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Reviewed: 10/26/23

Revised: 11/15/23

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.

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.

Non-wearable automatic defibrillators (E0617) used for the prevention of sudden cardiac death are considered **experimental or investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 (**investigational**)
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.

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
LifeCor WCD System
LifeVest Wearable Cardioverter Defibrillator (The LifeVest system)
Wearable cardiac defibrillator
Wearable cardioverter defibrillator
Zoll LifeVest

REFERENCES:

1. Adler A, Halkin A, Viskin S. Wearable cardioverter-defibrillators. Circulation 2013; 127: 854-860.
2. Al-Khatib SM, Stevenson WG, Ackerman MJ et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: Executive summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm 2018 Oct;15(10):e190-e252.
3. Aufderheide T, Hazinski MF, Nichol G, Steffens SS, Buroker A, McCune R, Stapleton E, Nadkarni V, Potts J, Ramirez RR, Eigel B, Epstein A, Sayre M, Halperin H, Cummins RO; American Heart Association Emergency Cardiovascular Care Committee; Council on Clinical Cardiology; Office of State Advocacy. Community lay rescuer automated external defibrillation programs: key state legislative components and implementation strategies: a summary of a decade of experience for healthcare providers, policymakers, legislators, employers, and community leaders from the American Heart Association Emergency Cardiovascular Care Committee, Council on Clinical Cardiology, and Office of State Advocacy. Circulation. 2006 Mar 7; 113(9): 1260-70.
4. Auricchio A, Klein H, Geller CJ, Reek S, Heilman MS, Szymkiewicz SJ. Clinical efficacy of the wearable cardioverter-defibrillator in acutely terminating episodes of ventricular fibrillation. Am J Cardiol. 1998 May 15; 81(10): 1253-6.
5. Blue Cross Blue Shield Association Evidence Positioning System® 2.02.15 Wearable Cardioverter Defibrillators, 06/23.
6. Chung MK, Szymkiewicz SJ, Shao M et al. Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. Journal of the American College of Cardiology 2010 July 13; 56(3): 194-203.Feldman AM, Klein H, Tchou P, Murali S, Hall WJ, Mancini D, Boehmer J, Harvey M, Heilman MS, Szymkiewicz SJ, Moss AJ; WEARIT investigators and coordinators; BIROAD investigators and coordinators. Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD. Pacing and Clinical Electrophysiology. 2004 Jan; 27(1): 4-9.

7. Clark MA, Szymkiewicz SJ, Volosin K. Mortality and Costs Associated with Wearable Cardioverter-defibrillators after Acute Myocardial Infarction: A Retrospective Cohort Analysis of Medicare Claims Data. J Innov Card Rhythm Manag. Oct 2019; 10(10): 3866-3873.
8. Francis J, Reek S. Wearable cardioverter defibrillator: A life vest till the life boat (ICD) arrives. Indian Heart Journal 2014; 66(1): 68-72.
9. Gregoratos G, Abrams J, Epstein AE, Freedman RA, Hayes DL, Hlatky MA, Kerber RE, Naccarelli GV, Schoenfeld MH, Silka MJ, Winters SL, Gibbons RI, Antman EM, Alpert JS, Hiratzka LF, Faxon DP, Jacobs AK, Fuster V, Smith SC Jr; American College of Cardiology/American Heart Association Task Force on Practice Guidelines American College of Cardiology/American Heart Association/North American Society for Pacing and Electrophysiology Committee. ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: summary article. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee to Update the 1998 Pacemaker Guidelines). J Cardiovasc Electrophysiol. 2002 Nov; 13(11): 1183-99.
10. Hohnloser SH, Kuck KH, Dorian P, Roberts RS, Hampton JR, Hatala R, Fain E, Gent M, Connolly SJ; DINAMIT Investigators. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med. 2004 Dec 9; 351(24): 2481-8.
11. Kao AC, Krause SW, Handa R et Kao AC, Krause SW, Handa R et al. Wearable defibrillator use in heart failure (WIF): results of a prospective registry. BMC Cardiovascular Disorders 2012 Dec 12; 12:123.
12. Kutyifa V, Moss AJ, Klein H et al. Use of the wearable cardioverter defibrillator in high-risk cardiac patients: data from the Prospective Registry of Patients Using the Wearable Cardioverter Defibrillator (WEARIT-II Registry). Circulation 2015; 132: 1613-1619.
13. Medicare DME MAC. CGS Administrators, LLC. Jurisdiction J-C. L33690 Automatic External Defibrillators, 10/01/2015.
14. Murray CL, Steffensen I. Automated external defibrillators for home use [Issues in emerging health technologies issue XX]. Ottawa: Canadian Coordinating Office for Health Technology Assessment; 2005.
15. Ontario Ministry of Health and Long-Term Care. Use of automated external defibrillators in cardiac arrest – health technology literature review. Toronto: Medical Advisory Secretariat, Ontario Ministry of Health and Long-Term Care (MAS). 2005:28.
16. Reek S, Geller JC, Meltendorf U, Wollbrueck A, Szymkiewicz SJ, Klein HU. Clinical efficacy of a wearable defibrillator in acutely terminating episodes of ventricular fibrillation using biphasic shocks. Pacing Clin Electrophysiol. 2003 Oct; 26(10): 2016-22.
17. Sasaki S, Tomita H, Shibutani S et al 2014. Usefulness of the wearable cardioverter-defibrillator in patients at high risk for sudden cardiac death-a single-center primary experience. Circulation Journal 2014; 78(12): 2987-2989.
18. U.S. Food and Drug Administration (FDA) 510(k) Summary of Safety and Effectiveness Data. #P010030, Lifecor, Inc, WCD® 2000 System.
19. U.S. Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data (SSEED). Wearable Cardioverter Defibrillator/LifeVest®. Wearable Cardioverter Defibrillator P010030/S056B, 12/17/15.

20. Zipes, DP, et al. ACC/AHA/ESC 2006 Guidelines for Management of patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death; A Report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for practice Guidelines J Am Coll Cardiol, 2006; 48:247-346.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/26/23.

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.