Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member’s plan contracts, state laws, and federal laws. Please reference the member’s plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Wearable Cardioverter-Defibrillator Devices

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 the clothing, usually contained within a garment such as a cloth vest, and function much in the same manner as an internal cardiac defibrillator (ICD) without requiring invasive implantation. Wearable cardioverter-defibrillators are appropriate for persons with certain life-threatening cardiac conditions. The wearable cardioverter-defibrillator both identifies cardiac arrest in a person wearing the device and also can apply the electric current when cardiac arrest is detected.

The only commercially available wearable cardioverter-defibrillator in the United States is the LifeVest® 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.
Definitions

"Wearable Cardioverter-Defibrillator" is a non-invasive 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 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 the 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" 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.

Clinical Indications and Coverage

Oscar considers a wearable cardioverter-defibrillator medically necessary when ALL of the following are present:

1. The device is being ordered by a cardiologist with appropriate specialization; and
2. The patient is at high risk for sudden cardiac death; and
3. The device can be properly fitted, which includes patients with a chest circumference of less than 57 inches (144 cm) and may preclude some morbidly obese patients; and
4. The total duration of device usage has not exceeded 6 months; and
5. ONE of the following exists:
a. Criteria for an ICD (MCG 21st edition: Electrophysiologic Study and Implantable Cardioverter-Defibrillator (ICD) Insertion - M-157) is 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; 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 due to an infection or mechanical complication; or
   iv. Listed for and awaiting heart transplantation; or
   v. Other medical contraindication to immediate ICD placement.

b. A wearable cardioverter-defibrillator may be covered as a bridge treatment to further ICD risk stratification and possible implantation in patients who have a left ventricular ejection fraction (LVEF) of ≤ 35% AND are determined to be at high risk for sudden cardiac death in one of the following settings:
   i. A newly diagnosed non-ischemic cardiomyopathy; or
   ii. Following discharge for a myocardial infarction (MI); or
   iii. Following discharge for coronary artery bypass grafting (CABG); or
   iv. Following percutaneous coronary intervention (PCI).

Pediatric Patients
Wearable cardioverter-defibrillators were recently approved by the FDA for usage in the pediatric population. There is currently insufficient information to evaluate the clinical efficacy and benefit of these devices in this population. Oscar understands the life threatening nature of sudden cardiac arrest and will consider coverage of wearable cardioverter-defibrillator in pediatric members on a case-by-case basis, assuming the following criteria necessary for safe fitting are met:

- Has a chest circumference of 26 inches or greater; and
- Weighs 18.75kg or greater; and
- Informed consent provided by their parent or legal guardian.

Authorization Period & Extension Requests
When approved, authorizations are provided for up to a 90 day period. For bridge treatment, the initial time period begins at the date of discharge for the index event. Requests to extend the authorization period must be submitted with documentation of compliance and continued medical necessity from the treating provider.
**Coverage Exclusions**

Wearable cardioverter-defibrillators are contraindicated for use in patients with an active ICD.

Oscar considers wearable cardioverter-defibrillators experimental and investigational for all other conditions as their safety and efficacy have not been established.

Oscar does not consider patient preference for wearable cardioverter-defibrillator over an ICD or patient refusal of ICD implantation to meet medical necessity for use of a wearable cardioverter-defibrillator.

Wearable cardioverter-defibrillators are not designed to keep people alive indefinitely, but rather 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.

**Applicable Billing Codes**

Codes covered if clinical criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>93292</td>
<td>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</td>
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<tr>
<td>93741</td>
<td>Electronic analysis of pacing cardioverter-defibrillator (includes interrogation, evaluation of pulse generator status, evaluation of programmable parameters at rest and during activity where applicable, using electrocardiographic recording and interpretation of recordings at rest and during exercise, analysis of event markers and device response); single chamber or wearable cardioverter-defibrillator system, without reprogramming</td>
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<tr>
<td>93745</td>
<td>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</td>
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<tr>
<td>K0606</td>
<td>Automatic external defibrillator, with integrated electrocardiogram analysis, garment type</td>
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<td>--------------------------------------------------------------------------------------</td>
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<tr>
<td>K0607</td>
<td>Replacement battery for automated external defibrillator, garment type only, each</td>
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<tr>
<td>K0608</td>
<td>Replacement garment for use with automated external defibrillator, each</td>
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<tr>
<td>K0609</td>
<td>Replacement electrodes for use with automated external defibrillator, garment type only, each</td>
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References


Clinical Guideline Revision / History Information

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<th>Original: Review/Revise Dates</th>
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<tr>
<td>Original Date:</td>
<td>8/25/2017</td>
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<tr>
<td>Reviewed/Revised:</td>
<td>1/18/2018</td>
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<tr>
<td>Signed:</td>
<td>Sean Martin, MD, Medical Director</td>
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