Cardioverter Defibrillator (ICD) and retired CP 0181. • Expanded coverage for home AEDs by removing the age limitation.	8/15/2024

Effective 12/15/2024