

# MEDICAL POLICY



<b>SUBJECT: HOME AUTOMATIC EXTERNAL DEFIBRILLATORS (AEDs) and WEARABLE CARDIOVERTER DEFIBRILLATORS (WCDs)</b> <b>POLICY NUMBER: 1.01.42</b> <b>CATEGORY: Technology Assessment</b>	<b>EFFECTIVE DATE: 08/21/03</b> <b>REVISED DATE: 06/17/04, 10/20/04, 4/21/05, 03/16/06, 03/15/07, 02/21/08, 01/15/09, 01/21/10, 01/20/11, 03/15/12, 03/21/13, 03/20/14, 03/19/15, 02/18/16, 05/18/17, 03/15/18</b> <b>PAGE: 1 OF: 7</b>
<ul style="list-style-type: none"><li>• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i></li><li>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i></li><li>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i></li></ul>	

## POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer-reviewed literature, use of a *Wearable Cardioverter Defibrillator (WCD)* will be considered a **medically appropriate** option for those who meet one of the following:
  - A. ICD explantation for infection or lead displacement; or
  - B. Contraindications such as, systemic infection, that temporarily delay ICD implantation; or
  - C. Patients on the waiting list for heart transplantation.
- II. Based upon our criteria and assessment of peer-reviewed literature, home use of an *Automatic External Defibrillator (AED)* will be considered a **medically appropriate** option for those who meet the criteria for an implantable cardiac defibrillator (ICD) device, but who are not candidates (have contraindications) to implanting the device. Approval of a home AED will also be contingent upon having a caregiver who is both capable (trained) and available to use the device.
- III. Based upon our criteria and assessment of peer-reviewed literature, the use of an *Automatic External Defibrillator (AED)* or a *Wearable Cardioverter Defibrillator (WCD)* for any other indication is considered **investigational**. This determination includes potential WCD use in the immediate post-myocardial infarction period for patients who do not meet criteria for coverage of an ICD device.

*Refer to Corporate Medical Policy # 1.01.00 regarding Durable Medical Equipment: Standard and Non-Standard.*

*Refer to Corporate Medical Policy # 7.01.06 regarding Implantable Cardioverter Defibrillators (ICD).*

*Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.*

## POLICY GUIDELINES:

- I. Continuation of WCD coverage beyond 90 days requires documented re-assessment of the current medical regimen and need for ICD implantation and compliance has been demonstrated as defined by the use of the device for 70% of the days during a consecutive 30 day period.
- II. Those patients who meet coverage criteria for a WCD, will also be able to receive an AED since the vest cannot be worn at all times (e.g. when showering).
- III. Home Automatic External Defibrillators and Wearable Cardioverter Defibrillators are considered durable medical equipment (DME). Coverage for DME is contract dependent. Please contact your local Customer (Provider/Member) Relations Department to determine contract coverage.
- IV. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

## DESCRIPTION:

*Automatic external defibrillators (AEDs)* are compact, portable devices that are capable of monitoring or assessing cardiac rhythms, detecting dysrhythmias and delivering an electrical shock. AED units use a microprocessor inside a portable defibrillator to recognize ventricular fibrillation (VF) or ventricular tachycardia, and either advises the operator that electrical defibrillation is needed or delivers a shock to the heart when appropriate, without any user decision-

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making. An AED specifically designed for home use is now available to consumers without a physician's prescription. In September 2004, the FDA approved the HeartStart Home Defibrillator (Philips Medical Systems); a simpler version of a model already marketed by the manufacturer to public places such as airports, shopping malls, and office centers, for over-the-counter sale.

The *Wearable Cardioverter Defibrillator (WCD)* is an external device that is intended to perform the same tasks as an implanted cardioverter defibrillator (ICD) without requiring any invasive procedures. It may be utilized for adult patients who are at risk for sudden cardiac arrest and are not candidates for, or refuse an implantable cardioverter defibrillator. LIFECOR's wearable defibrillator features a strap worn over the chest below the heart, which is connected to the central unit, and held in place by a belt around the waist or in a lightweight vest that may be worn under normal clothing. The device weighs a total of about three pounds. Patients wear it continuously removing it only for bathing or showering.

The wearable device continuously monitors the patient's heart to detect life-threatening abnormal heart rhythms. The defibrillator detects abnormal heart rhythms by sensing the heart's electrical activity on the surface of the chest. If a life-threatening rhythm is detected and the patient loses consciousness, the device delivers an electrical shock to restore normal rhythm. If the device alarms and the patient is conscious, the patient can disable the electrical charge by pressing a button(s) on the control panel. Typically, once a week the physician may want the patient to connect the monitor to an external modem and send the data over the phone for physician review.

**RATIONALE:**

While there are no studies showing the impact of home AEDs in high-risk patients who otherwise meet criteria for an ICD, the benefit of a defibrillator has been shown for these patients and studies have also demonstrated that the home AED can successfully treat the dysrhythmia. Thus, these devices are an alternative in patients who cannot receive an ICD.

In 2004, the FDA granted marketing clearance for the over-the-counter sale of the HeartStart Home Defibrillator, which was previously available for home use with a prescription. The FDA based its decision on a review of data submitted by the manufacturer that demonstrated the AED could be used by lay people without medical supervision. Mortality data was not collected.

In 2003, the Pediatric Advance Life Support Task Force recommended AED use in children aged 1-8 who have no signs of circulation. However, the Task Force made no recommendation regarding whether or when AEDs should be placed in the home setting.

The 2010 AHA recommendations for Electrical Therapies (Automated External Defibrillators, Defibrillation, Cardioversion, and Pacing) states that approximately 80% of out-of-hospital cardiac arrests occur in private or residential settings. One study demonstrated that survival was not improved in homes of high-risk individuals equipped with AEDs compared with homes where only CPR training had been provided. AEDs are of no value for arrest not caused by VF/pulseless VT, and they are not effective for treatment of non-shockable rhythms that may develop after termination of VF. Non-perfusing rhythms are present in most patients after shock delivery, and in general, CPR is required until a perfusing rhythm returns. Therefore, the AED rescuer should be trained not only to recognize emergencies and use the AED, but also to provide CPR until the AED is retrieved and ready for shock delivery and immediately after shock delivery. The mere presence of an AED does not ensure that it will be used when sudden cardiac arrest (SCA) occurs. Even in the PAD trial, in which almost 20 000 rescuers were trained to respond to SCA, lay rescuers attempted resuscitation before EMS arrival for only half of the victims of witnessed SCA, and the on-site AED was used for only 34% of the victims who experienced an arrest at locations with AED programs. These findings suggest that lay rescuers need frequent practice to optimize response to emergencies.

The American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of Cardiology (ESC) 2006 Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death states that placement of AEDs in the home appears to be reasonable and appropriate for patients at high risk for life-threatening arrhythmias.

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The National Heart, Lung, and Blood Institute (NHLBI) has completed recruitment of patients for the HAT (Home Automatic External Defibrillator Trial) to test whether the provision of an AED for home use improved survival of individuals following MI as compared to standard lay person response (call EMS/CPR). The study period was between 2003 and 2004 and included 7001 patients from 178 clinical sites in seven countries. 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). Participants were excluded if they were candidates for an implantable ICD or if they did not have a spouse or companion willing and able to call for assistance from emergency medical services (EMS), perform CPR, and use an AED. After a median follow-up of 37.3 months, the authors reported 450 patients died; 6.5% were in the control group while 6.4% were in the AED group (p=0.77). Only 35.6% of the deaths were considered to be from sudden cardiac arrest from tachyarrhythmia. One hundred seventeen of the deaths 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. The authors found that access to a home AED did not significantly improve overall survival in the intermediate risk population, compared to reliance on conventional resuscitation methods. The results are based upon the high proportion of unwitnessed events, the underuse of the AEDs in emergencies, rather than a lack of device efficacy.

In December 2001, the FDA approved a Wearable Cardioverter Defibrillator (WCD), a vest-like medical device that is worn under clothing to monitor and treat abnormal heart rhythms. FDA-labeled indications for the device are adult patients who are at risk for sudden cardiac arrest and either are not candidates for or refuse an implantable defibrillator. The approval was based on clinical data submitted to the FDA by the manufacturer, which has subsequently been published in the peer-reviewed literature. Patients were enrolled in two studies:

- I. WEARIT Study: 177 patients with symptomatic heart failure and an ejection fraction of less than 30%.
- II. BIROAD Study: 112 patients having complications associated with high risk for sudden death after a myocardial infarction or bypass surgery and not receiving an ICD for up to four months.

The results suggest that wearable defibrillators are beneficial in detecting and effectively treating ventricular tachyarrhythmias in patients at high risk for sudden death who are not clear candidates for ICDs. However, these data do not determine the true efficacy of the device or compare the efficacy to alternative treatment(s). For nearly all patients, the alternative is an AICD, which is currently the “gold-standard” treatment for preventing sudden death. Since complications of AICD placement are low and contraindications few, it is unlikely that the WCD can improve outcomes, even in patient populations where the need for an AICD is temporary.

A 2010 Blue Cross Blue Shield Technical Assessment concluded there is a lack of high-quality evidence on the efficacy of the WCD in preventing sudden cardiac death for high-risk individuals. There are no controlled trials that specifically evaluate the efficacy of the WCD in comparison to alternatives for patients at high risk of sudden cardiac death. The available evidence consists of uncontrolled trials that evaluate the success of the WCD in detecting and aborting arrhythmias, and randomized, controlled trials of early ICD use post-MI and post-CABG.

The available data establish that the WCD device can detect lethal arrhythmias and can successfully deliver a counter shock in the majority of cases. Based on review of existing studies, one can conclude that there are a small number of patients who meet established criteria for, and will benefit from an ICD but have a contraindication for an implantable device. The most common contraindication is an infectious process that precludes insertion or can occur when an ICD is removed due to infection and there must be a delay before reinsertion. In these patients who are scheduled for AICD placement, the WCD is considered medically necessary as an interim treatment. The evidence shows:

- I. that these patients benefit from the cardioverter-defibrillator, and
- II. that the WCD can detect and treat lethal dysrhythmias in these patients.

Thus, for these patients with a transient contraindication to AICD placement, the WCD improves outcomes compared to use of no device.

The AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death guidelines were updated in 2017. The guidelines state in patients at an increased risk of SCD but

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who are not ineligible for an ICD, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed NICM, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, wearable cardioverter-defibrillator may be reasonable. This is a Class IIb (may/might be reasonable and considered, usefulness, effectiveness unknown/unclear/uncertain or not well established), level of evidence: B (moderate quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies or registry studies, or meta-analyses of such studies) recommendation. In patients with an ICD and a history of SCA or sustained VA in whom removal of the ICD is required (as with infection), the wearable cardioverter-defibrillator is reasonable for the prevention of SCD (Class IIa (is reasonable, can be useful/effective/beneficial), LOE: B).

There is some interest in using the WCD in the immediate post-myocardial infarction period as a bridge to possible AICD after a 30-day period to determine the final ejection fraction. Some experts recommend that the WCD should be used for patients in the immediate post-MI period. The indications for a permanent ICD cannot be reliably assessed immediately post-MI since it is not possible to determine the final ejection fraction until at least 30 days after the event. Furthermore, the first 30 days following an acute MI represent a high-risk period for lethal ventricular arrhythmias.

In spite of the rationale for this potential indication, the available evidence does not support the contention that any cardioverter-defibrillator improves mortality of patients in the immediate post-MI period. The DINAMIT study evaluated the utility of an ICD for this patient population. This trial randomized 342 patients with an acute MI and an ejection fraction of 35% or less. The primary outcome was death from any cause and a predefined secondary outcome was death from an arrhythmia. After a mean follow-up of 30 months, there was no difference in overall survival for the ICD group compared to control (hazard ratio 1.08, 95% CI: 0.76–1.55, p=0.66). There was a significant difference for the ICD group in the secondary outcome of death from arrhythmia (hazard ratio 0.42, 95% CI: 0.22–0.83, p=.0090). The decrease in deaths from arrhythmias for the ICD group was offset by a corresponding increase in deaths due to nonarrhythmic cardiac causes. The authors suggest that the discrepancy in these outcomes may arise from the fact that patients in whom the ICD successfully aborted an arrhythmia may have eventually died from other cardiac causes, such as progressive heart failure.

Secondary analysis of data from the MADIT II trial corroborates the conclusion that a cardioverter-defibrillator does not improve mortality in the early post-MI period. MADIT II randomized 1,159 patients with prior MI and an ejection fraction of less than 30% to an ICD or control, and showed an overall mortality benefit for patients treated with an ICD. The secondary analysis examined the benefit of ICD according to length of time from the original MI, and showed that the benefit of ICD was dependent on the length of time since the original MI. Within the first 18 months post-MI, there was no benefit found for ICD implantation (hazard ratio 0.97, 95% CI: 0.51–1.81, p=0.92). In contrast, there was a significant mortality benefit when the length of time since MI was greater than 18 months (hazard ratio 0.55, 95% CI: 0.39–0.78, p=0.001).

The Immediate Risk Stratification Improves Survival (IRIS) trial was based on the hypothesis that early implantation of an ICD, as compared with optimal medical therapy, would improve survival among patients with acute myocardial infarction and predefined markers of elevated risk. LVEF, heart rate (as determined on the admission electrocardiogram [ECG]), and the occurrence of rapid, nonsustained ventricular tachycardia were the factors used to determine each patient's level of risk. Eight hundred ninety-eight patients were randomly assigned to either receive an ICD or receive medical therapy alone, 13±7 days after infarction. There were fewer sudden cardiac deaths in the ICD group than in the control group (27 vs. 60) (hazard ratio, 0.55; 95% CI, 0.31 to 1.00; P = 0.049). However, this decrease was paralleled by an increase in nonsudden cardiac death in the ICD group as compared with the control group (68 vs. 39) (hazard ratio, 1.92; 95% CI, 1.29 to 2.84; P = 0.001). The authors concluded there was no evidence that implantation of an ICD improved survival in patients with acute myocardial infarction who received optimal medical therapy and underwent risk stratification based on elevated heart rate on admission, low LVEF, and rapid, nonsustained ventricular tachycardia.

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**CODES:**     Number     Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

- CPT:**
- |       |                                                                                                                                                                                                                                                                                               |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 93292 | Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; wearable defibrillator system                                                                                                 |
| 93745 | Initial set-up and programming by a physician 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 |

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- HCPCS:**
- |       |                                                                                               |
|-------|-----------------------------------------------------------------------------------------------|
| 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 |

**ICD10:**     Multiple diagnosis codes

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\*Key article

**KEY WORDS:**

AED, Automatic External Defibrillator, HeartStart, LIFECOR, WCD, Wearable Cardioverter Defibrillators.

## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Automatic External Defibrillators. Please refer to the following LCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33690&ver=9&CtrctrSelected=137\\*1&Ctrctr=137&s=41&DocType=Active&bc=AggAAIAIAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33690&ver=9&CtrctrSelected=137*1&Ctrctr=137&s=41&DocType=Active&bc=AggAAIAIAAAAA%3d%3d&)