



# 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, automatic external defibrillators in the home and leadless cardiac pacemakers.

### 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 wearable cardioverter defibrillator (e.g., 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)  $\leq$  35%
- For primary prevention, as a bridge to ICD risk stratification and possible implantation for newly diagnosed dilated cardiomyopathy (ischemic or nonischemic) with LVEF  $\leq$  35%

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

**An automatic external defibrillator (AED) is primarily considered a safety device kept in the home as a precautionary measure to address a possible acute event, rather than a device needed for active treatment. An AED in the home is therefore not considered medically necessary.**

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

### **Secondary Prevention**

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

- **Coronary artery disease (CAD): ventricular fibrillation (VF) or hemodynamically unstable ventricular tachycardia (VT) associated with acute (< 48 hours) myocardial infarction (MI) (newly diagnosed, no recent prior assessment of left ventricular ejection fraction (LVEF), and ANY of the following:**
  - Revascularization completed after cardiac arrest, and EITHER of the following:
    - Recurrent VF or polymorphic VT during/following acute (< 48 hours) MI
    - VF or polymorphic VT during/following acute MI, nonsustained ventricular tachycardia (NSVT) 4 days post MI, Inducible VT/VF at electrophysiologic study (EPS)  $\geq$  4 days after revascularization
  - No revascularization needed (i.e., no significant CAD), but recurrent VF or polymorphic VT during/following acute MI
  - Obstructive CAD with coronary anatomy not amenable to revascularization, with VF or polymorphic VT during/following acute MI
- **CAD: VF or hemodynamically unstable VT < 48 hours post-elective revascularization, with no evidence for acute coronary occlusion, restenosis, preceding infarct, or other clearly reversible cause**
- **CAD: VF or hemodynamically unstable VT (no recent MI [within the past 40 days] prior to VF/VT and/or no recent revascularization [3 Months] prior to VF/VT) and ANY of the following:**
  - No identifiable transient and completely reversible causes, and no need for revascularization identified by catheterization performed following VF/VT
  - Significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization
  - Significant CAD identified at catheterization performed following VF/VT, and revascularization performed after cardiac arrest
- **CAD: VF or hemodynamically unstable VT during exercise testing associated with significant CAD and ANY of the following:**

- Significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization
  - Significant CAD identified at catheterization performed following VF/VT, and revascularization performed after cardiac arrest
- **No CAD, VF or Hemodynamically Unstable VT and ANY of the following:**
    - Dilated nonischemic cardiomyopathy
    - VT/VF associated with cocaine abuse, LVEF ≤ 35%
    - Severe valvular disease, VT/VF < 48 hours after surgical repair or replacement of aortic or mitral valve, with no evidence of postoperative valvular dysfunction
    - VF/hemodynamically unstable VT associated with ANY of the following:
      - Myocardial sarcoidosis
      - Myocarditis or giant cell myocarditis
      - Takotsubo cardiomyopathy (stress-induced cardiomyopathy, apical ballooning syndrome) ≥ 48 hours of onset of symptoms
- **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)**
- **Absence of structural heart disease (LVEF > 50%) or known genetic causes of sustained VT/VF, and EITHER of the following:**
    - Idiopathic VF with normal ventricular function
    - Bradycardia dependent VT/VF
- **Unexplained syncope in the absence of structural heart disease in an individual with long QT syndrome, Brugada ECG pattern, catecholaminergic polymorphic VT**
- **Unexplained syncope in an individual with prior MI and no acute MI, with LVEF 36%-49% and ANY of the following:**
    - Nonobstructive CAD, revascularization is not indicated, and EPS failed to define a cause of syncope
    - Obstructive CAD not amenable to revascularization, and EPS failed to define a cause of syncope
    - EPS revealed inducible sustained VT/VF
- **Unexplained syncope in an individual with prior MI and no acute MI LVEF ≤ 35%**
- **Unexplained syncope in an individual with left ventricular hypertrophy/hypertensive heart disease, LVEF ≤ 49%**
- **Unexplained syncope in individual with nonischemic cardiomyopathy and ANY of the following:**
    - Nonischemic dilated cardiomyopathy, LVEF ≤ 49%
    - Left ventricular non-compaction
    - Hypertrophic cardiomyopathy
    - Cardiac amyloidosis
    - Tetralogy of Fallot with prior corrective surgery
- **Unexplained syncope in individual with arrhythmogenic right ventricular cardiomyopathy**
- **Sustained hemodynamically stable monomorphic VT associated with structural heart disease and ANY of the following:**
    - CAD and prior MI
    - Nonischemic dilated cardiomyopathy

- Bundle branch re-entry successfully ablated in individual with nonischemic cardiomyopathy, LVEF ≤ 49%
- Bundle branch re-entry successfully ablated in individual with nonischemic cardiomyopathy, LVEF ≤ 49%

### **Primary Prevention**

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

- **Post-acute Myocardial Infarction (MI) (≤ 40 days) and revascularization, with LVEF ≤ 30% and BOTH of the following:**
  - Asymptomatic nonsustained ventricular tachycardia (NSVT) (>4 days post MI)
  - EPS with inducible sustained VT (EPS performed after revascularization, within 40 days after MI)
- **Post-acute MI (< 40 days), with obstructive CAD, not revascularized, with coronary anatomy not amenable to revascularization, and BOTH of the following:**
  - Asymptomatic NSVT (>4 days post MI)
  - EPS with inducible sustained VT (EPS performed within 40 days after MI)
- **Post acute MI (≤ 40 days) and revascularization, with LVEF 31%-40% and BOTH of the following:**
  - Asymptomatic NSVT (>4 days post MI)
  - EPS with inducible sustained VT (EPS performed after revascularization, within 40 days after MI)
- **Post acute MI (≤ 40 days) with pre-existing chronic cardiomyopathy (≥ 3 Months) and ANY of the following:**
  - LVEF < 30% due to old infarction. New York Heart Association (NYHA) class I
  - LVEF < 35% due to old infarction. NYHA class II-III
  - LVEF < 35% due to nonischemic causes. NYHA class I-III
- **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), with LVEF ≤ 40%**
- **Post-MI (>40 Days) with ischemic cardiomyopathy, no recent percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) and EITHER of the following:**
  - LVEF ≤ 35%
  - LVEF 36%-40%. asymptomatic NSVT with EPS showing inducible sustained VT/VF
- **Post-MI (>40 Days) with ischemic cardiomyopathy, with recent PCI or CABG (≤ 3 months, and ANY of the following:**
  - No known pre-existing cardiomyopathy, LVEF ≤ 35
  - Pre-existing documented cardiomyopathy. LVEF ≤ 35% on guideline-directed medical therapy > 3 months before PCI/CABG
  - LVEF ≤ 40%, with need for permanent pacemaker post-revascularization (e.g., SSS, CHB, or other guideline-directed indications for permanent pacemaker)
- **Ischemic cardiomyopathy without recent MI (revascularization not indicated), with LVEF ≤ 35%, on guideline-directed medical therapy**
- **Nonischemic cardiomyopathy, at least 3 months on guideline-directed medical therapy, with LVEF ≤ 35%, NYHA Class I-III**
- **Individual with ANY of the following conditions:**

- Sarcoid heart disease,
  - myotonic dystrophy
  - Chagas disease
  - Amyloidosis with heart failure
  - 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 with 1 or more risk factors
    - Arrhythmogenic right ventricular dysplasia/cardiomyopathy with no symptoms due to arrhythmia
    - Congenital long QT Syndrome with 1 or more risk factors
    - 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%

**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 ICD (S-ICD) system (CPT codes 33270, 33271, 33272, 33273) is considered medically necessary when an individual has meet 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 system is considered experimental, investigational or unproven for any other indication.**

**A leadless cardiac pacemaker (CPT codes 33274, 33275) is considered experimental, investigational or unproven for any other indication.**

## General Background

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 significant effort has been directed to the identification and treatment of high-risk patients, this group actually accounts for a small proportion of preventable SCD. 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. There is no single test capable of accurately predicting SCD risk in various clinical settings and patient populations. Although available tests can provide valuable information, they are

hampered by limited positive predictive value and are not sufficiently investigated in many categories of patients with structural heart disease (Zipes et al., 2006).

Ventricular fibrillation is the rhythm most frequently recorded at the time of sudden cardiac arrest. 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, 2019).

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, 2019).

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, 2019).

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, 2019).

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, 2019).

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,2019).

**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 15, 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 cited 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.

**Literature Review:** 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.

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  $52.6 \pm 69.6$  days, and mean daily use was  $19.9 \pm 4.7$  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 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).

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.

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  $124 \pm 123$  days for PPCM patients and  $96 \pm 83$  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  $\geq 35\%$ , 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<sup>th</sup> patient were not available.

Thirteen patients in the NIDCM group died after WCD usage at an average of 10.9 ( $\pm$  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.

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  $\leq$  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  $\geq$  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.

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  $\leq$  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.

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.

**Literature Review WCD Use In Children/Pediatrics:** 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  $\leq 18$  years of age to those aged 19-21 years. There were 81 patients  $\leq 18$  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  $\leq 18$  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  $\leq 18$  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  $\leq 18$  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  $\leq 18$  years and nine (9%) deaths in patients age 19–21 years. The wearable defibrillator was still prescribed in five of the deaths in patients  $\leq 18$  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.

In a discussion of the WCD, Chung (UpToDate 2019) notes 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.

### **Professional Societies/Organizations**

The 2016 American Heart Association Science Advisory for wearable cardioverter-defibrillator therapy for the prevention of sudden cardiac death (Piccini et al.) includes 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 note 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).

The 2013 American College of Cardiology Foundation (ACCF)/American Heart Association (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 state that the utility of a wearable cardioverter-defibrillator in high-risk patients during the first 4 to 6 weeks after STEMI is under investigation.

Use of a wearable cardioverter defibrillator is not mentioned in 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), and Society for Cardiovascular Magnetic Resonance (SCMR) 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy (Russo, et al., 2013).

The American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Rhythm Society (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).

The 2017 American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Rhythm Society (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)**

**U.S. Food and Drug Administration (FDA):** The Philips HeartStart Home OTC Defibrillator (Philips Medical Systems, Seattle, WA) received FDA approval through the 510(k) process on September 16, 2004. The previous version of the HeartStart was available by prescription only, while the HeartStart Home OTC ECD was approved for home use without a prescription. Data submitted to the FDA demonstrated that the device could be used successfully in a mock rescue by laypersons based on written instructions and the device itself. There was no evidence, however, to demonstrate that use of the device in the home by untrained persons improves outcomes.

The FDA issued a Final Order: Effective Date of Requirement for Premarket Approval for Automated External Defibrillator Systems; Republication on February 3, 2015, which represents a tailored approach to help manufacturers assure the quality and reliability of AEDs. AEDs can be highly effective in saving the lives of people suffering cardiac arrest when used in the first few minutes following collapse from cardiac arrest. To help to assure the quality and reliability of AEDs, the FDA is requiring manufacturers to obtain premarket approval for all future and currently-marketed AEDs and necessary AED accessories (e.g., pad electrodes, batteries, adapters and hardware keys for pediatric use). Manufacturers of currently legally marketed necessary AED accessories, such as batteries, pad electrodes, adapters and hardware keys for pediatric use, must file a premarket approval application (PMA) by February 3, 2020. FDA does not intend to enforce compliance with the February 3, 2020, deadline for necessary AED accessories for one year in order to allow health care facilities time to transition to FDA-approved AEDs (FDA, 2019).

**Literature Review**

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.

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.

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. 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.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and improved outcomes of use of an AED in the home. An AED in the home is primarily considered a safety device kept in the home as a precautionary measure to address a possible acute event, rather than a device for active treatment.

### **Professional Societies/Organizations**

The ACC/AHA/ESC Guideline for Management of Patients with ST-Elevation Myocardial Infarction (O'Gara, et al., 2013) recommendations do not include AED use in the home.

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).

The 2017 American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Rhythm Society (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.

### **Centers for Medicare & Medicaid Services (CMS)**

- National Coverage Determinations (NCDs): No NCD found.

- Local Coverage Determinations (LCDs): Automatic External Defibrillators (L33690). Effective date January 1, 2017. The LCD is broader in scope than the Cigna Medical Coverage Policy. Refer to the CMS LCD table of contents link in the reference section.

### Use Outside the U.S.

The 2015 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:

#### Class IIb

- The WCB may be considered for adult patients with poor LV systolic function who are at risk of sudden arrhythmic death for a limited period, but are not candidates for an implantable defibrillator (e.g. bridge to transplant, bridge to transvenous implant, peripartum cardiomyopathy, active myocarditis and arrhythmias in the early post-myocardial infarction phase) (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.

Per the manufacturer website, the LifeVest WCD is available in the United States, Europe, Australia, Israel, Japan, and Singapore.

## Coding/Billing Information

- Note:** 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
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:**

HCPCS Codes	Description
E0617	External defibrillator with integrated electrocardiogram analysis

ICD-10-CM Diagnosis Codes	Description
	All codes

\*Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.

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