MEDICAL POLICY

Medical Policy Title	**Home Automatic External Defibrillators (AEDs) and Wearable Cardioverter Defibrillators (WCDs)**
Policy Number	**1.01.42**
Current Effective Date	June 26, 2025
Next Review Date	June 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Wearable Cardioverter Defibrillator (WCD) for the prevention of sudden cardiac death will be considered **medically appropriate** as interim treatment in patients for **ANY** of the following indications:

- A. Require ex-plantation of the implantable cardioverter-defibrillator (ICD) due to infection or lead displacement;
- B. Experience Contraindications (i.e., infection, systemic instability) or reasonable delays in surgery (max of 30 days) for implantation or reimplantation;
- C. On the waiting list for heart transplantation;
- D. As a bridge in consideration to ICD implantation for **EITHER** of the following indications:
  1. Within 40 days following myocardial infarction (MI) and **EITHER** of the following indications:
     - a. History of ventricular tachycardia or ventricular fibrillation after the first 48 hours of the MI; or
     - b. Left ventricular ejection fraction (LVEF) less than or equal to 35%; **or**
  2. Primary prevention when **ALL** of the following criteria have been met:
     - a. For newly diagnosed dilated cardiomyopathy (ischemic or nonischemic);
     - b. LVEF less than or equal to 35%.

II. Home use of an Automatic External Defibrillator (AED) will be considered **medically appropriate** when **ALL** of the following criteria are met:

- A. Individuals meet the criteria for an ICD device, but who are not candidates for (have contraindications to) implanting the device;
- B. Must have a caregiver who is both capable (trained) and available to use the device.

III. AED or a WCD for any other indication is considered **investigational** including but not limited to:

- A. Immediate post-myocardial infarction period for patients who do not meet criteria for an ICD

device.

RELATED POLICIES

Corporate Medical Policy

1.01.00 Durable Medical Equipment: Standard and Non-Standard

7.01.06 Implantable Cardioverter Defibrillators

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

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).

II. 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), a full cardiac and non-cardiac workup (including but not limited to cardiac catheterization notes, electrophysiology studies and echocardiogram) and plan of care addressing ICD placement and reason that ICD or transplant cannot occur.

III. Continuation of WCD coverage beyond 60 days requires documented re-assessment of the current medical condition, re-evaluation of current LVEF, and current plan of care for ICD implantation or transplant. Additionally, documentation will require demonstration of compliance during the 60-day period, which would include both the amount of time and days worn.

IV. Home AEDs and WCDs are considered durable medical equipment (DME). Coverage for DME is contract dependent.

V. 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)

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 United States Food and Drug Administration (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.

Wearable Cardioverter Defibrillators (WCDs)

Wearable Cardioverter Defibrillators (WCDs) are external devices that are 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.

SUPPORTIVE LITERATURE

Poole et al. (2022) reported the results from ACE-DETECT, a multicenter prospective, nonrandomized study. 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, four 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.

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.

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.

PROFESSIONAL GUIDELINE(S)

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 was updated in 2017. The guidelines states:

- Patients who are at an increased risk of SCD but who are not ineligible for an ICD, such as those awaiting cardiac transplant, having a 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, (LOE): B.

- 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, LOE: B.

In 2007, the American Academy of Pediatrics recommended in children and infants of all ages who suffer ventricular fibrillation must be provided defibrillation as soon as possible after arrest. However, they have not made a recommendation regarding whether or when AEDs should be placed in the home setting.

The ACC/AHA/European Society of Cardiology (ESC) 2006 Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death states:

- Placement of AEDs in the home appears to be reasonable and appropriate for patients at high risk for life-threatening arrhythmias.

REGULATORY STATUS

Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 May 28]

In July 2021, the FDA granted pre-market approval for the ASSURE Wearable Cardiac Defibrillator (WCD) system by Kestra Medical Technologies.

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.

Zoll lifeVest, a wearable cardioverter defibrillator was FDA approved September 3, 2009.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I) =Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

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

Code	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

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	

REFERENCES

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Automatic External Defibrillators (LCD L33690) [accessed 2025 Mar 02].

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION

Committee Approval Dates	
08/21/03, 06/17/04, 10/20/04, 04/21/05, 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, 04/18/19, 05/21/20, 07/15/21, 05/19/22, 06/22/23, 06/20/24, 06/26/25	
Date	**Summary of Changes**
06/26/25	• Annual review, no changes to the intent of the policy.
01/01/25	• Summary of changes tracking implemented.
08/21/03	• Original effective date