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Subject: Wearable and Non-Wearable Cardioverter-Defibrillators (WCD) for the Prevention of Sudden Cardiac Death

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease. The automatic implantable cardioverter defibrillator (AICD) has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, the use of AICDs has been potentially broadened by studies reporting a reduction in mortality for patients at risk for ventricular arrhythmias, such as patients with prior myocardial infarction (MI) and reduced ejection fraction. AICDs consist of implantable leads in the heart that connects to a pulse generator implanted beneath the skin of the chest or abdomen. In the past, AICD placement required a thoracotomy, but current technology allows implantation with only a minor surgical procedure, with the cardiac leads placed percutaneously.

Potential adverse effects of AICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary countershocks. Automatic external defibrillators include wearable cardioverter-defibrillators (WCD) and non-wearable automatic defibrillators with integrated electrocardiogram analysis capabilities.

The wearable cardioverter-defibrillator (WCD) is an external device that is intended to perform the same tasks as an AICD, without requiring any invasive procedures. t consists of a vest that is worn continuously underneath the patient's clothing. Part of this vest is the 'electrode belt' that contains the cardiac monitoring electrodes, and the therapy electrodes that deliver a counter shock. The vest is connected to a monitor with a battery pack and alarm module that is worn on the patient's belt. The monitor contains the electronics that interpret the cardiac rhythm and determines when a counter

shock is necessary. The alarm module alerts the patients to certain conditions by lights or voice messages. The U.S. Food and Drug Administration (FDA) approved the LifeCor WCD® 2000 system via premarket application approval in December 2001 for "adult patients who are at risk for sudden cardiac arrest and are either not candidates for or refuse an implantable defibrillator."

The non-wearable automatic defibrillator is a portable automatic device used to restore normal heart rhythm to patients in cardiac arrest. An external electric shock is administered through conductive adhesive electrode pads applied to the person by a user. Built-in computers analyze the person's rhythm and determine if rhythm requires defibrillation shocks. The user is guided through the process by voice and visual prompts. The U.S. Food and Drug Administration (FDA) approved over-the-counter sale of these types of automatic external defibrillators (AEDs) in September 2004.

The U.S. Food and Drug Administration (FDA) approved the LifeVest Wearable Cardioverter Defibrillator (The LifeVest system) via premarket application approval in December 2015 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 (lack of parenteral consent). 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.

Summary and Analysis of Evidence: In an UpToDate article "Wearable cardioverter-defibrillator" (Chung)"The wearable cardioverter-defibrillator (WCD) is an external device capable of automatic detection and defibrillation of ventricular tachycardia (VT) or ventricular fibrillation (VF). The approved devices do not have pacing capabilities and therefore are unable to provide therapy for bradycardic events or antitachycardic pacing. The WCD is composed of dry, nonadhesive monitoring electrodes, defibrillation electrodes incorporated into a chest strap or vest assembly, and a defibrillation battery and monitor unit. The Assure WCD garment has two styles designed for female and male body habitus and different sizes. The monitoring electrodes are positioned circumferentially around the chest and provide two to four surface electrocardiogram (ECG) 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. Arrhythmia detection by the WCD is programmed using ECG rate and morphology criteria. The 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. The WCD is indicated as temporary therapy for patients with a high risk for sudden cardiac death (SCD)."

Kutyifa et al 2015 conducted a prospective study, the Prospective Registry of Patients Using the Wearable Defibrillator (WEARIT-II) Registry was designed to provide real-world data on the WCD as a strategy during a period of risk stratification. The WEARIT-II Registry enrolled 2000 patients with ischemic (n=805, 40%), or nonischemic cardiomyopathy (n=927, 46%), or congenital/inherited heart disease (n=268) prescribed WCD between August 2011 and February 2014. Clinical data, arrhythmia events, implantable cardioverter defibrillator implantation, and improvement in ejection fraction were captured. The median age was 62 years; the median ejection fraction was 25%. The median WCD wear time was 90 days, with median daily use of 22.5 hours. There was a total of 120 sustained ventricular tachyarrhythmias in 41 patients, of whom 54% received appropriate WCD shock. Only 10 patients (0.5%) received inappropriate WCD therapy. The rate of sustained ventricular tachyarrhythmias by 3 months was 3% among patients with ischemic cardiomyopathy and congenital/inherited heart disease, and 1% among nonischemic patients (P=0.02). At the end of WCD use, 840 patients (42%) were implanted with

an implantable cardioverter defibrillator. The most frequent reason not to implant an implantable cardioverter defibrillator following WCD use was improvement in ejection fraction. The authors concluded that the WEARIT-II Registry demonstrates a high rate of sustained ventricular tachyarrhythmias at 3 months in at-risk patients who are not eligible for an implantable cardioverter defibrillator and suggests that the WCD can be safely used to protect patients during this period of risk assessment.

In a prospective nonrandomized study, Poole et al (2022) tested a contemporary WCD designed for reduced false shock alarms and improved comfort. One hundred and thirty patients with left ventricular ejection fraction ≤40% and an active implantable cardioverter defibrillator (ICD) were fitted with the ASSURE WCD (Kestra Medical Technologies) and followed for 30 days. WCD detection was enabled and shock alarm markers recorded, but shocks and shock alarms were disabled. All WCD episodes and ICD ventricular tachycardia/ventricular fibrillation (VT/VF) episodes were adjudicated. The primary endpoint was the false-positive shock alarm rate with a performance goal of 1 every 3.4 days (0.29 per patient-day). Of 163 WCD episodes, 4 were VT/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%). The authors concluded that the ASSURE WCD demonstrated a low false-positive shock alarm rate, low patient-reported discomfort, and no serious adverse events.

POSITION STATEMENT:

An FDA approved wearable cardioverter defibrillator (K0606) **meets the definition of medical necessity** for **ANY** of the following indications:

- A documented episode of ventricular fibrillation or a sustained, lasting (30 seconds or longer), ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction; **OR**
- Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; **OR**
- Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; **OR**
- A previously implanted defibrillator now requires explantation (removal).

An FDA approved wearable cardioverter defibrillator (K0606) for pediatric members (below age 18) who are at risk for sudden cardiac arrest, but are not candidates for an implantable defibrillator due to certain medical conditions or lack of parental consent meets the definition of medical necessity when the following indications are met:

- Abnormal, life-threatening heart rhythms (arrhythmias); **OR**

- Diseases and conditions that can lead to sudden cardiac arrest such as heart disease, certain inherited disorders and structural changes in the heart (such as those due to infection or congenital heart disease)

AND

- Chest circumference of 26 inches (66 centimeters) or greater; **AND**
- Weight of 41.3 pounds (18.75 kilograms) or greater.

If member use of wearable cardioverter defibrillator (K0606) is beyond 90 days, the physician must submit documentation for continued medical necessity for any of the indications for which the wearable cardioverter defibrillator was initially provided. Documentation should include, but is not limited to physician notes and implantation status.

BILLING/CODING INFORMATION:

CPT Coding:

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

HCPCS Coding:

E0617	External defibrillator with integrated electrocardiogram analysis
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement battery for automated external defibrillator, each
K0608	Replacement garment for use with automated external defibrillator, each
K0609	Replacement electrodes for use with automated external defibrillator, each

REIMBURSEMENT INFORMATION:

Refer to sections entitled **POSITION STATEMENT** and **PROGRAM EXCEPTIONS**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Automatic External Defibrillators (L33690) located at cgsmedicare.com. No National Coverage Determinations (NCD) and/or Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

None applicable.

OTHER:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

AICD, wearable
Jewel Patch WCD
LifeCor WCD System
LifeVest Wearable Cardioverter Defibrillator (The LifeVest system)
Wearable cardiac defibrillator
Wearable cardioverter defibrillator
Zoll LifeVest

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/23/25.

GUIDELINE UPDATE INFORMATION:

09/15/03	New Medical Coverage Guideline; investigational.
07/15/03	Scheduled review and revision of guideline; consisting of updated references and maintain investigational status.
01/01/05	Annual HCPCS coding update: consisting of addition of 93741, 93742 and 93745.
08/15/05	Review and revision of guideline; consisting of updated references.
06/15/06	Review and revision of guideline consisting of updated references.
07/15/07	Review and revision of guideline consisting of updated references and reformatted guideline.
04/15/08	Review and revision of guideline consisting of updated references.
01/01/09	Annual HCPCS coding update: added code 93292. Deleted codes 93741 and 93742.
05/15/09	Scheduled review; no change in the position statement; references updated.
05/15/11	Scheduled review; position statement unchanged; references updated.

10/01/11	4th Quarter coding update; ICD-9 425.1 removed, ICD-9 425.11 and 425.18 added to Medicare Advantage Program Exception.
01/01/13	Annual HCPCS coding update: revised descriptors for 93292 and 93745.
05/11/14	Revision: Program Exceptions section updated.
05/15/16	Reviewed; Added FDA statement to description regarding indication for wearable cardioverter defibrillator 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. Added "an FDA approved" and "cardioverter" to position statement. Added position statement for external wearable cardioverter defibrillator (K0606) for pediatric members. Updated program exception. Added LifeVest Wearable Cardioverter Defibrillator (The LifeVest system) to other section. Updated references.
07/15/18	Revision; added medical necessity statement for wearable cardioverter defibrillator (K0606) beyond 90 days. Updated references.
09/15/20	Review; no change in position statement. Updated references.
11/15/21	Review; no change in position statement. Updated references.
11/15/23	Review; no change in position statement. Updated references.
11/15/25	Review; no change in position statement. Updated code E0617. Added Jewel Patch WCD to other section. Updated references.