MEDICAL POLICY DRAFT FOR REVIEW

MEDICAL POLICY DETAILS	
Medical Policy Title	**Home Automatic External Defibrillators (AEDs) and Wearable Cardioverter Defibrillators (WCDs)**
Policy Number	**1.01.42**
Category	**Technology Assessment**
Original Effective Date	**08/21/03**
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Current Effective Date	**~~05/19/22~~ 06/xx/23**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program(DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, use of a **Wearable Cardioverter Defibrillator (WCD) for the prevention of sudden cardiac death** will be considered **medically appropriate** ~~for~~ **as interim treatment in** patients who:
   A. Require ex-plantation of the implantable cardioverter-defibrillator (ICD) due to infection or lead displacement; **OR**
   B. ~~Experience contraindications such as, systemic infection, that temporarily delay ICD implantation;~~ Experience **Contraindications (i.e., infection, systemic instability) or reasonable delays in surgery (max of 30 days) for implantation or reimplantation OR**
   C. On the waiting list for heart transplantation. **OR**
   D. For primary prevention, as a bridge in consideration to ICD implantation for newly diagnosed dilated cardiomyopathy (ischemic or nonischemic) with LVEF less than or equal to 35% OR
   E. As a bridge in consideration to ICD implantation for patients within 40 days following myocardial infarction (MI) for EITHER of the following:
      1. History of ventricular tachycardia or ventricular fibrillation after the first 48 hours of the MI OR
      2. Left ventricular ejection fraction (LVEF) less than or equal to 35%.

II. Based upon our criteria and assessment of the peer-reviewed literature, home use of an **Automatic External Defibrillator (AED)** will be considered **medically appropriate** for those who meet the criteria for an ICD device, but who are not candidates for (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 the 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 an ICD device.

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

Refer to Corporate Medical Policy # 7.01.06 Implantable Cardioverter Defibrillators.

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

POLICY GUIDELINES

I. Patients who meet coverage criteria for a WCD, will also be able to receive an AED, as the vest cannot be worn at all times (e.g., when showering). **As part of the initial request, provider documentation must include the instructions provided to the patient regarding prescribed wear time (e.g., 23 hours/day, exception for showering)**

II. Continuation of WCD coverage beyond 90 days requires documented re-assessment of the current medical regimen **(including re-evaluation of LVEF)**, re-assessment for the need of ICD implantation and demonstration of compliance as defined by the use of the device for 70% of ~~the days during a consecutive 30-day period~~ **the prescribed time during the initial 90-day period.**

III. Home AEDs and WCDs 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.

NEW YORK HEART ASSOCIATION HEART FAILURE CLASSIFICATIONS	
Class I	Cardiac disease- No symptoms and no limitations in ordinary activity
Class II Mild	Mild symptoms and slight limitations in ordinary activity which may cause symptoms like fatigue, dyspnea, palpitations
Class III Moderate	Significant limitations in activity due to symptoms. Comfortable only at rest. Less than ordinary activity causes symptoms like fatigue, dyspnea, palpitations
Class IV Severe	Severe limitations. Symptoms of heart failure even while at rest. If any physical activity is undertaken, discomfort increases

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 (VT), and either advises the operator that electrical defibrillation is needed or delivers a shock to the heart when appropriate, without any user decision-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 for 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 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 ICD. LIFECOR's (ZOLL) 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 ASSURE device, styled and engineered by leading athletic and fashion designers, is tailored in two styles and a wide range of sizes, featuring non-adhesive cushioned ECG sensors and is washable. This device consists of an alert button (Heartpoint), a vest type garment (Sensorfit) and an ASSURE proprietary detection algorithm.

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 alarm sounds, and the patient is conscious, the patient can disable the electrical charge by pressing the 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, demonstrating that 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 one to eight years 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 2017 AHA recommendations for Electrical Therapies (Automated External Defibrillators, Defibrillation, Cardioversion, and Pacing) states that approximately 70% of sudden cardiac arrests (SCA) occur in the home, and the rate of survival to hospital discharge after AED placement by emergency medical services is significantly lower for arrest at home (12%) versus public settings (34%). However, in a randomized control trial (RCT) of AEDS, home AED placement did not improve the survival of patients recovering from an anterior MI. Appropriate device location to reduce time delay after onset of SCA is critical. In addition to prevention, critical components of survival from SCA include immediate recognition and activation of the emergency response system, early high-quality cardio-pulmonary resuscitation (CPR), and rapid defibrillation for shockable rhythms.

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. 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 or perform 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 which 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 that 450 patients had died, of which, 6.5% were in the control group and 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. Of the reported deaths, 117 occurred at home; 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, and the underuse of the AEDs in emergencies, rather than a lack of device efficacy.

In December 2001, the FDA approved a 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 have 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 an MI 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 automatic ICD (AICD), which is currently the "gold-standard" treatment for preventing sudden death. Since the rate of complications of AICD placement is 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.

In July 2021, the FDA granted pre-market approval for the ASSURE Wearable Cardiac Defibrillator (WCD) system by Kestra Medical Technologies. A trial was completed in 2019, which is published ahead of print:

I. The ASSURE WCD Clinical Evaluation - Detection and Safety Study (ACE-DETECT): 130 adult subjects at risk for sudden cardiac arrest but otherwise protected by an Implantable Cardioverter Defibrillator (ICD) were enrolled at 10 clinical sites in the United States. The device was worn for approximately 30 days during normal daily activities including sleep. The WCD shock alarms and shock functionality was disabled. Shock Alarm Event Markers were recorded by the WCD and used for analysis of the primary outcome measure.

The results of this study demonstrated 163 WCD episodes, 4 were Ventricular Tachycardia (VT)/Ventricular fibrillation (VF) and 159 non-VT/VF (121 rhythms with noise, 32 uncertain with noise, 6 atrial flutter without noise). Only three false-positive shock alarm markers were recorded; one false-positive shock alarm every 1333 patient-days (0.00075 per patient-day, 95% confidence interval: 0.00015-0.00361; $p < .001$). 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 (interquartile range [IQR] 2.0) and median daily use 23.0 h (IQR 1.7). Adverse events were mostly mild: skin irritation (19.4%) and musculoskeletal discomfort (8.5%). This study demonstrated that the ASSURE WCD demonstrated a low false-positive shock alarm rate, low patient-reported discomfort, and no serious adverse events.

Available data establish that a WCD device can detect lethal arrhythmias and can successfully deliver a counter shock in the majority of cases and based on review of then-existing studies, one could 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 either precludes insertion or requires the removal of an ICD, and there must be a delay before reinsertion. In these patients who are scheduled for AICD placement, the WCD is considered medically appropriate as an interim treatment. The evidence shows:

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

Thus, the Technical Assessment concluded, for 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 was updated in 2017. The guidelines states that in patients who are at an increased risk of SCD but who are not ineligible for an ICD, such as those awaiting cardiac transplant, having an left ventricular ejection fraction (LVEF) of 35% or less and within 40 days from an MI; or those who have newly diagnosed nonischemic cardiomyopathy (NICM), revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, a WCD may be reasonable. This is a Class IIb recommendation (may/might be reasonable and considered; usefulness, or effectiveness unknown/unclear/uncertain or not well established), level of evidence (LOE): 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). In patients with an ICD and a history of SCA or sustained ventricular arrythmia (VA) in whom removal of the ICD is required (as with infection), the WCD is reasonable for the prevention of SCD. This is a Class IIa recommendation (is reasonable, can be useful/effective/beneficial), LOE: B).

There is some interest in using the WCD in the immediate post-MI 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 patients in the immediate post-MI period. The 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 the control group (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 nonrhythmic 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 group and showed an overall mortality benefit for patients treated with an ICD. The secondary analysis examined the benefit of an 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. Left ventricular ejection fracture (LVEF), heart rate (as determined on the admission electrocardiogram [ECG]), and the occurrence of rapid, non-sustained VT 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 versus 60) (hazard ratio, 0.55; 95% CI, 0.31 to 1.00; P = 0.049). However, this decrease was paralleled by an increase in non-sudden cardiac death in the ICD group as compared with the control group (68 versus 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 MI who received optimal medical therapy and underwent risk stratification based on elevated heart rate on admission, low LVEF, and rapid, non-sustained VT.

Olgin, et al., (2018) reported results from the Vest Prevention of Early Sudden Death Trial (VEST) which assessed the efficacy of a WCD for patients during the period after an acute MI who have reduced LVEF (less than or equal to 35%) before and ICD is indicated. The primary outcome was the composite of sudden death or arrhythmic death (death from ventricular tachyarrhythmia) at 90 days. Patients were randomly assigned 2:1 to a WCD and guideline-directed therapy (n = 1524) or guideline directed therapy alone (control group) (n = 778). Arrhythmic death and death from any cause occurred in 1.6% and 3.1% of the WCD group and in 2.4% and 4.9% of the control group, respectively. Only 12 of the participants in the WCD group were wearing the WCD at the time of death. Appropriate shocks were delivered to 20 participants (1.3%) and nine patients received inappropriate shocks (0.6%). The WCD was worn for a median of 18.0 hours/day. The authors concluded in patients with recent MI and LVEF less than or equal to 35%, WCD use did not lead to a significantly lower rate of arrhythmic death compared to the control during the first 90 days.

Veltmann, et al., reported The 2020 WEARIT-II-EUROPE registry results, it is a prospective multicenter observational study aimed to assess the value of the wearable cardioverter defibrillator (WCD) prior to ICD implantation in patients with heart failure and reduced ejection fraction considered at risk of sudden arrhythmic death. It consisted of 781 consecutively enrolled patients with heart failure and reduced left ventricular ejection

fraction. All patients received a wearable cardiac device. Follow up time for all patients was 12months. Mean baseline LVEF was 26.9%. Mean wearing time was 75 days, mean daily WCD use was 20.3 hours. WCD shocks terminated 13 VT/VF events in ten patients (1.3%). Two patients died during WCD prescription of non-arrhythmic cause. Mean LVEF increased from 26.9 to 36.3% at the end of WCD prescription. After WCD use, ICDs were implanted in only 289 patients (37%). 44% of all patients, LVEF was higher than 35% at the end of WCD prescription, making ICD implantation redundant or at least not guideline indicated. Of the 51% of patients with a baseline LVEF < 25%, only 22% continued to have a LVEF < 35%. WEARIT-II-EUROPE showed that the WCD represents a promising approach for protected individual risk assessment prior to deciding for ICD implantation in patients with a presumed but not yet confirmed risk of sudden cardiac death.

CODES

- *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 Codes

Code	Description
93292	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system
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

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HCPCS Codes

Code	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

ICD10 Codes

Code	Description
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&ContrId=389&ver=20&ContrVer=1&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAQAAAIAAAAA&