VHA Office of Integrated Veteran Care
Clinical Determinations and Indications
Wearable Cardioverter Defibrillator

CDI Number: 00015

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I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

II. Clinical Determinations and Indications

a. Indications for the Wearable Cardioverter Defibrillator

A temporary U.S. Food and Drug Administration (FDA) approved wearable cardioverter defibrillator (WCD) is indicated for the prevention and management of sudden cardiac death (SCD) due to ventricular tachyarrhythmias. It will be considered **medically necessary** as a temporary bridge when **ALL** the following criteria are met:

- The Veteran is at high risk for SCD and meets clinical criteria for implantable cardioverter defibrillator (ICD) placement
- The Veteran is temporarily not a suitable candidate for ICD placement due to the following:
    - Awaiting heart transplantation and permanent ICD placement may be contraindicated
    - Presence of temporary contraindications to ICD implantation or immediate reimplantation after explantation
        - E.g., A previously implanted defibrillator that requires removal and an immediate reimplantation is not possible due to infection or cancer treatments
        - E.g., Systemic infection or other temporary medical condition that prevents ICD implantation

Note: It is strongly recommended to discontinue the use of a WCD once the Veteran is clinically stable, and therefore eligible to receive a permanent ICD placement.

b. Limitations/Exclusions

Conditions/indications for which a WCD is **not medically necessary** include, but are not limited to, the following:

- Veterans with an active ICD

For all conditions/indications not listed in section II.a. of this document, a WCD is considered **not medically necessary** due to insufficient evidence of efficacy and safety.

c. Request for Durable Medical Equipment

Community providers will utilize the Request for Service Form 10-10172 to submit DME and/or prosthetic requests to their local VA facility Community Care office.

All fields in the DME sections of the Request for Service Form 10-10172 must be filled out with accurate information to ensure proper processing and facilitation of the DME request. To facilitate timely review of the DME request, the most recent office notes and plan of care must accompany the request. Incomplete forms with missing information and/or supplementary documents will result in processing delays and prevent the local VA facility Community Care office from fulfilling the DME request, delaying care for the Veteran.

d. Description of Treatment

The WCD is a vest-like device that is worn continuously under clothing for 24 hours per day, with some exceptions. It continuously monitors the heart rhythm for ventricular tachyarrhythmias. If these arrhythmias are detected, the device automatically delivers an electric shock to restore the heart's normal rhythm.

For Veterans with a history of SCD, or sustained ventricular tachyarrhythmias, the WCD can be used as a temporary bridge to permanent ICD placement. The WCD allows the Veteran to be discharged from the hospital safely, until the clinical criteria are met, and the patient is stable for permanent implantation of an ICD.

The WCD's electrodes collect electrical signals from the heart, which are then sent to a processor for further analysis and evaluation of cardiac function. This processor gathers the electrical signals, analyzes the waveforms, and is programmed to detect shockable rhythms. If a shockable rhythm is detected, the device will provide an audible warning to alert the user that an automatic shock will be delivered. The device also includes an abort function for situations where the shock would be inappropriate.

III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

a. Background of Sudden Cardiac Death

Sudden cardiac death (SCD) or sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease, and accounts for approximately 15% of the total mortality in the United States. It is considered a medical emergency, in which the heart suddenly stops functioning properly and unexpected death occurs.

The prognosis for SCD varies significantly and depends on the underlying cause and the speed and effectiveness of resuscitation. Sudden cardiac death is most commonly caused by arrhythmias, specifically the most dangerous type, ventricular fibrillation (VF). Various underlying risk factors can lead to SCD, including coronary heart disease, congenital heart conditions, structural changes to the heart due to disease or infection (e.g., cardiomyopathy), and extreme physical activity or blood loss.

Treatment/Management of Sudden Cardiac Death

Emergency treatments for SCD include cardiopulmonary resuscitation (CPR) and defibrillation, where a shock is delivered to the patient to restart the heart's function. Patients with a left ventricular ejection fraction (LVEF) of less than 35% are considered candidates for an implantable cardioverter-defibrillator (ICD) placement if the LVEF does not improve.

The indications for an ICD include:

- A documented episode of ventricular fibrillation (VF) or a sustained ventricular tachyarrhythmia, lasting 30 seconds or longer
    - Dysrhythmias may be spontaneous or induced during an electrophysiologic study
    - Dysrhythmias due to a transient or reversible cause or dysrhythmias that occur during the first 48 hours of an acute MI do not meet this indication
- Familial or inherited conditions with a high risk of life-threatening ventricular tachycardia (VT), e.g., long QT syndrome or hypertrophic cardiomyopathy
- Documented prior MI or dilated cardiomyopathy and a measured LVEF less than or equal to 35%

Implantable cardioverter-defibrillators have been shown to improve survival from SCD and improve overall survival in several populations at high risk for SCD. If certain criteria are present, a wearable cardioverter defibrillator (WCD) may sometimes be reasonable as a bridge to ICD implantation. This may include the presence of an active infection, which precludes implantation or reimplantation of an ICD.

b. Research, Clinical Trials, and Evidence Summaries

Many studies have established the safety and efficacy of the WCD as an alternative treatment for patients who may be at temporary risk for SCD due to a dysrhythmia.

The 2017 report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society provided two recommendations for the use of WCDs:

- In patients with an ICD and a history of SCA or sustained ventricular arrhythmias (VA) in whom removal of the ICD is required (as with infection), the wearable cardioverter-defibrillator is reasonable for the prevention of SCD
- In patients at an increased risk of SCD but who are not eligible for an ICD, such as awaiting cardiac transplant, have an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed nonischemic cardiomyopathy (NICM), received revascularization within the past 90 days, have myocarditis or secondary cardiomyopathy or a systemic infection, the wearable cardioverter-defibrillator may be a reasonable treatment option

Olgin et al. (2018) conducted a randomized controlled trial called the Vest Prevention of Early Sudden Death Trial (VEST) to determine whether a WCD would reduce the incidence of sudden cardiac death during the high-risk period of 40 to 90 days post-MI among patients with low ejection fraction. Eligible participants were randomly assigned in a 2:1 ratio to receive a WCA plus guideline-directed medical therapy (the device group), or guideline-directed medical therapy alone (the control group) at hospital discharge. Of the 2302 participants, 1524 were randomly assigned to the device group and 778 to the control group. Arrhythmic death occurred in 1.6% of the participants in the device group and in 2.4% of those in the control group with no significant difference between the two groups. The total mortality was 3.1% in the device group, as compared with 4.9% in the control group. Results from the study found that the wearable cardioverter–defibrillator did not lead to a rate of arrhythmic death during the first 90 days — the primary outcome of the trial — that was significantly lower than the rate with guideline-directed medical therapy alone. The study concluded that among patients

with a recent MI and an ejection fraction of 35% or less, the WCD did not result in a significantly lower rate of arrhythmic death compared to medical therapy during the first 90 days.

c. U.S. Food & Drug Administration (FDA) Information

VA generally only approves use of medical devices that have received at least FDA clearance for 510(k) Premarket Notification. The following devices have received Premarket Approval from the FDA and are indicated for adult patients who are at risk for sudden cardiac arrest and are not a candidate for an implantable defibrillator.

To search for devices that have received FDA 510(k) clearance or Premarket Approval (PMA), please visit the FDA Devices database.

Information	Description
Product Name	LifeVest Wearable Defibrillator (P010030)
PMA Applicant	ZOLL MANUFACTURING CORPORATION
Address	121 Gamma Dr Pittsburgh, PA 15238
Approval Date	12/17/2015
Approval Letter	Premarket Approval (PMA) (fda.gov) P010030 Approval Letter

Information	Description
Product Name	ASSURE Wearable Cardioverter Defibrillator (WCD) System (P200037)
PMA Applicant	Kestra Medical Technologies, Inc.
Address	3933 Lake Washington Boulevard, N.E. Suite 200 Kirkland, WA 98033
Approval Date	07/27/2021
Approval Letter	Premarket Approval (PMA) (fda.gov) P200037 Approval Letter

d. Medicare Coverage Determinations

Available Medicare coverage determinations are listed below as a resource. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

NCD Number	Name	Effective Date
None	N/A	N/A

LCD Number	Contractor	Revision Effective Date
L33690	CGS Administrators, LLC Noridian Healthcare Solutions, LLC	01/01/2020

- NCD: National Coverage Determination
- LCD: Local Coverage Determination

IV. Definitions

Term	Definition
Arrhythmia/ Dysrhythmia	An irregular rate and/or rhythm of the heartbeat
Dilated cardiomyopathy	A condition in which the heart muscle becomes weakened and enlarged, resulting in decreased ability of the heart to pump blood
Electrocardiogram (ECG)	A diagnostic test that measures the electrical activity of the heartbeat
Electrophysiologic (EP) study	A series of tests that examine the heart's electrical activity
Hypertrophic cardiomyopathy	A disease in which the heart muscle becomes thickened, resulting in more effort for the heart to pump blood
Implantable defibrillator	A small battery-powered device placed in the chest to detect and stop irregular heartbeats (arrhythmias) through an electric shock
Ischemia/ Ischemic	A decrease in blood flow to an area of the body
Long QT syndrome	A conduction disorder of the heart’s electrical system that is seen on ECG, which can cause fast, chaotic heartbeats (arrhythmias)
Myocardial infarction	Commonly known as a heart attack, a life-threatening condition that occurs when there is a blockage in the coronary arteries which decrease blood flow to the heart, resulting in tissue damage
Ventricular fibrillation	A type of arrhythmia that is rapid (greater than 300 bpm) and has grossly irregular electrical activity with marked variability in waveform on ECG

Term	Definition
Ventricular tachyarrhythmia	A type of arrhythmia that is typically regular, where there are three or more consecutive complexes originating in the ventricles on ECG at a rate of greater than 100 beats per minute

V. References

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VI. CDI History/Revision Information

- Explanation of changes to the CDI

Revision Type	Date of Revision	Update(s) Made to CDI
	MM/DD/YYYY	
	MM/DD/YYYY	