# Medical Coverage Policy

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# Wearable Cardioverter Defibrillator and Automatic External Defibrillator

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## Related Coverage Resources

Biventricular Pacing/Cardiac Resynchronization Therapy (CRT)
Implantable Cardioverter Defibrillator (ICD)

***INSTRUCTIONS FOR USE***

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## Overview

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

## Coverage Policy

**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%

**A wearable cardioverter defibrillator (e.g., ASSURE System, LifeVest) is considered experimental, investigational or unproven for any other indication.**

**A U.S. Food and Drug Administration (FDA)-approved pediatric nonwearable automatic external defibrillator (AED) is considered medically necessary for an individual age 1–8 years who weigh less than 55 pounds (25 kilograms) and EITHER of the following:**

- individual meets criteria for implantable cardioverter defibrillator (ICD) however implantation of a permanent defibrillator is contraindicated
- individual does not meet both of the following criteria for a wearable cardioverter defibrillator:
  - a chest circumference of 26 inches (66 centimeters) or greater
  - a weight of 41.3 pounds (18.75 kilograms) or greater

***Criteria for ICD placement is listed below(Refer to Implantable Cardioverter Defibrillator Medical Coverage Policy for additional information):**

**<u>Secondary Prevention of Sudden Cardiac Death (SCD)</u>**

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

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

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

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

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

- **Individual with unexplained syncope due to ANY of the following:**
  - Cardiac sarcoidosis with documented spontaneous sustained ventricular tachycardia
  - Ischemic heart disease with inducible sustained monomorphic VT on electrophysiological study.
  - Left ventricular non-compaction
  - Nonischemic dilated cardiomyopathy, LVEF ≤ 49%
  - Structural heart disease (e.g. prior MI) with LVEF ≤ 35%
  - Structural heart disease (e.g. prior MI) with LVEF 36%–49% and inducible sustained VT/VF on electrophysiological study.
  - Tetralogy of Fallot with prior corrective surgery

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

**<u>Primary Prevention of Sudden Cardiac Death</u>**

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

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

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

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

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

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

- **Individual with ANY of the following conditions:**
  - Myotonic dystrophy
  - Chagas disease
  - Acute lymphocytic myocarditis, newly diagnosed (< 3 months)
  - Giant cell myocarditis
  - Peripartum cardiomyopathy, persists > 3 months postpartum, LVEF ≤ 35%

- **Individual with ANY of the following genetic conditions (excludes syncope and sustained VT, addressed above)**
  - Hypertrophic cardiomyopathy (HCM) with 1 or more risk factors:
    - Prior cardiac arrest or spontaneous nonsustained VT
    - Family history of SCD from HCM
    - LV thickness greater than or equal to 30 mm by echocardiography or cardiovascular magnetic resonance (CMR) imaging
    - abnormal blood pressure response to exercise
    - NSVT episodes on continuous ambulatory electrocardiographic monitoring
    - LV apical aneurysm, independent of size
    - LV systolic dysfunction (EF < 50%) by echocardiography or CMR imaging.
    - Extensive late gadolinium enhancement (LGE) on CMR imaging.
  - Arrhythmogenic right ventricular dysplasia/cardiomyopathy with no symptoms due to arrhythmia
  - Congenital long QT Syndrome with 1 or more risk factors (e.g., sudden cardiac arrest, family history of SCD, compliance/intolerance to drugs is a concern)
  - Catecholaminergic polymorphic VT with nonsustained VT (without syncope)

- Incidentally discovered Brugada by ECG (type I ECG pattern) in the absence of symptoms or family history of sudden cardiac death, with inducible VT or VF at EPS
- Familial dilated nonischemic cardiomyopathy (RV/LV) associated with sudden cardiac death, and ANY of the following:
  - Evidence of structural cardiac disease, but LVEF > 35%
  - Normal ECG and echo, but carrying the implicated gene
  - LV non-compaction with LVEF > 35%
- Nonischemic cardiomyopathy (NICM) due to a Lamin A/C mutation with 2 or more risk factors (e.g., NSVT, LVEF <45%, non-missense mutation, male sex)

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

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

**A transvenous ICD is considered experimental, investigational or unproven for ANY other indication.**

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

**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 experimental, investigational or unproven for ANY other indication.**

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

## 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, 2023a; Podrid, 2023b; Kusmirek and Gold, 2007; Zipes, et al., 2006).

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, 2023b).

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 (Zipes, et al., 2006).

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. 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. (Refer to Implantable Cardioverter Defibrillator Coverage Position). A wearable cardioverter defibrillator (WCD) has 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).

**Wearable Cardioverter Defibrillator (WCD)**

The WCD is an external device capable of automatic detection and defibrillation of VT or VF. The approved devices do not have pacing capabilities and therefore are unable to provide therapy for bradycardic events or antitachycardic pacing (Chung, 2023).

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

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

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

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

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

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

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

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

- need an ICD or already have an operating ICD
- are under age 18

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

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

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

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

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

syndrome, cardiomyopathy, Tetralogy of Fallot, and congenital heart disease) and five in the 18–21 age group (indications for use: cardiomyopathy for all five) experienced sudden cardiac arrest during LifeVest use that was successfully converted to a life sustaining rhythm.

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

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

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

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

The ASSURE WCD Clinical Evaluation (ACE-PAS), will be conducted. The study will consist of active surveillance using real-world data collected in the ASSURE Registry. A total of 271 appropriate shock episodes for VT/VF is required to provide the required level of statistical precision for the primary effectiveness outcome. It is estimated that a total of 5,179 patients will be required to provide data on 271 appropriate shock episodes. The device will be used temporarily (days of use), and the data will be obtained from that period of use. No additional patient follow-up is required. The primary safety outcome measures the inappropriate shocks per patient-month of use (total inappropriate shocks/cumulative months of device use for all patients) ≤ 0.0075. The FDA requires the first report to be provided after 500 patients. Following the initial report, subsequent reports will be provided every six months until the required sample size is achieved, and a final report is generated. PAS Progress Reports must be submitted every six months until

subject enrollment has been completed, and annually thereafter. If milestones are not met, quarterly enrollment status reports (i.e., every 3 months) must be submitted in addition to your periodic (6-months) PAS Progress Reports, until FDA states otherwise (FDA, 2021).

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

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

study. Eleven of the 14 studies reported the database kept by ZOLL. It is therefore possible that patients fulfilling inclusion criteria for more than one of the studies were reported more than once.

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

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

Rao et al. (2011) conducted an analysis of registry data to evaluate the short-and long-term outcomes of patients with congenital structural heart disease (CSHD) (n=43) and inherited arrhythmias (IA) (n=119) at risk for ventricular tachyarrhythmias and sudden cardiac death who received a wearable cardioverter defibrillator (WCD). The most frequent indication for WCD was pending genetic testing in the IA group and transplant listing in the CSHD group. Compliance was 91% in both groups. Three ventricular tachyarrhythmias were successfully terminated in IA patients during a median follow-up of 29 days of therapy. No arrhythmias occurred in the patients with CSHD during a median follow-up of 27 days. No patients died while actively wearing the WCD.

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

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

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

Evidence published to date from several randomized controlled trials has failed to show a survival benefit for ICD implantation early after MI. The reasons for this acute MI-sudden cardiac death paradox are not yet clear. The pathophysiology of sudden cardiac death in the early post-MI period may differ from that which occurs in the later post-MI period. Since sudden cardiac death is not synonymous with an arrhythmic event, it is possible that the increased incidence of sudden death after acute MI is largely not caused by a lethal ventricular arrhythmia. Neither an ICD nor a WCD, therefore, would be expected to have an impact on this type of sudden death. In addition, high-voltage ICD shocks have been associated with several deleterious effects, including transient myocardial dysfunction and troponin release/elevation, and whether these effects occur more

frequently in the setting of a healing vs. healed MI requires further study (Goldberger and Passman, 2009).

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

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

**Literature Review WCD Use in Children/Pediatrics**

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

Spar et al. (2018) conducted a retrospective review that assessed the effectiveness, safety, and compliance of the WCD in the identification and treatment of life-threatening ventricular arrhythmias in pediatric patients. Included patients (n=455) were < age 18 years who had a WCD prescribed by their physician. Patients were divided into two groups: patients who had the WCD placed because of an ICD problem (n=63) (ICD problem) group and patients with any other indication for the WCD (n=392) (non-ICD problem) group. Appropriate therapies delivered for ventricular tachycardia (VT) or ventricular fibrillation (VF). Therapy provided for any rhythm besides VT or VF was considered inappropriate. Successful therapies were defined as terminating the VT or VF. The wear duration in days was significantly shorter in the ICD problem group compared with the non-ICD problem group, 26 days versus 35 days ($p<0.05$). There were eight patients (1.8% of the total study population) that received therapy from WCD. There were six patients with appropriate therapies (1.3% of the study population). The median age for patients with appropriate therapies was 15.5 years (12–17). There were two inappropriate therapies (0.4% of the study population). The inappropriate therapies were secondary to oversensing of artifact during asystole (n=1) and noise/artifact during sinus rhythm (n=1). There were seven deaths (1.5 percent); none were wearing the WCD at the time of death. The authors concluded that the WCD

is safe and effective in treating ventricular arrhythmias that can lead to sudden cardiac death in pediatric patients. No health disparities were identified by the investigators.

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

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

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

Class IIa

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

A Class IIa, Level of Evidence C recommendation indicates it is reasonable to perform the procedure/administer the treatment. The benefit outweighs the risk, but additional studies with focused objectives are needed. The recommendation is in favor of the treatment or procedure being useful/effective. Only diverging expert opinion, case studies, or standard of care.

Class IIb

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

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

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

Class III

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

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

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

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

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

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

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

Class IIa

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

Class IIb

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

**Class (Strength) of Recommendation:**

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

**Level (Quality) of Evidence:**

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

**<u>Automatic External Defibrillator (AED)</u>**

Early defibrillation has been shown to be a critical factor in improving survival after out-of-hospital cardiac arrest. The use of automatic external defibrillators (AEDs) has become an important component of emergency medical services (EMS), and advances in technology have permitted expansion of AED use to minimally trained first responders and trained laypersons who witness an arrest.

**U.S. Food and Drug Administration (FDA):** The FDA requires premarket approval for all AEDs and AED accessories. After a PMA decision is made, only FDA-approved accessories can continue to be marketed. Once the AEDs and AED accessories are on the market, the FDA proactively

monitors their safety and reliability by reviewing the manufacturers' manufacturing and design changes, performance reports, and medical device reports (MDRs) (FDA, 2023)

The HeartStart Home Defibrillator (Model M5068A; Philips Medical Systems, Bothell, WA) received PMA FDA approval 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., for the HAT Investigators, 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 considered to be 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 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.) does not provide recommendations for an AED in the home.

**Use Outside the U.S.**
The 2022 European Society of Cardiology (ESC) Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death WCD contains the following recommendation pertinent to a WCD (Zeppenfeld, et al.):

Class IIa
- The WCD should be considered for adult patients with a secondary prevention ICD indication, who are temporarily not candidates for ICD implantation (Level of Evidence C).

Class IIb
- The WCD may be considered in the early phase after MI in selected patients (Level of Evidence: C).
- The WCD may be considered in patients awaiting heart transplant (Level of Evidence C).

Class IIb recommendation indicates that usefulness/efficacy is less well established by evidence/opinion.
Level of evidence C indicates a consensus of opinion of the experts and/or small studies, retrospective studies, or registries.

## Medicare Coverage Determinations

| | Contractor | Determination Name/Number | Revision Effective Date |
|---|---|---|---|
| NCD | | No Determination found | |
| 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.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**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 |
|---|---|
| E0617 | External defibrillator with integrated electrocardiogram analysis |
| K0606 | Automatic external defibrillator, with integrated electrocardiogram analysis, garment type |
| K0607 | Replacement battery for automated external defibrillator, garment type only, each |
| K0608 | Replacement garment for use with automated external defibrillator, each |
| K0609 | Replacement electrodes for use with automated external defibrillator, garment type only, each |

**Considered Not Medically Necessary when the criteria in the applicable policy statements listed above are NOT met:**

| HCPCS Codes | Description |
|---|---|
| E0617 | External defibrillator with integrated electrocardiogram analysis |

| ICD-10-CM Diagnosis Codes | Description |
|---|---|
| | All codes |

***Current Procedural Terminology (CPT®) ©2022 American Medical Association: Chicago, IL.**

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