Subject: Wearable Cardioverter Defibrillator (WCD)

Overview: 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.

Policy and Coverage Criteria:

NOTE: Prior Authorization is NOT required

HPHC covers LifeCor Wearable Cardioverter Defibrillators as a bridge to automatic implantable cardioverter defibrillators (AICD) in situations where the PCP or attending provider determines the member is at high risk for sudden cardiac death.

Exclusions: N/A

Supporting Information:

1. Technology Assessment: The LifeVest™ is a wearable cardioverter defibrillator (WCD) used on an outpatient basis that was developed by Lifecor Inc. The LifeVest is designed to perform the same functions as an automatic implantable cardioverter defibrillator (ICD), but is worn outside the body and therefore is noninvasive. The LifeVest is a combination of two different devices. As a cardioverter, it uses low-energy electrical shocks to return a heart undergoing ventricular tachycardia (abnormally rapid heartbeat) to a normal rhythm. As a defibrillator, it uses high-energy shocks to a heart in a state of ventricular fibrillation to return it to a normal rhythm. If a life-threatening arrhythmia is detected, the nonadhesive therapeutic electrodes release a conductive gel and deliver a shock. Alarms sound prior to shock delivery, and if the patient is conscious the device may be disarmed.

2. Literature Review:

Two pivotal studies were designed to examine the safety and efficacy of the LifeVest WCD system. The WEARIT study enrolled ambulatory patients typical of those awaiting a heart transplant and who had an LVEF < 30% and New York Heart Association (NYHA) functional Class III or IV heart failure. These patients went on to receive the heart transplant, implantation of an ICD, or a circulatory assist device. The BIROAD study enrolled patients who were waiting for ≤ 4 months for implantation of an ICD, and included patients who had experienced a recent MI or received a coronary artery bypass graft (CABG). Additional inclusion criteria for the BIROAD study were complication of the CABG or MI with ventricular tachyarrhythmias within 48 hours of the event, an LVEF < 30% at least 3 days after the event; a Killip Class III or IV 3 days following the infarction and syncopal ventricular tachyarrhythmias 2 days postinfarction. Although the BIROAD and WEARIT studies were initiated independently in a total of 18 centers in the United States and 1 center in Germany, the FDA requested that the two studies be combined with each group being considered as a subpopulation. The LifeVest WCD version used in these studies was programmed to produce a monophasic waveform with a maximum output of 285 joules. The trial was designed to end when the primary efficacy endpoint was attained. The primary endpoint was a successful defibrillation in 25% of events with a 90% confidence interval with > 50% power. A total of 289 patients were
enrolled prior to the study reaching the primary endpoint (177 and 112 patients in the WEARIT and BIROAD arms, respectively). In the combined study, patients had an LVEF of 23%, had a mean age of 55 years, and were predominantly male (82%). Patients used the LifeVest WCD for a total of 873 months with an individual mean usage time of 94 days (range 1 to 1032), and a mean daily wear time of 19.1 hours. During 901 patient months of use, there were six successful defibrillation attempts and two unsuccessful attempts. In both unsuccessful attempts, the device was being worn incorrectly (the defibrillating pads were reversed and not directed to the skin). There were six inappropriate shocks. Six sudden deaths occurred during the study; in five cases, the patient was not wearing the device at the time, and in one, it was being worn incorrectly. Of the 289 subjects, 65 (22 percent) stopped using the device because of discomfort or inconvenience; 17 patients reported skin rash or itching.

Chung et al. published aggregate data from the manufacturer's database on national event rates, compliance, and survival. The average duration of use was 52.6 ± 69.9 days, and mean daily use was 19.9 ± 4.7 hours. Of the 2169 patients with recorded data, 14.2% stopped wearing the WCD prematurely due to comfort issues or adverse reactions. Eighty sustained VT/VF events occurred in 59 patients (1.7%). First-shock success was 76 of 76 (100%) for unconscious VT/VF and 79 of 80 (99%) for all VT/VF. Eight patients died after successful conversion of unconscious VT/VF (89.5% survival of VT/VF events). Asystole occurred in 23 (17 died), pulseless electrical activity in 2, and respiratory arrest in 1 (3 died), representing 24.5% of sudden cardiac arrests. During WCD use, 3,541 of 3,569 patients (99.2%) survived overall. Survival occurred in 72 of 80 (90%) VT/VF events and 78 of 106 (73.6%) for all events. Long-term mortality was not significantly different from first ICD implant patients but highest among patients with traditional ICD indications. Chung et al. concluded compliance was satisfactory with 90% wear time in >50% of patients and low sudden death mortality during use. Survival was comparable to that of ICD patients. However, asystole was an important cause of mortality in sudden cardiac arrest events.

Additional studies support the use of WCD devices as a bridge for high-risk patients before ICD implantation (Sasaki et al., 2014; Epstein et al., 2013; Klein et al., 2013; Adler et al., 2013; Knops et al., 2012).

3. Professional/Governmental Agencies:

FDA: LIFECOR Wearable Cardioverter Defibrillator (WCD) 2000 – Approved by FDA on December 18, 2001
Content archived
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm083949.htm#

Codes:

CPT codes:
93745: Initial set-up and programming by a physician of wearable cardioverterdefibrillator 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 Codes:
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

References:

Summary of Changes

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<th>Date</th>
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<tbody>
<tr>
<td>4/17</td>
<td>Removed Benchmarks</td>
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