

Protocol

Wearable Cardioverter-Defibrillators

(20215)

(Formerly Wearable Cardioverter-Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator Placement)

Medical Benefit		Effective Date: 07/01/14	Next Review Date: 05/15
Preauthorization	Yes	Review Dates: 05/07, 05/08, 05/09, 03/10, 01/11, 01/12, 01/13, 01/14, 05/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

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.

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. ICDs consist of implantable leads in the heart that connect to a pulse generator implanted beneath the skin of the chest or abdomen. 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 counter shocks.

The wearable cardioverter-defibrillator (WCD) is an external device that is intended to perform the same tasks as an ICD, without requiring 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 counter shock. 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 determines when a counter shock is necessary. The alarm module alerts the patient to certain conditions by lights or voice messages.

The U.S. Food and Drug Administration (FDA) approved the Lifecor WCD® 2000 system via premarket application approval in December 2001 for "adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator." The vest was renamed and is now called the Zoll® LifeVest®.

Related Protocol

Implantable Cardioverter Defibrillator (ICD)

Policy (Formerly Corporate Medical Guideline)

Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered **medically necessary** as interim treatment for those who:

- meet the criteria for an implantable cardioverter-defibrillator (refer to Protocol Implantable Cardioverter Defibrillator); and
- have a temporary contraindication to receiving an ICD, such as a systemic infection, at the current time; and
- have been scheduled for an ICD placement or who had an ICD removed and have been rescheduled for placement of another ICD once the contraindication is treated.

Use of WCDs for the prevention of sudden cardiac death is considered **investigational** for the following indications when they are the sole indication for a wearable cardioverter-defibrillator:

- Patients in the immediate (i.e., less than 40 days) period following an acute myocardial infarction.
- Patients post-CABG [coronary artery bypass graft] surgery
- Patients with newly diagnosed nonischemic cardiomyopathy
- Women with peripartum cardiomyopathy
- High-risk patients awaiting heart transplant

Use of wearable cardioverter-defibrillators is considered **investigational** for all other indications.

Policy Guideline

It is uncommon for patients to have a temporary contraindication to implantable cardioverter-defibrillator (ICD) placement. The most common reason will be a systemic infection that requires treatment before the ICD can be implanted. The wearable cardioverter-defibrillator should only be used short term while the temporary contraindication (e.g., systemic infection) is being clinically managed. Once treatment is completed, the permanent ICD should be implanted.

Medicare Advantage

A wearable defibrillator is **medically necessary** for patients at high risk for sudden cardiac death (SCD) if they meet one of the criteria (1-4), described below:

1. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (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; or
2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
3. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or
4. A previously implanted defibrillator now requires explantation.

All other indications for Medicare Advantage members are considered **not medically necessary**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are

considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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