Cardiac Defibrillators, External

Date of Origin: 11/2006 **Last Review Date: 12/2020** **Effective Date: 01/01/2021**

Dates Reviewed: 12/2007, 01/2009, 02/2011, 01/2012, 09/2012, 07/2013, 06/2014, 05/2015, 02/2016, 03/2017, 12/2018, 12/2019, 12/2020

Developed By: Medical Necessity Criteria Committee

I. Description

An external cardiac defibrillator, also called a wearable cardiac defibrillator (WCD) is a vest-like device that is worn by the member. The WCD is intended to perform the same functions as an implanted cardiac defibrillator (ICD) without requiring an invasive procedure. This device is used to monitor and treat abnormal heart rhythms in people at risk of dying from sudden cardiac arrest. A WCD consists of a vest that is worn under clothing for 24 hours a day except when the member is bathing or showering. The vest includes an electrode belt that contains the cardiac monitoring electrodes and the therapy electrodes that deliver an electrical shock if a life-threatening ventricular arrhythmia is detected. The WCD is programmable and communicates with the member through voice and display messages, tones, or alarms and vibration against the skin. When an arrhythmia is detected, the device instructs the member to stop the impending shock by pressing a response button to avoid receiving a shock while conscious. The WCD is designed to deliver an electric shock within 60 seconds of the onset of ventricular tachycardia or ventricular fibrillation unless a conscious member presses the response button. The member can also connect the WCD to an external modem and send the data it has collected over the phone to a physician's computer for review. The Lifecor Wearable Cardioverter Defibrillator 2000 System received FDA approval on December 18, 2001. The trade name of the WCD 2000 was changed to LifeVest in 2002, and the LIFECOR business was acquired by Zoll Medical Corporation (Philadelphia, PA) in 2006. This system is intended for adults in situations in which implantation of an ICD is immediately not feasible (e.g. members with an active infection), may be of uncertain benefit, may not be covered by third-party payers (e.g. early post-myocardial infarction, members with limited life expectancy or new onset systolic heart failure), or when an ICD must be removed (e.g. infection) who are at risk for sudden cardiac arrest and who are not candidates for or refuse an implanted cardiac defibrillator.

An **automatic external defibrillator** (AED) is a compact, portable device that is used to deliver an electrical shock to a victim of sudden cardiac arrest. The use of AEDs has become an important component of emergency medical systems and advances in technology have allowed the expansion AED use to trained first responders and laypersons who witness an arrest. There is little published medical literature regarding the efficacy of AED use in the home.

II. Criteria: CWQI HCS-0014A

A. Moda Health will cover an FDA approved wearable cardiac defibrillator (WCD) when ALL these requirements are met:
   a. The member is at high risk for sudden cardiac death
   b. Member has had a face-to-face examination within 6 months prior to the request
   c. The member meets eligibility for an implantable cardiac defibrillator (ICD)
   d. The member is an adult, 18 years of age or older
   e. The member has completed electrophysiologic studies to determine the type of arrhythmia present and confirm that an automatic cardiac defibrillator is the best course of treatment and **1 or more** of the following criteria is met:
      i. The member has a hereditary condition with high risk incidence of ventricular tachyarrhythymias such as long QT syndrome or hypertropic cardiomyopathy
      ii. A documented episode of VF, or a sustained (lasting 30 seconds or longer) VT; (these dysrhythmias may be either spontaneous or induced during an EP (electrophysiology 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 (AMI).
      iii. The WCD is being used temporarily until the member receives a heart transplant of ICD
      iv. The member is not a suitable candidate for an ICD
      v. The WCD is being used post MI as a bridge during the first 40 days post event while waiting for an ICD with a history of 1 or more of the following:
         1. Ventricular tachycardia or ventricular fibrillation in the first 48 hours post infarct
         2. Reduced Left ventricular ejection fraction (LVEF) of less than or equal to 35
      vi. The member refuses ICD placement
      vii. The member has a systemic infection or other temporary condition that precludes ICD implantation.
   f. The requested WCD is for no more than 3 months or after 3 months, a new request is submitted with additional clinical documentation

Note – WCDs (i.e. Zoll LifeVest) are intended for short-term use. If approved, the WCD will be rented on a monthly basis. If the rental cost exceeds the cost of purchase for longer term use, purchase of the WCD will be considered.

B. Non-wearable automatic external defibrillators (AED) for adults (age 18 and older) are considered investigational for home use. There are few peer-reviewed published studies that report on clinical outcomes of AEDs used in the home setting for adults by lay persons, and no studies that evaluate the efficacy of AEDs in reducing mortality compared to alternatives (i.e. ICD or emergency treatment by first responders).
   a. Refer to Noridian L33690 for Medicare coverage requirements

Medicare Reference:
LCD: L33690

III. Information Submitted with the Prior Authorization Request:

1. History and physical from treating physician
2. Results for electrophysiology studies
3. Patient contraindication to ICD
4. Anticipated length of time that WCD will be used

IV. Applicable CPT or HCPC codes covered:

Codes	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; single, dual, or multiple lead pacemaker system, or leadless pacemaker system; 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
K0606	Wearable, automatic, EXTERNAL DEFIBRILLATORs with integrated electrocardiogram analysis
K0607	Replacement battery for automated external defibrillator, garment type only
K0608	Replacement garment for use with automated external defibrillator
K0609	Replacement electrodes for use with automated external defibrillator, garment type only

V. CPT or HCPC codes NOT covered:

Codes	Description
E0617	Non wearable automatic EXTERNAL DEFIBRILLATORS with integrated electrocardiogram capability

VI. Annual Review History

Review Date	Revisions	Effective Date
07/2013	Annual Review: Added table with review date, revisions, and effective date.	07/2013
06/2014	Annual Review: Moved criteria of hereditary condition as one or more of the following; added purchase if rental cost exceeds purchase price.	06/2014
05/2015	Annual Review: Corrected the manufacturer to Zoll. Added I.B Face to face exam per CMS guideline. Added Medicare LCD reference. Added I.E.h – additional clinical documentation submitted after 3 mos. Added ICD-9 codes per CMS guideline	05/2015

02/2016	Updated criteria, ICD-10 codes, removed AED criteria and removed ICD-9 codes	02/24/2016
03/2017	Annual Review: Added criteria A.e.ii and A.e.vii, updated reference to Medicare guideline	03/22/2017
12/2018	Annual Review: Updated reference to Medicare LCD	01/01/2019
12/2019	Annual Review: No changes	01/01/2020
12/2020	Annual Review: Grammar updates. No content changes	01/01/2021

VII. References

1. Barclay L. LIFEPAK 500 AED accurate in infants and children. Ann Emerg Med. 2003;42:185-196.
2. Cecchin D, Jorgenson D, Berul C, et al. Is arrhythmia detection by automatic external defibrillator accurate for children? Sensitivity and specificity of an automatic external defibrillator algorithm in 696 pediatric arrhythmias. Circulation 2001;103;2483-2488.
3. Cram P, Katz D, Vijan S, et al. Implantable or external defibrillators for individuals at increased risk of cardiac arrest: where cost-effectiveness hits fiscal reality. Value Health. 2006 Sep-Oct;9(5):292-302.
4. Divekar A, Soni R. Successful parental use of an automated external defibrillator for an infant with long-QT syndrome. Pediatrics. June 2006. (doi:10.1542/peds.2006-0129).
5. Feldman AM, Klein H, Tchou P, et al. Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD. Pacing Clin Electrophysiol. 2004 Jan;27(1):4-9.
6. HAYES alert™ newsletter. Technology Assessment Brief. Wearable Cardioverter Defibrillator. Lansdale, PA: HAYES, Inc.; 2002 Winifred S. Hayes, Inc. 2002 Dec V(12).
7. International liason committee on resuscitation lowers the bar on use of AED recommendations-approves use in children 1 to 8 years of age. Accessed on February 7, 2011 at: http://www.medscape.com/viewarticle/458298.
8. Martinez-Rubio A, Baron-Exquivias G. The automatic external cardioverter-defibrillator. Indian Pacing Electrophysiol J. 2004 Jul 1;4(3):114-21.
9. Infant/Child Reduced Energy Defibrillation Electrodes Instruction for Use.Medtronic 2005; 1-11..
10. Reek S, Geller JC, Meltendorf U, et al. 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.
11. Reek S, Geller JC, Meltendorf U, et al. 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.
12. Reek S, Meltendorf U, Geller JC, et al. The wearable cardioverter defibrillator (WCD) for the prevention of sudden cardiac death-a single center experience. Z Kardiol. 2002 Dec;91(12):1044-52.
13. Samson R, Berg R, Bingham R. Use of automated external defibrillators for children: an update-an advisory statement from the pediatric advanced life support task force, international liaison committee on resuscitation. Pediatrics. 2003; 112:163-168.

14. Sanna T, Fedele F, Genuini I, et al. Home defibrillation: a feasibility study in myocardial infarction survivors at intermediate risk of sudden death. Am Heart J. 2006 Oct;152(4):685.e1-7.
15. Schott R. Wearable defibrillator. J Cardiovasc Nurs. 2002 Apr;16(3):44-52.
16. Klein HU, Meltendorf U, Reek S, et al. Bridging a temporary high risk of sudden arrhythmic death. Experience with the wearable cardioverter defibrillator (WCD). Pacing Clin Electrophysiol 2010; 33:353.
17. Centers for Medical Coverage; Noridian Healthcare Solutions, LLC (19003); Local Coverage Determination (LCD) Automatic External Defibrillators (L33690); Original Effective Date 10/1/2015, Revision Effective Date 07/01/2016
18. UpToDate, Chung, Mina K, MD; Wearable cardioverter-defibrillator; Feb 2017.
19. Physician Advisors

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
B57.0	Acute Chagas' disease with heart involvement
B57.2	Chagas' disease (chronic) with heart involvement
D86.9	Sarcoidosis, unspecified
I25.3	Aneurysm of heart
I25.5	Ischemic cardiomyopathy
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
I40.0	Infective myocarditis
I40.1	Isolated myocarditis
I42.1	Obstructive hypertrophic cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.5	Other restrictive cardiomyopathy
I42.6	Alcoholic cardiomyopathy
I42.7	Cardiomyopathy due to drug and external agent
I42.8	Other cardiomyopathies
I43	Cardiomyopathy in diseases classified elsewhere
I45.81	Long QT syndrome

ICD-10	ICD-10 Description
I45.89	Other specified conduction disorders
I46.9	Cardiac arrest, cause unspecified
I47.2	Ventricular tachycardia
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
I50.1	Left ventricular failure
I50.20	Unspecified systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.9	Heart failure, unspecified
R55	Syncope and collapse
T82.6XXA	Infection and inflammatory reaction due to cardiac valve prosthesis, initial encounter
T82.7XXA	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter
T82.817A	Embolism of cardiac prosthetic devices, implants and grafts, initial encounter
T82.827A	Fibrosis of cardiac prosthetic devices, implants and grafts, initial encounter
T82.837A	Hemorrhage of cardiac prosthetic devices, implants and grafts, initial encounter
T82.847A	Pain from cardiac prosthetic devices, implants and grafts, initial encounter
T82.857A	Stenosis of cardiac prosthetic devices, implants and grafts, initial encounter
T82.867A	Thrombosis of cardiac prosthetic devices, implants and grafts, initial encounter
T82.897A	Other specified complication of cardiac prosthetic devices, implants and grafts, initial encounter
T82.9XXA	Unspecified complication of cardiac and vascular prosthetic device, implant and graft, initial encounter
Z76.82	Awaiting organ transplant status
Z82.41	Family history of sudden cardiac death

ICD-10	ICD-10 Description
Z86.74	Personal history of sudden cardiac arrest
Z97.810	Presence of automatic (implantable) cardiac defibrillator

Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): D (DME)	NCD/LCD Document (s):
Local Coverage Determination (LCD): Automatic External Defibrillators (L33690)	

NCD/LCD Document (s):
https://med.noridianmedicare.com/documents/2230703/7218263/Automatic+External+Defibrillators/10f0b92d-0c55-4b5d-aa15-b952b37c70ce accessed: 12/11/2018

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC