Subject: Wearable Cardioverter Defibrillator (WCD), LifeVest® as a Bridge to Implantable Cardioverter-Defibrillator Placement	Original Effective Date: 1/5/2007
Guidance Number: MCG-022	**Revision Date(s):** 2/28/08, 7/09, 9/10/09, 6/29/12
Medical Coverage Guidance Approval Date: 6/29/12	

PREFACE

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: http://www.cms.hhs.gov/center/coverage.asp.

FDA INDICATIONS

The FDA has approved LifeVest products (e.g., LifeVest WCD 2000 System and LifeVest WCD 3000 System) via premarket approval application. Several supplemental approvals have been issued for the LifeVest for minor software, design, and trade name changes. The FDA labeled indications for use is for "adult patients at risk for sudden cardiac arrest and are either not candidates for or refuse an implantable defibrillator."[1,38]

According to the FDA Patient Safety News, "in clinical trials, the Wearable Cardioverter Defibrillator was 71% successful in the treatment of sudden cardiac arrest compared to 25% success rate for patients who called 911. The device effectively detected and treated five incidents of sudden cardiac arrest, and detected two other incidents that were untreatable. The two failures to treat occurred because the patients incorrectly assembled the electrodes in the vest. As a result, Lifecor made some modifications to the vest in order to make it more user-friendly.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

A National Coverage Determination has not been developed by CMS addressing wearable cardioverter defibrillators or LifeVest Products. Local coverage determinations are available for wearable external cardiac defibrillators. A National Coverage determination exists for implantable cardioverter-defibrillators.

INITIAL COVERAGE CRITERIA

A wearable Cardioverter Defibrillator (WCD) LifeVest is considered medically necessary and may be authorized for adult patients who are 18 years of age and older and at high risk of sudden cardiac arrest that meet ***ALL*** of the following criteria:

- ❑ The WCD serves as a temporary bridge to ICD implantation due to a temporary contraindication or complication to receiving an ICD (e.g., current systemic infection, less than 40 days post MI,[1,6,29] mechanical failure of current ICD waiting for reimplantation). The ICD is scheduled for implantation once resolved.

- ❑ The WCD is prescribed by a cardiologist

- ❑ The rationale for the use of the Wearable Cardioverter Defibrillator must not fall under the definition of a convenience item.

- ❑ A candidate for WCD must submit chart note documentation meeting one of the following indications for the surgical placement of an implantable cardioverter defibrillator (ICD)[6]:

    - History of cardiac arrest due to ventricular fibrillation (VF) or hemodynamically unstable ventricular tachycardia (VT) following an evaluation to define the cause of the event and to exclude any completely reversible causes (e.g., electrolyte imbalance, drug-induced, trauma, hypoxia).[6,17,20,21] One of the following criteria must also be met[6,17,20,21]:

        - ◊ NO CAD by angiogram
        - ◊ CAD by angiogram with one of the following:
            - ➢ Percutaneous coronary Intervention (PCI)/CABG performed > 12 weeks prior
            - ➢ Not remediable by PCI/CABG

    - Left ventricular dysfunction with prior MI (Ischemic Cardiomyopathy) and one of the following:

        - ◊ *LVEF less than 35% due to prior MI who are minimally 40 days[1,6,29] postmyocardial infarction and who are in NYHA functional class II or III.

        - ◊ OR

        - ◊ *LVEF less than 30%, due to prior MI who are minimally 40 days[1,6,29] postmyocardial infarction and are in NYHA Class I.[6]

        - ◊ *LVEF $\leq$ 40 percent with nonsustained ventricular tachycardia (<30 seconds) due to prior MI who are minimally 40 days[1,6,29] postmyocardial infarction would require a Holter monitor. [2,6,34] Nonsustained ventricular tachycardia on Holter monitoring would warrant a referral for EP study (MUSTT and MADIT I and II trials).[3,4,5] If the EP study is positive and ICD is contraindicated WCD would be appropriate.[2]

    AND

One of the following criteria must also be met: [6,17,20,21]:

NO CAD by angiogram

- ◊ CAD by angiogram with one of the following:
  - ➢ PCI/CABG performed > 12 weeks prior
  - ➢ Not remediable by PCI/CABG

- ❑ Nonischemic dilated cardiomyopathy
  - o *LVEF less than or equal to 35% and who are in NYHA functional class II or III.

    * ***NOTE***- Ejection fractions must be measured by angiography, radionuclide scanning, echocardiography[36]

- ❑ Ventricular fibrillation or sustained ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an (EP) 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. One of the following criteria must also be met: [6,17,20,21]
  - o No CAD by angiogram
  - o CAD by angiogram with one of the following:
    - ◊ PCI/CABG performed >12 weeks prior
    - ◊ Not remediable by PCI/CABG

- ❑ Inherited or familial conditions that carry a high risk for life-threatening ventricular tachyarrhythmias such as hypertrophic cardiomyopathy or long QT Syndrome (QRS duration $\geq$ 120 msec)[6,35] that are not related to transient or reversible causes. One or more of the following risk factors must be present:
  - o Prior cardiac arrest
  - o A family history of one of the following:
    - ◊ Sudden cardiac death in a first degree relative (e.g., sibling, parent or child) $\leq$ 40
    - ◊ Sudden cardiac death in a first degree relative (e.g., sibling, parent or child) with hypertrophic cardiomyopathy
    - ◊ left ventricular/septal thickness > 30 mm[6,16,34]
    - ◊ Unexplained Presyncope/syncope $\geq$ 2 episodes by hx
    - ◊ Abnormal exercise BP including failure BP to rise >25mmHg from baseline or decrease <10mmHg from the maximal BP during exercise [9]

- ❑ Long-QT syndrome (QRS duration $\geq$ 120msec)[6,23] and/or VT while receiving beta-blockers who are experiencing recurrent syncope or have a history of sudden cardiac arrest[6,23]

  Note: Literature indicates beta blocker-treatment is effective on about 70% of long QT

syndrome patients, and 30% of patients remain at increased risk despite treatment[35]

- Inducible ventricular fibrillation at EP testing with one of the following[6,40]:

  - ◊ No CAD by angiogram
  - ◊ CAD by angiogram with one of the following:
    - ➢ PCI/CABG performed > 12 weeks prior
    - ➢ Not remediable by PCI/CABG

Equipment Approval Information:

1. WCD meeting coverage criteria will be approved as a monthly rental (average approvals are from 1 to 3 months)

2. The monthly rental includes all necessary equipment, delivery, maintenance and repair costs, parts, supplies and services for equipment set-up, maintenance and replacement of worn essential accessories or parts.

   NOTE: The 'Coverage Criteria" for implantable cardioverter-defibrillators are based upon the 2008 ACC/AHA/HRS Guidelines[6] for Device-Based Therapy of Cardiac Rhythm (evidence Levels A and B)

CONTINUATION OF THERAPY

The lifeVest WCD should be worn temporarily to bridge the gap between an ICD insertion/reinsertion. The WCD should not be required for use for longer than 3 months. A monthly review of the patient's condition should be conducted to evaluate the need for an additional month rental.

COVERAGE EXCLUSIONS

A WCD LifeVest is considered ***experimental/investigational*** or ***not medically necessary*** in the following patients :

- Any indication that is not listed under the 'Coverage Criteria ' section
- Members whose ventricular tachyarrhythmia's may be resulting from reversible causes such as digitalis intoxication, electrolyte imbalance, hypoxia or whose ventricular tachyarrhythmia's have a transient cause such as acute myocardial infarction[6]
- a physical or mental deficit that would impair your interaction with the LifeVest[39] (e.g., chest wall deformity, uncontrollable movement disorders, skin conditions under the vest, psychiatric illnesses that clearly interfere with patient understanding and acceptance of the vest, etc.)
- Irreversible NYHA class IV congestive heart failure without an option of cardiac transplantation[6]
  Note: The ACC/AHA/HRS 2008 guidelines indicate "Class IV status itself is a heterogeneous and dynamic state in which the absolute incidence of sudden death increases but the proportion of sudden

deaths prevented by ICD's declines, and heart failure deaths account for greater proportion of overall mortality."[6]

- Patients that do not have a reasonable expectation of survival with an acceptable functional status for at least 1 year even if they meet ICD implantation criteria[6]

The following are considered contraindications outlined by the FDA in members with the following[38]:

- need an ICD or already have an operating ICD
- are under age 18
- have a vision or hearing problem that may interfere with reading or hearing the WCD messages
- are taking medication that would interfere with pushing the response buttons on the WCD alarm module
- are unwilling or unable to wear the device continuously, except when bathing or showering
- are pregnant or breastfeeding
- are of childbearing age and not attempting to prevent pregnancy
- are exposed to excessive electromagnetic interference (EMI) from machinery such as powerful electric motors, radio transmitters, power lines, or electronic security scanners, as EMI can prevent the WCD from detecting an abnormal heart rhythm

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

The LifeVest wearable cardioverter defibrillator (WCD) is an external device that is intended to perform the same tasks as an ICD, without requiring invasive procedures.[7] The device is designed for use by adult patients, 18 years of age or older, 24 hours a day to monitor and treat ventricular fibrillation and ventricular tachycardia, life-threatening arrhythmias that require immediate treatment. The system is programmed to sense heart function and to automatically deliver an electric shock when needed to restore normal heart rhythm. This vest-like medical device, worn under clothing, is the first cardioverter defibrillator that can be worn outside the body rather than require surgical implantation in the chest. The wearable defibrillator offers another option for patients who are not suitable candidates for an implantable defibrillator.

The WCD is a combination of two different devices. The cardioverter provides low-energy electrical shocks to return an abnormally fast heartbeat, or ventricular tachycardia, to a normal rhythm. The defibrillator delivers high-energy electrical shocks to return a very fast, disordered heartbeat, or ventricular fibrillation, to a normal rhythm. The WCD does the same job as an implantable cardioverter defibrillator (ICD) but is noninvasive, requiring no surgery, implantation, or entry into the body.

The WCD is fully automatic and requires no patient action to deliver treatment. The device continuously monitors the patient's heart rhythm. The detection of an abnormal heart rhythm requires the patient to depress and hold two response buttons to prevent the treatment shock from occurring. The device is programmed to identify if the patient releases the buttons as a result of loss of consciousness; the WCD will then deliver the

electrical shock. Usually, once a week, the patient connects the monitor to an external modem that will relay data by telephone to the physician's computer for medical review purposes.

Complications/Potential Adverse Events[25]

The most commonly observed adverse events in the combined FDA pivotal trial included 5.9% with skin rashes, and 2.1% with inappropriate defibrillation. The inappropriate defibrillations were noted in 873 patient-months in 6 patients resulting in 0.69% rate per patient-month. There were no induced arrhythmias resulting from the inappropriate defibrillations. The manufacturer made modifications to the device during the last year of the combined trial study and no appropriate defibrillations were observed following these modifications. The inappropriate defibrillation rate reported by the manufacturer during commercial use is 1.1% per month of use. Other reported potential adverse events include: disability or death resulting from failure of the device in detecting an arrhythmia or unsuccessful defibrillation or cardioversion, inappropriate shock resulting in abnormal heart patterns, external forces causing device failure such as electromagnetic interference, random component failure, risk of fire if near high oxygen concentrations, shock to bystander from patient contact during treatment, superficial skin burns from treatment, skin breakdown or allergic dermatitis from continuous electrode and skin contact.

New York Heart Association (NYHA) definitions: [32]

The NYHA functional classification system is used to categorize heart failure patients based upon the degree of compromise. This subjective physician review evaluates everyday activities and classifies a patient into one of the four categories:

- Class I (Mild)-No limitation of activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.
- Class II (Mild) - Slight limitation in activity. Comfortable at rest but moderate ordinary physical activity (e.g., such as carrying bags up a flight of stairs) results in fatigue, palpitation, dyspnea, or anginal pain.
- Class III (Moderate) - Marked limitation of physical activity. Comfortable at rest but less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- Class IV (Severe) - Inability to carry out physical activity without discomfort. Symptoms of heart failure or anginal syndrome are present at rest. Any physical activity increases discomfort.

GENERAL INFORMATION

Summary of Medical Evidence

The safety and efficacy of ***implantable cardiac defibrillators (ICD)*** are well established for appropriately selected patients at high risk for sudden cardiac death. ICD placement has become the routine "gold standard" of treatment.[6] Large prospective, randomized, multicenter studies have established that ICD therapy is effective for primary prevention of sudden cardiac death and improves total survival in selected patient populations who

have not previously had a cardiac arrest or sustained ventricular tachycardia.[9-16] Multiple clinical trials have established that ICD use results in improved survival compared with antiarrhythmic agents for secondary prevention of sudden cardiac death.[9,17-24]

There are no randomized control trials and only few published peer-reviewed studies that report on clinical outcomes of ***WCD's.*** There are limited studies comparing the efficacy of WCD use in reducing mortality with alternative treatments such as implantable cardiac defibrillators (ICD), cardiac arrest treatment by emergency medical services personnel, nonwearable external cardioverter defibrillators and pharmacological treatment with antiarrhythmic drugs or neurohormonal agents. There is minimal evidence that establishes the safety or efficacy of WCD. The limited evidence is not considered high quality but does demonstrate that the WCD device can detect lethal arrhythmias and can successfully deliver a counter shock in the majority of cases. These data do not determine the true efficacy of the device or efficacy in comparison to other alternative treatments. ICD is considered superior treatment compared to WCD due to its established safety and efficacy.

Wearable Cardioverter Defibrillator Vest Supporting Evidence

The BIROAD and WEARIT studies were two prospective non-randomized clinical studies performed by the manufacturer and submitted to the FDA for premarket approval.[25] Patients aged 18-75 years (n=289) who were at high risk for sudden cardiac death but did not meet eligibility criteria for placement of an ICD or who would not receive an ICD for several months were included in the trials.

The WEARIT study consisted of 177 patients who had New York Heart Association (NYHA) functional class III or IV symptomatic congestive heart failure with a left ventricular ejection fraction (LVEF) of $\leq$ 30%. These patients either received a heart transplant, implantation of an ICD, or a circulatory assist device.[25] The BIROAD Study enrolled patients having complications associated with a high risk for sudden death following a myocardial infarction complicated by ventricular tachycardia, ejection fraction $\leq$ 0.30% minimally 3 days following the infarct, or an episode of syncope or sudden cardiac arrest minimally 48 hours following an MI but were not candidates for ICD.[25] This study also accepted patients with a ventricular arrhythmia following coronary artery bypass graft (CABG) surgery, left ventricular ejection fraction of <0.30%, 3 days following CABG or had syncope or cardiac arrest at least 48 hours following CABG but were unable to have an ICD implanted.

Although both studies were initiated independently in a total of 18 centers in the United States and 1 center in Germany, the FDA requested the two studies be combined with each group being considered as a subpopulation.[25] This combined prospective non-randomized study with historical controls enrolled 289 patients into 1 of 2 categories: 1) patients awaiting cardiac transplantation, a circulatory-assist device, or a permanent ICD using the WCD as a "bridge" to these procedures; or 2) patients post-myocardial infarction (MI) and/or post-coronary artery bypass graft (CABG) surgery and temporarily at high risk for ventricular arrhythmias (due to documented ventricular tachycardia or fibrillation [VT/VF] during the acute event , or class III or IV congestive heart failure [CHF] post-event) who wore the device up to 4 months or until implantation of a permanent AICD. During 901 patient-months of device use, there were 8 episodes of VT/VF detected, with 6 of these successfully treated with counter shock. There were 6 unnecessary shocks delivered by the device during this period, for a rate of 0.67% per patient-month (95% CI:0.30-1.35). Using historical controls

consisting of patients suffering sudden cardiac arrest who called emergency services (911), a "control" rate of 25% success doe surviving sudden cardiac arrest was obtained. Assuming that the device detected all episodes of VT/VF, the FDA review determined that the device had greater efficacy than the "control" group with 90% confidence.

Reek et al. (2002) published results of a three year study consisting of 84 patients using the WCD.[26] The patients mainly had a history of myocardial infarction, coronary artery bypass surgery or were awaiting heart transplantation. Five patients reported 7 episodes of ventricular tachyarrhythmia's were detected and successfully terminated by the WCD in a mean follow-up of 116 =/-90 days. One patient received an inappropriate shock due to the device over sensing electrical noise in 9720 days. Four deaths were reported that were unrelated to cardiac arrest while wearing the WCD. Five patients were excluded from the study as a result of irregular device use.[26]

One small prospective study (n=15) evaluated the efficacy of transthoracic defibrillation using a WCD in Patients following cardiac arrest with documented ventricular tachycardia/ventricular fibrillation.[27] Five patients had a current ICD that was inactivated during WCD testing. The study was performed during ICD testing or as part of routine electrophysiologic testing. Ventricular defibrillation with or without rapid ventricular tachycardia was induced in 10 of the 15 patients. One shock delivered by the WCD successfully terminated ventricular fibrillation in all patients. Nine of the 10 patients were correctly diagnosed by the device. The induced ventricular tachycardia was not detected in 1 patient as the sensing electrode was erroneously disconnected. The authors concluded "WCD could be used as a feasible bridge to definitive implantation of an ICD in patients in whom risk stratification for sudden death is not completed."[27] One study limitation included a potential difference in device response to a naturally occurring arrhythmia versus an induced arrhythmia.[27]

Chung et al (2010) investigated compliance and effectiveness of antiarrhythmic treatment by using the wearable cardioverter-defibrillator (WCD). Compliance and events were recorded in a nationwide registry of post-market release WCDs. Survival, using the Social Security Death Index, was compared with survival in implantable cardioverter-defibrillator (ICD) patients. Of 3,569 patients wearing the WCD daily use was >90% of the day in 52% of patients. During the study period there were eighty sustained VT/VF events occurring in 59 patients (1.7%). 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. The authors concluded that 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. [43]

Collins et al (2010) investigated the use of a wearable defibrillator in the pediatric population in a retrospective clinical database review, comparing a wearable defibrillator in patient's ≤18 years of age to those aged 19-21 years. There were 81 patients' ≤18 years of age and 103 patients aged 19-21 years There was no difference between groups in average hours/day or in total number of days the patients wore the defibrillator. In patient's ≤18 years of age, there was one inappropriate therapy and one withholding of therapy due to a device-device interaction. In patients aged 19-21 years, there were five appropriate discharges in two patients and one inappropriate discharge in a single patient. The authors concluded it is reasonable to consider the wearable automated external defibrillator as a therapy for pediatric patients who are at high risk of sudden cardiac arrest

but who have contraindications to or would like to defer placement of a permanent ICD, however, as there were no appropriate shocks in our patients ≤18 years of age, the study cannot address efficacy of the therapy. [45]

Implantable Cardioverter Defibrillator Study Results

Two prospective, randomized controlled trials were performed comparing implantable ICD's to conventional therapy for primary prevention of sudden cardiac death.[13,10,28] The Multi-Center Automatic Defibrillator Implantation Trial (MADIT I) trial evaluated 196 patients with a prior myocardial infarction (MI), New York Heart Association functional class I, II, or III and left ventricular ejection fraction of ≤ 35%, and documented asymptomatic unsustained ventricular tachycardia and inducible nonsuppressible ventricular tachyarrhythmia were randomly assigned to receive conventional medical therapy (n=101) or an implanted defibrillator (ICD) (n=95).[13] After 27 months, the conventional therapy group had 27 cardiac related deaths versus 11 in the ICD group. (hazard ratio for mortality 0.46; 95 % confidence, 0.26 to 0.82 p=0.009).[10] The MADIT II study enrolled 1232 patients with an MI one month or more evidenced by an abnormal Q wave and coronary artery disease (CAD) and an ejection fraction of ≤ 30% over a 4 year period.[10,28] This study was a continuation to evaluate ICD versus conventional medical therapy. The results indicated that QRS > 120 ms had a significant reduction in mortality compared with conventional therapy (16% versus 30% respectively; P=0.001) and a small but not statistically significant reduction in mortality (13% versus 16%, respectively). The study was stopped earlier than the original 4 year intent as a 30% reduction in mortality was seen in patients randomized to receive an ICD. The independent review board observed that post-MI patients with impaired LV function had better survival rates compared to those receiving conventional treatment[11]

The DINAMIT trial evaluated the role of prophylactic ICD implantation within the first few weeks after an MI. The criteria for inclusion included patients that had an MI within 6 to 40 days, an LVEF ≤ 35% with elevated resting heart rate (≥ 80 beats/minute or reduced heart rate variability.[16] There was no difference in annual all-cause mortality between ICD and the control groups (7.5 versus 6.9%). The ICD group experienced more nonarrhythmic deaths and the control groups had more arrhythmic deaths. Current guidelines recommend a deferral of ICD implantation until 40 days following an MI. According to Gantz (2007), "waiting one month after MI before considering ICD implantation may expose some patients, especially those with a large MI, to significant risk. In such patients, it may be reasonable to consider use of an ambulatory defibrillator vest."[2]

Connolly et al (2000) performed a meta-analysis evaluating ICD with antiarrhythmic drug therapy.[20] The mortality benefit of an ICD was more prominent in patients with LEVF ≤ 35%, minimal or no benefit was found in LVEF greater than 35%.[14] Sheldon et al. (2000) evaluated 659 patients with resuscitated ventricular tachycardia's who were randomly chosen to receive either ICD or amiodarone therapy for 3 years.

Hayes, Cochrane, UpToDate, MD Consult etc.

A Hayes brief was developed in March of 2007. The brief summarized the LifeVest system as having some potential benefit but unable to establish true efficacy and safety due to the insufficient data and lack of large volume, confirming studies conducted outside of the manufacture sponsored study. The technology is supported by some positive published data regarding safety and efficacy; however, the number of abnormal fibrillation events evaluated in the studies was small volume. Hayes research recommends the device to be

prescribed for use by a cardiologist with training in clinical electrophysiology. Per Hayes, the literature suggests the potential use for bridging the gap following a myocardial infarction prior to the safe ability for implantation of a cardioverter-defibrillator or while waiting for heart transplantation. Literature also suggests it may be considered as a replacement technology for patients that are not candidates for implantable cardioverter-defibrillator (ICD) or following removal of an ICD.[31] Updated research reviews conducted on March 4, 2009 and May 4, 2012 indicate unchanged efficacy from the original 2007 report.

UpToDate [46]

WCD therapy is indicated for those patients who are at risk of sudden cardiac death as a temporary measure including:

- In patients with LVEF ≤35 % and are less than 40 days postmyocardial infarction
- In patients with LVEF ≤35 percent who have undergone coronary revascularization with coronary artery bypass graft (CABG) surgery in the past three months
- In selected patients with severe but potentially reversible cardiomyopathy, such as tachycardia- or myocarditis-associated cardiomyopathy
- In patients with severe heart failure awaiting heart transplantation

A 48 center clinical trial called Evaluating the Effectiveness of the LifeVest Defibrillator and Improving Methods for Determining the Use of Implantable Cardioverter Defibrillators (The VEST/PREDICTS Study NCT00628966) started in 2008. The trial is sponsored by the National Heart Lung and Blood Institute and the manufactures of various cardioverter/defibrillator devices, and is scheduled to end in 2015. [41]

Professional Organizations

The ACC/AHA/Heart Rhythm Society (HRS) 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities does not address use of a WCD.[6] These guidelines have not been updated since the time this document was last reviewed in April 2012.

The American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of Cardiology (ESC) 2006 Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death provides a summary section including Wearable defibrillators. The section indicates that these devices are available for use following FDA approval. Specific recommended criteria for use is not mentioned in the guideline recommendations.[9] These guidelines have not been updated since the time this document was last reviewed in April 2012.

The California Technology Assessment Forum (CTAF) reviewed the scientific evidence for the use of the wearable cardioverter defibrillator (Zoll Lifecor Life Vest) in patients at risk of sudden cardiac arrest. The published peer reviewed literature consisted of uncontrolled case series and case reports and one multicenter prospective trial. The results indicated that the WCD appears to be a useful device in patients who are at risk of

sudden cardiac arrest who are unable to receive an ICD or may not require a permanent ICD. WCD is not appropriate for patients who are not candidates for ICD or refuse ICD placement. [47]

A BlueCross BlueShield Association Technology Assessment Report in 2010 was conducted to determine if the wearable cardiac defibrillator improves outcomes when used as a bridge to permanent ICD placement. The term "bridge" refers to use in patients who are at high risk of sudden cardiac death, but who do not yet meet the criteria for a permanent ICD. A total of 5 studies were reviewed. Two of the 5 were uncontrolled studies that evaluated the ability of the WCD to detect and abort ventricular arrhythmias. The other 3 were randomized, controlled trials of early ICD implantation for patients at high risk for ventricular arrhythmias, 2 evaluating the early post-MI period, and the third evaluating patients following coronary artery bypass graft (CABG) surgery. The authors concluded that the WCD successfully aborts arrhythmias but should not be used as a replacement for an ICD in patients who are able to get an ICD, but only considered in those situations where the patient does not meet criteria for a permanent ICD. [42]

The National Institute for Health and Clinical Excellence (NICE) published guidelines for ICD therapy for arrhythmias. These guidelines do not address external wearable defibrillators but indicate that ICD therapy is recommended in patients who have survived a cardiac arrest due to VT or VF as secondary prevention and as primary prevention in patients who are post MI (4 weeks or more) with LVEF $\leq$ 35 % and in patients with familiar conditions that place them at high risk for sudden death. [44]

CODING INFORMATION

CPT	Description
93292	Interrogation device evaluation (in person) with physician analysis, review, and report, includes connection, recording and disconnection per patient encounter; wearable defibrillator system
93745	Initial set-up and programming by a physician 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

HCPCS	Description
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-9	Description
410.0x-410.9x	Acute myocardial infarction

412	Old Myocardial Infarction (use with 429.9)
414.00-414.07	Coronary Atherosclerosis
414.8	Ischemia, myocardial
425.0-425.9	Cardiomyopathy
426.82	Long QT syndrome
427.1	Proxysmal Ventricular tachycardia
427.41	Ventricular fibrillation
427.5	Cardiac arrest
429.9	Heart disease, unspecified (left ventricular dysfunction)
780.2	Syncope and collapse (in conjunction with:425.4/426.82)
796.4	Other abnormal clinical findings(abnormal exercise BP (in conjunction with 425.4/426.82)
996.04	Mechanical complication of cardiac device, implant, and graft due to automatic implantable cardiac defibrillator
996.61	Infection and inflammatory reaction due to internal prosthetic device, implant, and graft
V17.41	Family History of sudden cardiac death (in conjunction with one of the following; 425.4/426.82)
V45.81	CABG Status (in conjunction with 414.00-414.07)
V45.82	PTCA Status (in conjunction with 414.00-414.07)

ICD-10	**Description**
I21.09	ST elev stemi MI invlv oth cor art ant wall
I21.09	ST elev stemi MI invlv oth cor art ant wall
I22.0	Subsqt st elev stemi MI ant wall
I21.09	ST elev stemi MI invlv oth cor art ant wall
I21.09	ST elev stemi MI invlv oth cor art ant wall
I21.01	ST elev stemi MI invlv LMCA

I21.02	ST elev stemi MI invlv LAD
I21.09	ST elev stemi MI invlv oth cor art ant wall
I22.0	Subsqt st elev stemi MI ant wall
I21.09	ST elev stemi MI invlv oth cor art ant wall
I21.19	ST elev stemi MI invlv oth cor art inf wall
I21.19	ST elev stemi MI invlv oth cor art inf wall
I22.1	Subsqt ST elev stemi MI inf wall
I21.19	ST elev stemi MI invlv oth cor art inf wall
I21.11	ST elev stemi MI invlv RCA
I21.11	ST elev stemi MI invlv RCA
I22.1	Subsqt ST elev stemi MI inf wall
I21.11	ST elev stemi MI invlv RCA
I21.19	ST elev stemi MI invlv oth cor art inf wall
I21.19	ST elev stemi MI invlv oth cor art inf wall
I22.1	Subsqt ST elev stemi MI inf wall
I21.19	ST elev stemi MI invlv oth cor art inf wall
I21.29	ST elev stemi MI invlv other sites
I21.29	ST elev stemi MI invlv other sites
I22.8	Subsqt ST elev stemi MI other sites
I21.29	ST elev stemi MI invlv other sites
I21.29	ST elev stemi MI invlv other sites
I21.29	ST elev stemi MI invlv other sites
I22.8	Subsqt ST elev stemi MI other sites
I21.29	ST elev stemi MI invlv other sites
I21.4	Non-ST elevation nstemi MI
I21.4	Non-ST elevation nstemi MI

I22.2	Subsequent non-ST elevation nstemi MI
I21.4	Non-ST elevation nstemi MI
I21.29	ST elev stemi MI invlv other sites
I21.21	ST elev stemi MI invlv lt circumflex cor art
I21.29	ST elev stemi MI invlv other sites
I22.8	Subsqt ST elev stemi MI other sites
I21.29	ST elev stemi MI invlv other sites
I21.3	ST elev stemi MI unspec site
I21.3	ST elev stemi MI unspec site
I22.9	Subsqt ST elev stemi MI unspec site
I21.3	ST elev stemi MI unspec site
I25.10	ASHD native cor art w/o angina pectoris
I25.10	ASHD native cor art w/o angina pectoris
I25.110	ASHD native cor art w/unstable angina pec
I25.111	ASHD native cor art w/angina pectoris doc spasm
I25.118	ASHD native cor art w/other forms angina pectoris
I25.119	ASHD native cor art w/uns angina pectoris
I25.710	Atheroscler autol vein cor art bp gft unstable angina
I25.711	Athero autol vein cor art bp gft w/ap doc spasm
I25.718	Atheroscler autol vein CABG w/oth forms ap
I25.719	Atheroscler autol vein cor art bp gft uns ap
I25.810	Atheroscler CABF w/o angina pectoris
I25.730	Atheroscler nonautol bio cor art bp gft unstable ap
I25.731	Atheroscler nonautol bio CABG w/ap w/doc spasm
I25.738	Atheroscler nonautol bio CABG w/other forms ap
I25.739	Atheroscler nonautol gio cor art bp gft w/uns ap

I25.810	Atheroscler CABG w/o angina pectoris
I25.720	Atheroscler autol art cor art bp gft unstable ap
I25.721	Atheroscler autol art CABG w/ap doc spasm
I25.728	Atheroscler autol art cor art BP graft oth form ap
I25.729	Atherosclero autol art CABG w/uns ap
I25.790	Atheroscler other CABG w/unstable ap
I25.791	Atheroscler oth CABG w/ap doc spasm
I25.798	Atheroscler oth CABG other forms ap
I25.799	Atheroscler oth CABG w/unst ap
I25.810	Atheroscler CABG w/o angina pectoris
I25.700	Atheroscler CABG uns unstable ang pec
I25.701	Atheroscler CABG uns w/ap doc spasm
I25.708	Atheroscler CABG uns angina pect
I25.709	Atheroscler CABG uns w/uns ap
I25.790	Atheroscler oth CABG uns w/unstable ap
I25.791	Atheroscler oth CABG uns w/ap doc spasm
I25.798	Atheroscler oth CABG uns oth forms ap
I25.799	Atheroscler oth CABG w/unst ap
I25.810	Atheroscler CABG w/o angina pectoris
I25.750	Aheroscler natv cor art tplnt hrt w/unstable ap
I25.751	Atheroscler natv cor art tplnt hrt w/ap doc spasm
I25.758	Atheroscler natv cor art tplnt hrt w/oth forms ap
I25.759	Atheroscler natv cor art tplnt hrt w/uns ap
I25.811	Atheroscler natv cor art tplnt hrt w/o ap
I25.760	Atheroscler byps gft cor art tplnt hrt unstbl ap
I25.761	Atheroscler bp gft cor art tplnt hrt w/ap spasm

I25.768	Atheroscler bp gft cor art tplnt hrt oth form ap
I25.769	Atheroscler bp gft cor art tplnt hrt w/uns ap
I25.812	Atheroscler bp gft cor art tplnt hrt w/o ap
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.89	Other forms chronic ischemic heart dz
I25.9	Chronic ischemic heart disease unspecified
I42.1	Obst hypertrophic cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.8	Other cardiomyopathies
I42.4	Endocardial fibroelastosis
I42.0	Dilated cardiomyopathies
I42.5	Other restrictive cardiomyopathy
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy unspecified
I45.81	Long QT syndrome
I47.0	Re-entry ventricular arrhythmia
I47.2	Ventricular tachycardia
I49.01	Ventricular Fibrillation
I46.2	Cardiac arrest d/t underly cardiac cause
I46.8	Cardiac arrest d/t oth underly condition
I46.9	Cardiac arrest cause unspecified
I51.9	Heart disease unspecified
I52	Other heart disorders in dz clas elsw
R55	Syncope and collapse
T82.110A	Breakdwn mech card electrode init enc

T82.111A	Brkdwn mech card pulse gen batt init enc
T82.118A	Brkdwn mec oth card elec device init enc
T82.119A	Bkdwn mech uns card elec device init enc
T82.120A	Displacement cardiac electrode init enc
T82.121A	Displacement card pulse gen batt init enc
T82.128A	Dsplacement oth card elec device init enc
T82.129A	Dsplacment uns card elec device init enc
T82.190A	Oth mech comp card electrode init enc
T82.191A	Oth mech comp cardiac pulse gen batt init encounter
T82.198A	Oth mech comp oth card elec device init enc
T82.199A	Oth mech comp uns card device init enc
Z82.41	Family history of sudden cardiac death
Z95.1	Presence of aortocoronary bypass graft
Z95.5	Presence of coronary angioplasty implant & graft

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