

Medical Policy Manual

Topic: Wearable Cardioverter-Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator Placement

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

A wearable cardioverter-defibrillator (WCD) is a temporary, external device that is an alternative to an implantable cardioverter-defibrillator (ICD). It is primarily intended for temporary conditions for which an implantable device is contraindicated, or for a period of time during which the need for a permanent implantable device is uncertain.

Background

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease. The implantable cardioverter-defibrillator (ICD) has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, the use of ICDs has been potentially broadened by studies reporting a reduction in mortality for patients at risk for ventricular arrhythmias, such as patients with prior myocardial infarction (MI) and reduced ejection fraction. ICD placement is a minor surgical procedure, with the ICD device placed under the skin on the chest wall and the cardiac leads placed percutaneously. Potential adverse effects of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary countershocks; however, ICD placement is associated with low complication rates.^[1]

Wearable Cardioverter-Defibrillator (WCD)

The wearable cardioverter-defibrillator (WCD) is an external device that is intended to perform the same tasks as an ICD, without requiring any invasive procedures. It consists of a vest that is worn continuously underneath the patient's clothing. Part of this vest is the "electrode belt" that contains the cardiac monitoring electrodes and the therapy electrodes that deliver a countershock. The vest is connected to a monitor with a battery pack and alarm module that is worn on the patient's belt. The monitor contains the electronics that interpret the cardiac rhythm and determine when a countershock is necessary. The alarm module alerts the patient to certain conditions by lights or voice messages.

Regulatory Status

The Wearable Cardioverter Defibrillator (WCD)[®] 2000 "LifeVest" (Zoll[®] Medical Corporation) received U.S. Food and Drug Administration (FDA) premarket approval (PMA) for "adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator."^[2] However, contraindications to an ICD are few. According to the American Heart Association/American College of Cardiology (AHA/ACC) guidelines on ICD use, the device is contraindicated in patients with terminal illness, with drug-refractory Class IV CHF who are not candidates for transplantation, and in patients with a history of psychiatric disorders that interfere with the necessary care and follow-up post-implantation.^[3] It is not known how many patients refuse an ICD after it has been recommended for them.

MEDICAL POLICY CRITERIA

- I. Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death may be considered **medically necessary** as interim treatment for patients who require an implantable cardioverter defibrillator (ICD) but have a temporary contraindication for ICD placement which is expected to resolve, such as systemic infection. The time period immediately following an acute myocardial infarction (<40 days), during which an ICD would not be implanted, is not considered a temporary contraindication.

See the plan's Medical Policy, [Surgery No. 17, Implantable Cardioverter Defibrillators](#) for ICD criteria.

- II. Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered **investigational** for all other indications including, but not limited to, permanent placement or use immediately (i.e. less than 40 days) following an acute myocardial infarction.

SCIENTIFIC EVIDENCE^[4]

Wearable Cardioverter Defibrillators (WCDs) as an Interim Treatment to Implantable Cardioverter Defibrillator (ICD) Placement

Technology Assessments

The 2010 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment of Wearable Cardioverter-Defibrillators (WCD) identified no controlled trials that specifically evaluated the efficacy of the WCD in comparison to alternatives for patients at high risk of sudden cardiac death.^[5]

The available evidence consisted of two uncontrolled studies that evaluated the ability of the WCD to detect and abort ventricular arrhythmias:

- The first study included 15 patients who were survivors of sudden cardiac arrest (SCA) and scheduled to receive an ICD.^[6] During the procedure to implant a permanent ICD or to test a previously inserted ICD, patients wore the WCD while clinicians attempted to induce ventricular arrhythmias. Of the 15 patients, 10 developed ventricular tachycardia or ventricular fibrillation. The WCD correctly detected the arrhythmia in 9 of 10 cases and successfully terminated the arrhythmia in all 9 cases.
- The prospective WEARIT/BIROAD study evaluated the WCD in 289 patients at high risk for sudden cardiac death who did not meet criteria for an ICD or who could not receive an ICD for several months.^[7] During the main follow-up time of 3.1 months, there were 8 documented episodes of arrhythmia requiring shock in 6 separate patients. Six of the 8 episodes were successfully resuscitated by the WCD (successful resuscitation = 69%). In the 2 cases of unsuccessful defibrillation, the authors reported that the WCD was placed incorrectly (electrodes reversed and not directed to the skin). In addition, the high study dropout rate (22%) was due to the inconvenience and discomfort associated with wearing the device.

Although limited, the TEC Assessment found the evidence sufficient to conclude that WCD can successfully identify and terminate malignant ventricular arrhythmias because:

- It is established that correctly placed sensor leads can successfully detect and characterize arrhythmias and that successful countershock can be delivered externally (the novelty of WCD relates to its packaging and the way it is utilized).
- The small amount of evidence supported that the device successfully terminated arrhythmias (both studies showed relatively high rates of success for the device).

However, the study results also indicated that a WCD is likely to be inferior to an ICD due to suboptimal compliance and difficulty with wearing the device correctly. Therefore, these data corroborated the assumption that a WCD should not be used as a replacement for an ICD, but only considered in those situations where the patient does not meet criteria for permanent ICD placement.

WCD Use Immediately Following an Acute Myocardial Infarction (MI)

Technology Assessments

The 2010 TEC Assessment also evaluated whether treatment with a defibrillator (WCD or ICD) improved overall survival in patients who were at high risk for SCA immediately following an acute MI, or in other high risk patients, when used as a bridge to permanent ICD placement.^[8]

The Assessment failed to identify any direct studies of early WCD treatment. The available evidence consisted of 2 randomized controlled trials (RCTs) of early ICD use post-MI and one RCT of early ICD use post coronary artery bypass graft (CABG):

- Two RCTs that evaluated immediate post-MI patients did not support the hypothesis that early ICD implantation post-MI improves overall survival.^[8,9] Taken together, the trials offered compelling evidence that immediate ICD placement post-MI did not improve mortality compared with delayed placement. However, the main limitation of these trials in extrapolating this data to the WCD as a bridge to permanent ICD placement is that the time frame of the trials

did not correspond precisely to the period of time for which the WCD was intended. The ICD was implanted within 30 or 40 days in these trials, but follow-up continued for 2-3 years and results were analyzed over this entire time period. This is considerably longer than the 1-2 month period that might be expected for WCD use.

- The trial in high-risk post-CABG patients also found no improvement in mortality and no trends toward improvement associated with early ICD placement.^[10]
- The TEC Assessment identified no other clinical trials on the use of defibrillators for other bridging purposes.

In summary, the indirect evidence (studies of ICDs) is suggestive of no benefit to early WCD use. However, randomized clinical trials that specifically study WCDs during this time period are needed to definitively answer this question.

WCD Use for Other Indications

Several non-randomized studies were identified which evaluated the use of WCD as a method to prevent sudden death in a variety of populations.

- Use of WCDs in patients with congenital structural heart disease (CSHD) and inherited arrhythmias (IAs) was described in one registry-based, observational study of 162 patients (CSHD = 43, IA = 119).^[11] The main indication for a WCD was transplant listing in the CSHD group and pending genetic testing in IA group. Although the study suggests that a WCD could be safely used, this study was limited by short-term follow-up and observational design which is not considered a sufficient level of evidence for establishing the safety and effectiveness of WCD use in patients with CSHD or IA.
- A report based on data from a nationwide WCD registry corroborated the conclusion of the 2010 TEC Assessment that device compliance was a significant limitation to WCD effectiveness.^[12] Of more than 3,500 patients enrolled in the registry, full compliance with treatment (defined as wearing the WCD for at least 90% of the day) was achieved in only 52% of patients. The device was discontinued by 14.2% of patients, primarily due to discomfort and/or inconvenience.
- In 2012, a retrospectively matched registry study evaluated WCD in peripartum cardiomyopathy patients.^[13] The study included 107 women with peripartum cardiomyopathy treated with a WCD device and 159 matched women with nonischemic dilated cardiomyopathy, during the period of 2003 through 2009. Patients were identified from a registry of WCD use maintained by the manufacturer of the device. The average length of time that the WCD was used was 124±123 days in the peripartum group and 96±83 days in the matched nonischemic group. There were no appropriate shocks or patient deaths during the time of WCD treatment in the peripartum group compared to 2 appropriate shocks and 11 deaths in the nonischemic group. Following discontinuation of the WCD, there were 3 deaths over a mean follow-up of 3.0±1.2 years in the peripartum group. Ultimately, authors suggest further study is needed to help determine the usefulness of WCD in patients with peripartum cardiomyopathy.
- In another registry study, 809 patients with WCD were compared to 4149 patients who were discharged without a defibrillator after coronary revascularization for left ventricular ejection fraction ≤35%.^[14] Early mortality, within 90 days of surgery, was higher among the non-defibrillator group compared to the WCD group, (post-coronary artery bypass graft surgery 7% versus 3%, P=0.03; post-percutaneous coronary intervention (PCI) 10% versus 2%, P<0.0001). In addition, an adjusted lower risks of long-term mortality in the total cohort (39%, P<0.0001) was observed across the entire WCD group.

- Mitrani and colleagues published a study of 259 patients with newly diagnosed cardiomyopathy who were consecutively prescribed a WCD.^[15] The study was limited by a high rate of lost to follow-up (35%) and non-randomized design, which precluded conclusions regarding the usefulness of WCDs for the detection and treatment of arrhythmias within this group.
- Kao and colleagues published an observational study of 82 patients who were either listed for cardiac transplantation, diagnosed with dilated cardiomyopathy, or receiving inotropic medications and were prescribed a WCD.^[16] Although no sudden cardiac deaths or arrests were reported, this study was limited by a lack of comparison group, variable application of the device and mixed patient demographic.
- In 2013, Tanawuttiwat et al. reported the results of a retrospective, evaluation of 97 patients who received a WCD after their ICD was explanted due to device infection.^[17] Subjects wore the device for a median of 21 days; and during the study period, 2 patients had 4 episodes of arrhythmia that were appropriately terminated by the WCD, 1 patient experienced 2 inappropriate treatments, and 3 patients experienced sudden death outside the hospital while not wearing their WCD device. Similar to the previous nonrandomized studies mentioned above, this study is limited by a lack of controlled comparison group. In addition, this study adds to the body of evidence regarding suboptimal compliance associated with WCD use.

Clinical Practice Guidelines

Guidelines from the major cardiology specialty societies do not make specific recommendations for the use of WCDs. For example, the American College of Cardiology/American Heart Association (ACC/AHA) guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death include a description of WCDs, but do not make a formal recommendation concerning their use.^[18]

Summary

Evidence from a limited number of studies suggests that wearable cardioverter-defibrillators (WCDs) can successfully identify and terminate malignant ventricular arrhythmias in patients who are temporarily not candidates for implantable cardioverter-defibrillator (ICD) placement. However, the evidence also indicates that WCD use is associated with suboptimal compliance and challenges with wearing the device correctly. Evidence on all other uses of WCDs, such as permanent placement or use immediately following an acute myocardial infarction (MI) is extremely limited. Therefore, use of WCDs for prevention of sudden cardiac death is considered investigational for all indications except as interim treatment for patients who require an ICD but have a temporary contraindication.

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CROSS REFERENCES

[Implantable Cardioverter Defibrillator](#), Surgery, Policy 17

CODES	NUMBER	DESCRIPTION
CPT	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
	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
HCPCS	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