Medical Coverage Policy

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Cardioverter-Defibrillator Devices

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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 transvenous implantable cardioverter defibrillators, subcutaneous implantable cardioverter defibrillators, substernal implantable cardioverter-defibrillators, wearable cardioverter-defibrillators, and automatic external defibrillators in the home setting.

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 ANY 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 ≥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)

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, 2024). 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, 2025; Podrid, 2024; 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 for cardiac implantable electronic devices range from two to six percent. 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 (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 (Zipes, et al., 2006).

U.S. Food and Drug Administration (FDA): Multiple transvenous implantable ICD devices have been approved by the FDA through the Premarket Approval (PMA) process for patients who are at high risk of sudden cardiac death (FDA, 2025).

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

Indication	Recommendation for ICD placement	COR/LOE*
	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
	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	1/B-NR

Indication	Recommendation for ICD placement	COR/LOE*
	concordant with the patient's goals of care and clinical status.	
	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., 2024).

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

- "In patients with HCM, application of individual clinical judgment is recommended when assessing the prognostic strength of conventional risk marker(s) within the clinical profile of the individual patient, as well as a thorough and balanced discussion of the evidence, benefits, and estimated risks to engage the fully informed patient's active participation in ICD decision-making (C-EO)."

- "For patients with HCM and previous documented cardiac arrest or sustained VT, ICD placement is recommended (B-NR)."

Class IIa

- "For adult patients with HCM with ≥1 major risk factors for SCD, it is reasonable to offer an ICD. These major risk factors include:
  - Sudden death judged definitively or likely attributable to HCM in ≥1 first-degree or close relatives who are ≤50 years of age;
  - Massive LVH ≥30 mm in any LV segment;
  - ≥1 recent episodes of syncope suspected by clinical history to be arrhythmic (ie, unlikely to be of neurocardiogenic [vasovagal] etiology, or related to LVOTO);
  - LV apical aneurysm with transmural scar or LGE;
  - LV systolic dysfunction (EF <50%) (B-NR)."

- For children with HCM who have ≥1 conventional risk factors, including unexplained syncope, massive LVH, NSVT, or family history of early HCM-related SCD, ICD placement is reasonable after considering the relatively high complication rates of long-term ICD placement in younger patients (B-NR)."

- "For patients with HCM with ≥1 major SCD risk factors, discussion of the estimated 5-year sudden death risk and mortality rates can be useful during the shared decision-making process for ICD placement (B-NR)."

Class IIb

- "In select adult patients with HCM and without major SCD risk factors after clinical assessment, or in whom the decision to proceed with ICD placement remains otherwise uncertain, ICD may be considered in patients with extensive LGE by contrast-enhanced CMR imaging or NSVT present on ambulatory monitoring (B-NR)."

- "In pediatric patients with HCM, it can be useful to consider additional factors such as extensive LGE on contrast-enhanced CMR imaging and systolic dysfunction in risk stratification for ICD shared decision-making (B-NR)."

Class III: Harm

- "In patients with HCM without risk factors, ICD placement should not be performed (B-NR)."

- "In patients with HCM, ICD placement for the sole purpose of participation in competitive athletics should not be performed (B-NR)."

As stated above, the guideline includes a recommendation for ICD use in high-risk children with HCM, based on unexplained syncope, massive LV hypertrophy, NSVT, or family history of SCD, after taking into account the relatively high complication rate of long-term ICD implantation. Massive LV hypertrophy is defined as "an absolute or z-score threshold for wall thickness has not been established; however a maximal wall thickness that corresponds to a z-score ≥20 (and >10 in conjunction with other risk factors) appears reasonable". 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, higher baseline heart rates, 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

<u>Level (Quality) of Evidence:</u>

- 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
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

Indication	Recommendation for ICD placement	COR/LOE
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 inducible sustained VA is reasonable if meaningful survival of greater than 1 year is expected.	IIa/B-NR
	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

Indication	Recommendation for ICD placement	COR/LOE
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 cardiac sympathetic denervation, and/or an ICD is recommended.	I/B-NR
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

Indication	Recommendation for ICD placement	COR/LOE
	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
	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

Indication	Recommendation for ICD placement	COR/LOE
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
	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	Ia/B-NR

Indication	Recommendation for ICD placement	COR/LOE
	beneficial if meaningful survival of greater than 1 year is expected.	
	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
	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
	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, cardiac resynchronization therapy, and pacing

described the appropriate use of these devices for selected patient populations (Russo, et al., 2025).

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.

Appropriate Care (median score 7-9):

Secondary Prevention

Coronary artery disease (CAD): Hemodynamically Unstable or Sustained VT, Polymorphic VT, or VF Associated With Acute (<48 hours) MI (Newly Diagnosed, No Prior Assessment of LVEF, or Prior Normal LVEF):

- 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: Hemodynamically Unstable or Sustained VT, Polymorphic VT, or VF <48 Hours (Acute) Post-Elective Revascularization:

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

CAD: Hemodynamically Unstable or Sustained
VT, Polymorphic VT, or VF (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
  - LVEF ≥50% (8)
  - LVEF 36-49% (9)

    - LVEF ≤35% (9)
- Significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization. No revascularization performed.
    - LVEF ≥50% (8)
    - LVEF 36-49% (9)
    - LVEF ≤35% (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)
    - LVEF 36-49% (8)
    - LVEF ≤35% (8)

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

- Significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization. No revascularization performed
    - LVEF ≥50% (8)
    - LVEF 36-49% (9)
    - LVEF ≤35% (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 ≥50% (7)
    - LVEF 36-49% (7)
    - LVEF ≤35% (8)

No CAD: Hemodynamically Unstable or Sustained VT, Polymorphic VT, or VF:

- Nonischemic dilated cardiomyopathy
    - LVEF ≥50% (8)
    - LVEF 36-49% (9)
    - LVEF ≤35% (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 syndrome (9)
- Short QT syndrome (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 (8)

- 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 (7)
- Unexplained Syncope in a Patient with Brugada ECG Pattern
  - No EPS performed (7)
  - EPS performed. No ventricular arrhythmia induced (7)
  - EPS performed. Sustained VT/VF induced (9)
- Unexplained Syncope in a Patient with Catecholaminergic Polymorphic VT
  - While on treatment with beta blockers (7)

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. Prior MI (8)

Unexplained Syncope with Prior MI and no Acute MI. LVEF ≤ 35%
- EPS not performed (8)
- 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~~ 7)
- Unexplained Syncope in a Patient with Nonischemic Cardiomyopathy
  - Nonischemic dilated cardiomyopathy
    - LVEF ≤ 35% (8)
  - Left ventricular noncompaction
    - LVEF 36%–49% (7)
    - LVEF ≤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 ≥50% (7)
  - LVEF 36-49% (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)
  - LVEF ≤35% (9)
- Nonischemic dilated cardiomyopathy.
  - LVEF ≥ 50% (7)

    - LVEF 36%–49% (7)
    - LVEF ≤ 35% (9)
- Nonischemic dilated cardiomyopathy. All inducible VTs successfully ablated.
    - LVEF 36%–49% (7)
    - LVEF ≤ 35% (8)
- Bundle branch re-entry successfully ablated in a patient with nonischemic cardiomyopathy.
    - LVEF ≤ 35% (7)

Primary Prevention

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

- Revascularization After Acute MI
    - Asymptomatic nonsustained ventricular tachycardia (NSVT) ≥4 days post-MI). EPS with inducible sustained VT (EPS performed after revascularization, within 40 days of MI) (7)

- 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 40 days of MI) (7)

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 40 days of MI) (7)

Post-Acute MI (≤ 40 days) and Pre-Existing Chronic Cardiomyopathy (≥ 3 Months)

- LVEF ≤30% due to old infarction. NYHA functional class I (7)
- LVEF ≤35% due to old infarction. NYHA functional class II–III (8)
- LVEF ≤35% due to nonischemic causes. NYHA functional 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) (≤3 Months)
    - LVEF ≤30%
        - New York Heart Association (NYHA) Class I (8)
        - New York Heart Association (NYHA) Class II or III (9)
    - LVEF 31%–35%
        - NYHA Class I (7)
        - NYHA Class II or III (9)
    - LVEF 36%–40%. Asymptomatic NSVT. EPS with inducible sustained VT/VF
        - NYHA Class I (7)
        - NYHA Class II or III (8)
- Recent PCI or CABG (≤3 months)
    - Pre-existing documented cardiomyopathy. LVEF ≤ 35% on guideline-directed medical therapy ≥3 months before PCI/CABG (7)
    - 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 (<3 Months vs ≥3 Months) 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 and Treatment Duration

- On Guideline-Directed Medical Therapy for ≥3 Months, Idiopathic Nonischemic Cardiomyopathy
  - <35 years of age, LVEF ≤35%, Normal QRS duration
    - NYHA Functional Class I (7)
    - NYHA Functional Class II-III (8)
  - 35-64 years of age, LVEF ≤35%, Normal QRS duration
    - NYHA Functional Class I (7)
    - NYHA Functional Class II-III (9)
  - 65-84 years of age, LVEF ≤35%, Normal QRS duration
    - NYHA Functional Class I (7)
    - NYHA Functional Class II-III (8)
  - LVEF ≤35%, On medical therapy including beta-blocker, ACE inhibitor, or ARB, but not sacubitril-valsartan
    - NYHA Functional Class I (7)
    - NYHA Functional Class II-III (8)

Nonischemic Cardiomyopathy and Need for Pacing After Valve Intervention

- Recent Valve Surgery (i.e., Same Hospitalization or <3 Months), Which Included Incidental Bypass Graft
  - LVEF ≤35%, Need for pacemaker and LV function felt not likely to improve (7)
- Recent TAVR, Same Hospitalization
  - LVEF ≤35%, Need for pacemaker and LV function felt not likely to improve (7)

Nonischemic Cardiomyopathy, Specific Etiologies

- Specific Etiologies, on Guideline-Directed Medical Therapy for <3 Months
  - Sarcoid heart disease, no MRI performed
    - LVEF ≤35% (7)
  - Myotonic dystrophy
    - LVEF ≤35% (8)
  - Chagas disease
    - LVEF ≤35% (8)
  - Giant cell myocarditis
    - LVEF ≤ 35% (8)
    - LVEF > 35% (7)
- Peripartum Cardiomyopathy, on Guideline-Directed Medical Therapy for ≥3 Months
  - Peripartum cardiomyopathy, Persists > 3 months postpartum
    - LVEF ≤ 35% (7)

Genetic Conditions With Structural Heart Disease Assumptions and Considerations

- Genetic Arrhythmogenic Cardiomyopathies Associated With Sudden Cardiac Death
  - Hypertrophic cardiomyopathy with ≥1 risk factor* (8)
  - Arrhythmogenic right ventricular dysplasia/cardiomyopathy with no symptoms due to arrhythmia (7)
  - Evidence of structural cardiac disease with Lamin A/C mutation or other genetic ACM, but LVEF > 35% and <45% (7)

*Risk factors include maximum LV wall thickness ≥30 mm, SCD in ≥1 first-degree relatives presumably caused by HCM, ≥1 episodes of unexplained syncope within the preceding 6 months, spontaneous NSVT, and an abnormal blood pressure response with exercise.

Genetic Conditions Without Structural Heart Disease

- Catecholaminergic Polymorphic VT With Nonsustained VT (Without Syncope)
  - Not tolerating medical therapy or breakthrough nonsustained ventricular arrhythmias on medical therapy (beta-blockers, flecainide, or propafenone) (8)
- Spontaneous, Incidentally Discovered Brugada by ECG (Type IECG Pattern) in the Absence of Symptoms or Family History of Sudden Cardiac Death
  - Inducible VT or VF at EPS (7)

Special Conditions/Comorbidities in Patients for Primary Prevention (Meeting Indications of ICD Implant Related to HF Diagnosis With LVEF ≤30% on Guideline-Directed Medical Therapy >3 Months)

- Class IV HF
  - On waiting list for heart transplant (outpatient status) (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, retrospective studies (n=118-1637) and a systematic review of an RCT (n=849) and four controlled observational studies (n=7149) 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) (Wolf, et al., 2023; 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., 2012).

Professional Societies/Organizations
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 2025 appropriate use criteria (Russo, et al., 2025) for implantable cardioverter-defibrillators, cardiac resynchronization therapy, and pacing described the appropriate use of totally subcutaneous ICDs for selected patient populations. The authors stated that the following assumptions were made in determining the appropriateness of S-ICDs:

- It is assumed that all patients considered for subcutaneous implantable cardioverter-defibrillator (S-ICD) implantation already meet standard indications for ICD implantation.
- As currently available technology does not include standard bradycardia backup pacing or CRT, it is assumed that patients considered for S-ICD implantation do not have bradycardia or CRT pacing indications, unless a previously implanted PM is already present. If a pre-existing PM is present, it is assumed that standard testing will be performed at implantation to exclude potential PM-ICD interactions.
- For secondary prevention indications, it is assumed that frequent ATP is not needed for treatment of frequent MMVT (as this is noted in the FDA labeling of this device).

- All indications assume patients have met appropriate screening for implantation with criteria met in ≥1 of 3 leads in 2 different postures (eg, supine and sitting or standing). Additional screening may be appropriate for some disease processes (eg, hypertrophic CM), such as stress testing, to exclude T-wave oversensing.

Recommendations are provided based on the scoring method described above in the section on Transvenous ICDs. Indications rated as Appropriate are detailed below.

Primary Prevention

Primary Prevention (patient otherwise meets indications for primary prevention ICD)

- Ischemic CM, LVEF ≤35% (7)
- Nonischemic CM, LVEF ≤35% (7)
- Hypertrophic CM (7)
- Congenital heart disease (7)

Primary Prevention, LVEF ≤35% With Comorbidities

- ESRD on dialysis (7)
- CKD, not yet on dialysis (7)
- Prior endovascular infection on prior lead extraction for infection, infection resolved (7)
- Unresolved infection associated with risk for hematogenous seeding (7)
- Patient factors that increase risk for infection, e.g., immunocompromised, cancer with anticipated longevity >1 year (7)
- Venous access issues/venous obstruction (8)

Secondary Prevention

Secondary Prevention, VF/PMVT (Sustained)

- Ischemic CM, LVEF ≤35% (7)
- Nonischemic CM, LVEF ≤35% (7)
- Hypertrophic CM (7)
- Congenital heart disease (7)

Secondary Prevention (Syncope Felt to Be Due to Ventricular Arrhythmia

- Unexplained Syncope, No Structural Heart Disease (Inherited Arrhythmia Syndromes – Genetic Channelopathy)
  - Brugada ECG (7)
  - Catecholaminergic PMVT (7)
- Unexplained Syncope, With Structural Heart Disease (inherited Arrhythmia Syndromes – Arrhythmogenic Cardiomyopathy)
  - RV cardiomyopathy

Primary or Secondary Prevention

Primary or Secondary Prevention, Concomitant Atrial Arrhythmias

- Persistent or permanent atrial arrhythmias (7)

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 the 2019 ACC/AHA evidence-based methodologies previously mentioned by Heidenreich, et al., 2022 (Ommen, et al., 2024).

- "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, age, lifestyle, and potential need for pacing

for bradycardia or VT termination (Class of Recommendation (COR): 1; Level of Evidence: B-NR)."

The subtext 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 inability to pace, 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). (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). (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.

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. Published, peer-reviewed evidence evaluating the safety and efficacy of substernal ICD systems is limited and additional, well-designed studies are needed.

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."

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 address the use of substernal implantable cardioverter-defibrillators 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, 2025). 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 dry, non-adhesive monitoring electrodes, 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 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, 2025).

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 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, 2025).

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) (also known as "LifeVest™") 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

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.

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".

Literature Review - Wearable Cardioverter Defibrillator (WCD): The peer-reviewed, published literature indicates that WCDs are appropriate for a 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. Some patients may demonstrate an improvement in LVEF after a period of guideline-directed medical therapy to the degree that an ICD is not required. Special consideration for compliance and fit should be given to the pediatric population. (Poole, et al., 2022; Kovacs, et al., 2018; Spar, et al., 2018; Epstein, et al., 2013; Saltzberg, et al., 2012; Rao, et al., 2011; Chung, et al., 2010; Collins, et al., 2010; Everitt, et al., 2010; Passman, 2009; Feldman, et al., 2004).

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)/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., 2025).

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.

Automatic External Defibrillator (AED)

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, 2025)

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.

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)
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
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)
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

HCPCS Codes	Description
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

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	No clinical policy statement changes.	7/15/2025
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