



Children's Medical Services Health Services (CMS Health Plan)

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WellCare Prescription Insurance

WellCare TexanPlus (Medicare – Dallas & Houston markets)

External and Wearable Defibrillators for the Prevention of Sudden Cardiac Death

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Sudden cardiac death (SCD) is typically defined as unanticipated death due to cardiac causes that occur within 1 hour of the onset of acute symptoms. In the United States, the American Heart Association (AHA) states that

approximately 330,000 people die from heart disease each year without being admitted to the hospital. The annual risk of sudden cardiac arrest (SCA) is around 0.1% for the general population and the incidence is 3 to 4 times higher in men than women, but this disparity diminishes with increasing age. There are a number of known risk factors for SCD including male sex, smoking, obesity, diabetes, inactivity, previous myocardial infarction (MI)/history of coronary artery disease, decreased left ventricular ejection fraction (LVEF) and heart failure, previous SCA or ventricular tachycardia, atrial fibrillation, and abnormal electrophysiological parameters. Although ventricular fibrillation is listed as the cause of relatively few deaths, the overwhelming majority of SCD from coronary artery disease are thought to be from ventricular fibrillation, with ventricular tachycardia also being implicated. Early defibrillation is instrumental for a patient's chances of surviving an episode of ventricular fibrillation. Of those who receive defibrillation during the first minute, 97% survive, but the survival rate drops to 15% to 40% for defibrillation in minutes 4 to 5, and to only 5% survival for interventions given 10 minutes or more after the incident. As the average response time for emergency medical services is 8 to 15 minutes in the United States, the chances of survival are low for patients whose ventricular fibrillation occurs in the community. Although the survival rate of ventricular fibrillation in public places may be improved by the availability of non-wearable automatic external cardioverter defibrillators, 75% of ventricular fibrillations occur in the home environment, which are not typically equipped with a defibrillator.^{1,2}

Defibrillation Devices

The non-wearable automatic external defibrillator (AED) 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 unconscious person by a user. Built-in computers analyze the person's rhythm and determine if the rhythm requires defibrillation shocks. User is guided through the process by voice and visual prompts.³

The LifeVest is a wearable cardioverter defibrillator (WCD) developed by Lifecor Inc. The LifeVest is "a combination of two different devices. As a cardioverter, it uses low-energy electrical shocks to return a heart exhibiting ventricular tachycardia (abnormally rapid heart rhythm) to a normal rhythm. As a defibrillator, it uses high-energy shocks to a heart in a state of ventricular fibrillation (disorganized heart rhythm) to return it to a normal rhythm. However, note that it is the defibrillatory functionality of the device that is most critical because of mortality associated with fibrillation. The LifeVest system comprises wearable and non-wearable parts. The wearable parts are the monitor, battery pack, alarm module, electrode belt, vest, and holster. The non-wearable parts are the battery charger, modem, modem cable, computer cable, a secure Internet website that maintains patient information, and a diagnostic tester. The LifeVest WCD monitors electrocardiogram (ECG) changes through a programmable microprocessor-based device and an electrode belt containing non-adhesive electrodes that is integrated into the vest. If a life-threatening arrhythmia is detected, the non-adhesive therapeutic electrodes release a conductive gel to the skin and deliver a shock to the heart. Prior to shock delivery a tactile vibratory, visual light; 2-stage audible noise alarm; and bystander warning are delivered. The 2-stage audible alarm consists of a low-volume siren, followed by a high-volume siren (approximately 100 dB) designed to wake a sleeping patient. If the patient is conscious, the device may be disarmed at any point throughout this sequence. The alarm and an ECG monitor are worn on a belt around the patient's waist. It usually takes 15 to 25 seconds to detect a life-threatening arrhythmia and the WCD is designed to deliver a shock within 60 seconds from the onset of the arrhythmia. The LifeVest WCD can deliver up to 5 biphasic defibrillating shocks during a single arrhythmic episode. The physician can program the size of the shocks from 75 to 150 joules (note that most physicians do not change the default setting of 150 joules) and also the length of delay before a response to ventricular fibrillation or tachycardia event is initiated. The device also records up to 75 minutes of ECG data allowing physician playback of any arrhythmic events through the secure website and monitoring of patient compliance".⁴

The LifeVest WCD is an appealing option in adult patients who are at a high risk of SCA. The LifeVest WCD has several potential advantages to current treatment modalities:

- Is a noninvasive therapy.
- May allow patients to be released from the hospital earlier than would otherwise be possible (cost savings).

- As the LifeVest WCD system is worn at all times except when bathing, the time from onset of an event to defibrillation should be lower with the device than relying on emergency services or the presence of non-wearable automatic external cardioverter defibrillators and hence improving the chances of survival.

Criteria for Changing the Recommendations for Use of AEDs in Children⁵

First, it is necessary to determine whether the rhythm analysis system of a particular AED is safe and effective for children. This means that the rhythm analysis system must be evaluated to determine its capability to safely differentiate between shockable and non-shockable rhythms in children. Every effort must be made to confirm that the AED is safe when attached to and used in a child who does not have a shockable rhythm and who could be harmed by an inappropriate shock. Second, it is necessary to demonstrate that each AED delivers shocks that effectively defibrillate a child's heart and at the same time avoids any myocardial damage.

Limitations of AEDs in Children⁵

One important limitation that arose during task force deliberations on this topic was the lack of data on clinical use of newly developed pediatric pad/cable systems that reduce the energy delivered by AEDs designed for use in the adult. This was especially problematic when discussing the risks and benefits of use of AEDs in very young infants. Relevant points of discussion included the following:

1. The experimental data in the Atkinson study³⁸ examining sensitivity and specificity included infants, but the sample size diminished with decreasing age, and thus there is less confidence in the data from that study analyzing sensitivity/specificity in the youngest patients.
2. Very small infants might receive doses demonstrated to cause myocardial damage in animal studies.
3. The incidence of shockable rhythms as a clinical cause of unresponsiveness in young infants is lower than in older children.

The AED is becoming widely available and may be the first device available for defibrillation in the prehospital setting. Current evidence suggests that AEDs are capable of appropriate sensitivity and specificity for pediatric arrhythmias and are both safe and effective for defibrillation of children 1 to 8 years of age. Ideally pediatric pads/cables should be used, whenever available, to deliver a child dose. Each specific AED model must be tested against a library of pediatric arrhythmias to document its efficacy in detection of shockable and non-shockable rhythms. The task force strongly encourages industry to continue to develop pediatric rhythm diagnostic programs and investigate appropriate pediatric AED energy doses. The task force applauds efforts in this area and will conduct a comprehensive review of new data as they become available.

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets (Excluding AZ, KY, NC)
- Children's Medical Services Health Plan (CHIP)
- Medicare

Adults

Wearable Cardioverter defibrillators (K0606; LifeVest™ System by ZOLL Lifecor) **may be considered medically necessary** and a covered benefit when ANY of the following criteria are met:

- Member is in a waiting period before implantation of an implantable cardioverter defibrillator (ICD); **OR**,
- The use of an implantable cardioverter defibrillator is contraindicated; **OR**,
- A previously implanted defibrillator now requires removal; **OR**,
- The member has been approved and is on the waiting list for a heart transplant, or the member is currently in Phase 2 of the heart transplant process;

AND,

- Any of the following situations exist:
 - 1) An episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia is documented. 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 may not occur during the first 48 hours of an acute myocardial infarction; **OR,**
 - 2) Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy is indicated; **OR,**
 - 3) Either a documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35 exists.

Non-wearable automatic external defibrillators (E0617; HeartStart Home Defibrillator by Philips) **may be considered medically necessary and a covered benefit** when members meet the criteria described below:

- Implantation surgery is contraindicated or a previously implanted defibrillator now requires removal; **AND,**
- The member has **ONE** of the following conditions (1-8):
 - 1) A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause.
 - 2) A sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, either spontaneous or induced during an electrophysiologic (EP) study, not associated with acute myocardial infarction, and not due to a transient or reversible cause.
 - 3) Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy.
 - 4) Coronary artery disease with a documented prior myocardial infarction, with a measured left ventricular ejection fraction less than or equal to 0.35, and inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) during an EP study. To meet this criterion;
 - a) The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription; **AND,**
 - b) EP test must have been performed more than 4 weeks after the qualifying myocardial infarction.
 - 5) Documented prior myocardial infarction and a measured left ventricular ejection fraction less than or equal to 0.30. Patients must not have:
 - a) Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; **OR,**
 - b) Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months; **OR,**
 - c) Had an enzyme-positive MI within past month; **OR,**
 - d) Clinical symptoms or findings that would make them a candidate for coronary revascularization; **OR,**
 - e) Irreversible brain damage from preexisting cerebral disease; **OR,**
 - f) Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
 - 6) Members with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction LVEF) \leq 35%.
 - 7) Members with nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart

failure, and measured LVEF \leq 35%.

- 8) Members who meet one of the previous criteria (1-7) and have NYHA Class IV heart failure.

The LifeVest WCD system is contraindicated for use in patients with an active implantable cardioverter defibrillator (ICD) nor is it recommended for use in the following patients:^{6,7}

- Anyone with a vision or hearing problem that may interfere with perception of alarms or messages from the WCD as well as anyone taking medications that would interfere with responding to alarms or messages from the WCD by depressing buttons.
- Those unwilling or unable to wear the device continuously except when bathing.
- Women who are either pregnant or breast feeding or of childbearing age and not attempting to prevent pregnancy. NOTE: Despite this contraindication, the efficacy and safety of the WCD has been investigated for treatment of PPCM (Saltzberg et al., 2012).
- Those exposed to high levels of electromagnetic interference that may prevent the WCD from operating.

Children and Adolescents

Automated external defibrillators (AEDs) **may be considered medically necessary** for children 1 to 8 years of age who have no signs of circulation. Ideally the device should deliver a pediatric dose. The arrhythmia detection algorithm used in the device should demonstrate high specificity for pediatric shockable rhythms (e.g., it will not recommend delivery of a shock for non-shockable rhythms).⁵

In addition, there is insufficient evidence to support a recommendation for or against the use of AEDs in children <1 year of age.

Defibrillation is recommended for documented ventricular fibrillation (VF)/pulseless ventricular tachycardia (VT).

CODING

Covered CPT® Codes for Wearable Cardioverter Defibrillator (WCD) – *This list may not be all inclusive.*

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

* Do not report 93745 in conjunction with 93282, 93292.

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

*Do not report 93292 in conjunction with 93745.

Covered HCPCS Level II ® Codes for Wearable Cardioverter Defibrillator (WCD) – *This list may not be all inclusive.*

A9999 Miscellaneous DME supply or accessory, not otherwise specified

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

ICD-10-PCS Codes – No applicable code(s).

Covered ICD-10-CM Diagnosis Codes – *This list may not be all inclusive.*

A18.84 Tuberculosis of heart

I21.01 – I21.09 ST elevation (STEMI) myocardial infarction involving coronary artery of anterior wall

I21.11, I21.19	ST elevation (STEMI) myocardial infarction involving coronary artery of inferior wall
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery
I21.29	ST elevation (STEMI) myocardial infarction involving other sites
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
I22.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site
I25.2	Old myocardial infarction
I42.0	Dilated cardiomyopathy
I42.3	Endomyocardial (eosinophilic) disease
I42.4	Endocardial fibroelastosis
I42.5	Other restrictive cardiomyopathy
I42.6	Alcoholic cardiomyopathy
I42.7	Cardiomyopathy due to drug and external agent
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified.
I43	Cardiomyopathy in diseases classified elsewhere
I45.81	Long QT syndrome
I46.2 - I46.9	Cardiac Arrest
I47.0	Re-entry ventricular arrhythmia
I47.1	Supraventricular tachycardia
I47.2	Ventricular tachycardia
I47.9	Paroxysmal tachycardia, unspecified
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
I50.1	Left ventricular failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure I50.22 – Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.9	Heart failure, unspecified
T82.110A	Breakdown (mechanical) of cardiac electrode, initial encounter
T82.111A	Breakdown (mechanical) of cardiac pulse generator (battery), initial encounter
T82.118A	Breakdown (mechanical) of other cardiac electronic device, initial encounter
T82.119A	Breakdown (mechanical) of unspecified cardiac electronic device, initial encounter
T82.120A	Displacement of cardiac electrode, initial encounter
T82.121A	Displacement of cardiac pulse generator (battery), initial encounter
T82.128A	Displacement of other cardiac electronic device, initial encounter
T82.129A	Displacement of unspecified cardiac electronic device, initial encounter
T82.190A	Other mechanical complication of cardiac electrode, initial encounter
T82.191A	Other mechanical complication of cardiac pulse generator (battery), initial encounter

T82.198A	Other mechanical complication of other cardiac electronic device, initial encounter
T82.199A	Other mechanical complication of unspecified cardiac device, initial encounter
T82.110A-T82.199S	Mechanical complication of cardiac electronic device
T82.6XXA-T82.6XXS	Infection and inflammatory reaction due to cardiac valve prosthesis
T82.7XXA-T82.7XXS	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts
T82.817A	Embolism due to cardiac prosthetic devices, implants and grafts, initial encounter
T82.827A	Fibrosis due to cardiac prosthetic devices, implants and grafts, initial encounter
T82.837A	Hemorrhage due to cardiac prosthetic devices, implants and grafts, initial encounter
T82.847A	Pain due to cardiac prosthetic devices, implants and grafts, initial encounter
T82.857A	Stenosis of cardiac prosthetic devices, implants and grafts, initial encounter
T82.867A	Thrombosis due to cardiac prosthetic devices, implants and grafts, initial encounter
T82.9xxA	Unspecified complication of cardiac and vascular prosthetic device, implant and graft, initial encounter
T82.897 - T82.898	Other specified complication of cardiac and vascular prosthetic devices, implants, and grafts
Z76.82	Awaiting organ transplant status
Z82.49	Family history of ischemic heart disease and other diseases of the circulatory system
Z86.74	Personal history of sudden cardiac arrest

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

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MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
11/7/2019, 12/6/2018, 8/3/2017, 10/6/2016, 10/1/2015	<ul style="list-style-type: none"> • Approved by MPC. No changes.
3/5/2015, 3/6/2014	<ul style="list-style-type: none"> • Approved by MPC. Addition of pediatric criteria.
4/11/2013	<ul style="list-style-type: none"> • Approved by MPC. No changes.
4/5/2012	<ul style="list-style-type: none"> • Approved by MPC. Added contraindications for use.
12/1/2011	<ul style="list-style-type: none"> • Approved by MPC. No changes.
8/2/2011	<ul style="list-style-type: none"> • New template design approved by MPC. • Approved by MPC. No changes.