

Wearable Cardioverter-Defibrillator Devices

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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Summary

External defibrillators are medical devices applied to the chest wall that can stimulate an electric current in the heart when cardiac arrest has occurred. When properly applied, free-standing external defibrillators such as automated external defibrillators (AEDs) have proven to be life-saving for individuals undergoing cardiac arrest.

Wearable cardioverter-defibrillators are defibrillators worn under clothing, usually contained within a garment such as a cloth vest, and function much in the same manner as an implantable cardiac defibrillator (ICD) without requiring surgical placement. Wearable cardioverter-defibrillators are appropriate for persons with certain life-threatening cardiac conditions to identify life-threatening ventricular tachycardia or fibrillation in a person wearing the device. The device can also apply an electric current when cardiac arrest is detected.

Wearable cardioverter-defibrillators are designed to act as a bridge to prevent sudden cardiac death in patients during periods of high risk. In general, wearable cardioverter-defibrillators are no longer needed once a patient receives definitive treatment, such as permanent ICD insertion or a cardiac transplant, or once they have recovered from a previous high-risk condition, such as a heart attack.

There are two FDA-approved wearable cardioverter-defibrillators in the United States. LifeVest® is manufactured by Zoll Medical Corporation, which received premarket approval by the Food and Drug Administration (FDA) in 2001. The Zoll® LifeVest® Wearable Defibrillator was initially approved only for patients 18 years of age and older, but approval was extended to include children in 2015. ASSURE Wearable Cardioverter Defibrillator (WCD) System (ASSURE System), which is manufactured by Kestra Medical Technologies, Inc received premarket approval by the FDA in July 2021. It is indicated for patients 18 years of age or older who are at risk for sudden cardiac arrest and are not candidates for, or refuse, an implantable defibrillator.

Definitions

“Wearable cardioverter-defibrillator” is a noninvasive external defibrillator that is used to prevent sudden cardiac death. It is worn under the clothing and is able to check the heart rhythm and can send an electric shock to the heart to try to restore a normal rhythm if needed.

“Zoll® Lifevest®” refers to the LifeVest®, a type of wearable cardioverter-defibrillator made by Zoll Medical Corporation. This term refers to models 3000, 3100, and 4000.

“Sudden cardiac arrest (SCA)” is a sudden, unexpected cessation of cardiac activity.

“Sudden cardiac death (SCD)” is a sudden, unexpected death caused by loss of heart function.

“Automated external defibrillator (AED)” is a portable device that checks the heart rhythm and can send an electric shock to the heart to try to restore a normal rhythm. It is typically applied by a bystander to a person undergoing cardiac arrest in an attempt to restore or correct a cardiac arrhythmia.

“Cardiac arrhythmia” is an abnormal heart rhythm that may lead to cardiac arrest.

“Asystole” refers to cardiac arrest, or the cessation of cardiac (heart) activity, leading to death.

“Implantable cardioverter-defibrillator (ICD)” consists of a lead placed transvenously into the heart attached to a generator implanted in the chest wall. Alternatively, a lead may be placed subcutaneously (below the skin) and attached to a generator implanted in the chest wall.

“Subcutaneous implantable cardioverter-defibrillator (SICD)” consists of a lead placed under the skin near the heart and the generator is implanted into a subcutaneous pocket or intramuscular that delivers heart-regulating electrical shocks.

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers a wearable cardioverter-defibrillator (WCD) medically necessary when the device has received FDA approval (premarket, etc.) and ALL of the following criteria are met:

1. Device is being ordered by a cardiologist (including electrophysiologist or heart failure specialist); *and*
2. Member is at high risk for sudden cardiac death; *and*
3. Device can be properly fitted. For pediatric members (requesting LifeVest), the chest circumference must be at least 26 inches and body weight of 18.75 kilograms (41.3 lbs); *and*
4. Current request is for no more than 3 months for this authorization. For requests of additional extended use beyond 3 months, please see Authorization Period & Extension Requests. The total duration of device usage should not exceed 6 months; *and*
5. Member meets ONE of the following criteria in 5a, 5b, 5c, OR 5d:
 - a. MCG Cardioverter-Defibrillator Insertion (M-157) criteria are met, but a wearable cardioverter-defibrillator is needed as an interim treatment due to ONE of the following:
 - i. Awaiting scheduled placement of an ICD within 3-months; *or*
 - ii. Placement of the ICD is precluded by a temporary condition, such as a systemic infection requiring treatment; *or*
 - iii. ICD requires temporary explantation (removal) due to an infection or mechanical complication; *or*
 - iv. Listed for and awaiting heart transplantation; *or*
 - v. Other medical contraindications to immediate ICD placement.
 - b. Member has ALL of the following:
 - i. Ischemic heart disease; *and*
 - ii. Documented left ventricular ejection fraction (LVEF) $\leq 35\%$; *and*
 - iii. Currently within 40 days of myocardial infarction (MI) and/or within 90 days of revascularization with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG); *and*
 - iv. Reevaluation of LVEF and functional class is scheduled for 1-2 months from the time of MI or for 3 months from the time of diagnosis of cardiomyopathy in the case of revascularization without MI; *and*

- v. Documentation provided from the cardiologist that the member has been counseled regarding the estimated save rate, inappropriate shock rate, and the member is highly motivated to comply with the WCD; *and*
 - vi. A provider is responsible for critical data transmissions from the monitoring function of the WCD; *or*
- c. Member has ALL of the following:
 - i. Non-ischemic cardiomyopathy (NICM) and class II-III HF; *and*
 - ii. \leq LVEF of 35%, and HF is newly diagnosed (<3 months guideline-directed medical therapy (GDMT) or not on optimal GDMT); *and*
 - iii. Reevaluation of LVEF and functional class is scheduled for approximately 3 months from the time of initial diagnosis of NICM, and guideline-directed medical therapy is initiated with a documented plan for follow-up to up-titrate to maximum tolerated GDMT within 90 days; *and*
 - iv. Documentation provided from the cardiologist that the member has been counseled regarding the estimated save rate, inappropriate shock rate, and the member is highly motivated to comply with the WCD; *and*
 - v. A provider is responsible for critical data transmissions from the monitoring function of the WCD; *or*
- d. Member had sudden cardiac arrest due to ventricular fibrillation, or sustained ventricular tachycardia, with LVEF more than 35%, when reversible cause is established and could be treated (electrolyte abnormalities, drug poisoning, etc.).

Pediatric Patients

The Plan understands the life-threatening nature of sudden cardiac arrest and will consider the medical necessity of wearable cardioverter-defibrillator in pediatric members on a case-by-case basis, assuming the following criteria necessary for safe fitting are met:

1. Has a chest circumference of 26 inches or greater; *and*
2. Weighs 18.75kg or greater; *and*
3. Informed consent is provided by the parent or legal guardian.

Note: Wearable cardioverter-defibrillators were recently approved by the FDA for usage in the pediatric population (e.g., LifeVest). There is currently insufficient information to evaluate the clinical efficacy and benefit of these devices in this population.

Authorization Period & Extension Requests

The Plan considers the following medically necessary when ONE of the following criteria is met:

1. For initial requests, when approved, authorizations are generally provided for up to a 90-day period; *or*

2. For bridge treatment, the authorization duration is from discharge until the ICD placement surgery; *or*
3. Requests to extend the authorization period must be submitted with documentation of $\geq 70\%$ compliance and continued medical necessity from the treating provider.

Experimental or Investigational / Not Medically Necessary

The Plan considers the following as contraindications to wearable cardioverter-defibrillators:

1. Use in members with an active implantable cardioverter-defibrillator (ICD).

The Plan considers wearable cardioverter-defibrillators as NOT medically necessary for the following:

1. Members with a history of significant nonadherence with medical therapy and lack of follow-up. Furthermore, if the member does not consistently wear the wearable cardioverter-defibrillator, the device should be discontinued from the plan of care and returned.
2. Members diagnosed with cardiomyopathy more than 2 years ago. The indication for a wearable cardioverter-defibrillator is to prevent sudden death, and a time lapse of 2 years may be beyond the period of clinical utility or benefit.

The Plan considers wearable cardioverter-defibrillators experimental, investigational, or unproven for any indication not listed in the medical necessity criteria, as safety and efficacy have not been established.

This includes, but is not limited to, the following:

1. Members with a life expectancy of less than 6 months.

Applicable Billing Codes

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
93282	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system
93289	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 transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
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
93295	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
93745	Initial set-up and programming by a physician or other qualified healthcare 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	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

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Clinical Guideline Revision / History Information

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