Introduction

Sudden cardiac arrest is when the heart stops beating. It can cause death within minutes if not treated. A cardiac defibrillator is a device that shocks the heart back into normal rhythm to prevent sudden cardiac arrest. A wearable cardiac defibrillator is one type of defibrillator. It’s strapped around the chest and worn underneath clothes. Electrodes (small patches applied to the skin) monitor the heart’s rhythm. Other electrodes deliver the current. The electrodes are attached to a small defibrillation unit, usually worn at the waist. When a life-threatening heart rhythm is detected, an alarm alerts the person and the defibrillator sends a shock to return the heart to a normal rhythm. These vests are useful when surgery to implant a permanent defibrillator is temporarily delayed due to a medical reason. This policy describes when a wearable cardioverter-defibrillator may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
## Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Device</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| **Wearable cardioverter-defibrillator** | The use of a wearable (external) cardioverter-defibrillator (WCD) to prevent sudden cardiac arrest or death (SCD) may be considered medically necessary as interim treatment as a bridge to permanent implantable (internal) cardioverter-defibrillator (ICD) surgery when ALL of the following criteria are met:  
  - The criteria for an ICD placement are met (see Related Coverage Indications section)  
  AND  
  - A temporary contraindication to receiving an ICD placement exists, such as a current systemic infection is being treated  
  OR  
  - An ICD was removed due to a concurrent infection or malfunction  
  AND  
  - The ICD placement or an ICD replacement surgery, if appropriate, will be scheduled once the temporary contraindication is treated or managed |

<table>
<thead>
<tr>
<th>Device</th>
<th>Investigational</th>
</tr>
</thead>
</table>
| **Wearable cardioverter-defibrillator** | Use of a wearable cardioverter-defibrillator for the prevention of sudden cardiac death (SCD) is considered investigational for the following indications when they are the sole indication for a WCD:  
  - Patients in the immediate ( ie, < 40 days) period following an acute myocardial infarction (AMI)  
  - Patients post coronary artery bypass graft (CABG) surgery  
  - High-risk patients awaiting heart transplant  
  - Patients with newly diagnosed nonischemic cardiomyopathy  
  - Women with peripartum cardiomyopathy  
  **Use of WCDs is considered investigational for all other indications.** |
Related Coverage Indications

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

Indications for Implantable Cardioverter-Defibrillator (ICD) implantation
Indications for ICD implantation can be broadly subdivided into two categories:

1. Primary prevention, in patients who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening ventricular arrhythmia such as ventricular tachycardia (VT) or ventricular fibrillation (VF).
2. Secondary prevention, in patients who have experienced a life-threatening episode of VT, after reversible causes have been excluded.

Primary Prevention indication\textsuperscript{31,32} for the use of the automatic ICD in adults includes:

- Ischemic cardiomyopathy with New York Heart Association (NYHA) functional Class II or Class III symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 35% or less

OR

- Ischemic cardiomyopathy with NYHA functional Class I symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 30% or less

OR

- Nonischemic dilated cardiomyopathy (NIDCM) and left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined

OR

- Hypertrophic cardiomyopathy (HCM) with one or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in one or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; one or more runs of non-sustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin)
Related Coverage Indications

and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with HCM

OR

- Diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death:
  - Brugada syndrome
  - Catecholaminergic polymorphic ventricular tachycardia
  - Congenital long QT syndrome
  - Short QT syndrome

Secondary Prevention:

- Patients with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes (eg, acute ischemia) have been excluded

Indications where use of an ICD is considered investigational in primary prevention patients:

- Individual has had an acute myocardial infarction (ie, less than 40 days before ICD treatment)
- Individual has NYHA Class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy ICD device)
- Individual has had a cardiac revascularization procedure in the past 3 months (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) or are candidates for a cardiac revascularization procedure
- Individual has noncardiac disease that would be associated with life expectancy less than 1 year

Documentation Requirements

The patient’s medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Plans for placement of an implantable cardioverter-defibrillator (ICD)
- Temporary contraindication(s) to ICD placement

Coding
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>93292*</td>
<td>Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; wearable defibrillator system</td>
</tr>
<tr>
<td>93745</td>
<td>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</td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>K0606</td>
<td>Automatic external defibrillator, with integrated electrocardiogram analysis, garment type</td>
</tr>
<tr>
<td>K0607</td>
<td>Replacement battery for automated external defibrillator, garment type only, each</td>
</tr>
<tr>
<td>K0608</td>
<td>Replacement garment for use with automated external defibrillator, each</td>
</tr>
<tr>
<td>K0609</td>
<td>Replacement electrodes for use with automated external defibrillator, garment type only, each</td>
</tr>
</tbody>
</table>

*Code 93292 cannot be reported with code 93745.

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**Related Information**

N/A

**Evidence Review**

**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 the period during which the need for a permanent implantable device is uncertain.
Background

Sudden Cardiac Arrest

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease.

Treatment

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, use of ICDs has been broadened by studies reporting a reduction in mortality for patients at risk for ventricular arrhythmias, such as patients with prior myocardial infarction and reduced ejection fraction.

ICDs consist of implantable leads, which are placed percutaneously in the heart, that are connected to a pulse generator placed beneath the skin of the chest or abdomen. ICD placement is a minor surgical procedure. Potential adverse effects of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks.

The wearable cardioverter defibrillator is a external device intended to perform the same tasks as an ICD, without requiring invasive procedures. It consists of a vest 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 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, during which time a conscious patient can abort or delay the shock (see Appendix for graphic).

U.S. Food and Drug Administration (FDA)–labeled indications for the WCD are adults at risk for sudden cardiac arrest (SCA) and either are not candidates for or refuse an implantable ICD. Some experts have suggested that the indications for a WCD should be broadened to include other populations at high risk for SCA. The potential indications include:

- Bridge to transplantation (ie, the WEARIT study population)
- Bridge to implantable device or clinical improvement (ie, the BIROAD study population)
- Post bypass with ejection fraction less than 30%
- Post bypass with ventricular arrhythmias or syncope within 48 hours of surgery
- Post myocardial infarction with ejection fraction less than 30%
- Post myocardial infarction with ventricular arrhythmias within 48 hours
- Drug-related arrhythmias (during drug washout or after, during evaluation of long-term risk)
- Patients awaiting revascularization
- Patients too ill to undergo device implantation
- Patients who refuse device therapy.

**Immediate Post Myocardial Infarction Period**

Evidence on the use of a WCD in the immediate post myocardial infarction (MI) period as a bridge to permanent ICD placement was reviewed in a TEC Assessment (2010). For these patients, indications for a permanent ICD cannot be reliably assessed immediately post-MI because it is not possible to determine the final EF until at least 30 days after the event. Because the first 30 days after an acute MI represent a high-risk period for lethal ventricular arrhythmias, there is a potential to reduce mortality using other treatments. Despite the rationale for this potential indication, the TEC Assessment concluded that the available evidence does not support the contention that any cardioverter defibrillator improves mortality in patients in the immediate post-MI period. Two RCTs (Defibrillator in Acute Myocardial Infarction Trial [DINAMIT], Immediate Risk Stratification Improves Survival [IRIS]) and a post hoc analysis of an RCT the Prophylactic Implantation of a Defibrillator in Patients with Myocardial Infarction and Reduced Ejection Fraction (MADIT-II) led to this conclusion. In the DINAMIT (674 patients) and IRIS (898 patients) trials, which randomized patients with left ventricular ejection fraction (LVEF) of 35% or less to early ICD implantation 6 to 40 days after acute MI or medical therapy alone, there was no significant improvement in overall mortality. The hazard ratio (HR) for overall survival in the DINAMIT and IRIS trial were 1.08 (95% confidence interval [CI], 0.76 to 1.55; p=0.66) and 1.04 (95% CI, 0.81 to 1.35; p=0.78), respectively. Despite a reduction in arrhythmic deaths among patients with an ICD, there was a higher risk of nonarrhythmic deaths during this early period, resulting in similar overall mortality rates in the 2 trials. Secondary analysis of data from the MADIT-II trial showed that the survival benefit associated with ICDs appeared to be greater for remote MI and remained substantial for up to 15 or more years after MI. Within the first 18 months post-MI, there was no benefit found for ICD placement (HR= 0.97; 95% CI, 0.51
to 1.81; p=0.92). In contrast, there was a significant mortality benefit when the length of time since MI was greater than 18 months (HR=0.55; 95% CI, 0.39 to 0.78; p=0.001).

Epstein et al (2013) reported on the results of a postmarket registry data from 8453 post-MI patients who received WCDs for risk of sudden cardiac arrest while awaiting ICD placement. The WCD was worn a median of 57 days (mean, 69 days), with a median daily use of 21.8 hours. Study characteristics and results are summarized in Tables 1 and 2, respectively. While 1.4% of this registry population was successfully treated with WCDs, interpretation of registry data is limited. It is not possible to determine whether outcomes were improved without a control group, and the registry contained limited patient and medical information making interpretation of results difficult.

Uyei and Braithwaite (2014) reported on the results of a systematic review conducted to evaluate the effectiveness of WCD use in several clinical situations, including individuals soon after post-MI (≤40 days) with a LVEF of 35% or less. Four studies (Chung et al [2010], Epstein et al [2013], 2 conference abstracts) assessed the effectiveness of WCD use in post-MI patients. Outcomes reported were heterogeneous. For 2 studies that reported VF- and VT-related mortality, on average, 0.52% (2/384) of the study population died of VF or VT over a mean of 58.3 days of WCD use. For 2 studies that reported on VT and VF incidence, on average, 2.8% (11/384) of WCD users experienced a VT and/or VF event over a mean of 58.3 days of WCD use (range, 3-146 days). Among those who experienced a VT or VF event, on average, 82% (9/11) had successful termination of 1 or more arrhythmic events. Reviewers concluded that the quality of evidence was low to very low quality and confidence in the reported estimates was weak.

The Vest Prevention of Early Sudden Death and PREDiiction of ICD Therapies trial (NCT00628966), which is testing the hypothesis that the WCD reduces sudden death mortality in the first 90 days after an MI in patients with reduced left ventricular function, is anticipated to report its results in 2018 and will yield valuable prospective information on the proportion of patients who improve their LVEF more than 35% percent when receiving acute revascularization after MI.

In summary, two RCTs of ICD use in the early postacute MI period concluded that mortality rates did not improve compared with usual care. In both trials, SCD was reduced in the ICD group, but non-SCD events increased, resulting in no difference in overall mortality. Analysis of data from a retrospective postmarket registry reported a success rate of 82% but interpretation of registry data was limited in absence of a control group. Because a permanent ICD does not appear to be beneficial in the early post-MI period, a WCD would also not be beneficial for these patient populations.
Table 1: Key Nonrandomized Trial Characteristics in Immediate Post-MI Period

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Dates</th>
<th>Participants</th>
<th>Treatment</th>
<th>FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epstein et al (2013)14</td>
<td>Retrospective registry (postmarket study)</td>
<td>U.S.</td>
<td>2005-2011</td>
<td>High-risk post-MI patients during the 40-d and 3-mo waiting periods</td>
<td>WCD</td>
<td>3 mo</td>
</tr>
</tbody>
</table>

FU: follow-up; MI: myocardial infarction; WCD: wearable cardioverter defibrillator.

Table 2: Key Nonrandomized Trial Results in Immediate Post Myocardial Infarction Period

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epstein et al (2013)14</td>
<td>N=8453</td>
</tr>
</tbody>
</table>

Wearable cardioverter defibrillator

- Number of patients receiving shock: 133
- Shock events: 146
- Appropriate shocks: 309
- Shocks successful in terminating VT or VF: 252 (82% success)
- Shocks leading to asystole: 9
- Unsuccessful shocks: 41 (10% failure)
- Inappropriate shocks: 99 patients received 114 inappropriate shocks

VF: ventricular fibrillation; VT: ventricular tachycardia.

*Shocks deemed appropriate if they occurred during sustained (> 30 seconds) VT or VF and inappropriate if not.

Newly Diagnosed Nonischemic Cardiomyopathy

In patients with newly diagnosed nonischemic cardiomyopathy, final EF is uncertain because some patients show an improvement in EF over time. The Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation (DEFINITE) RCT compared ICD implantation plus standard medical therapy with standard medical therapy alone for primary prevention of SCD in patients who had nonischemic cardiomyopathy, nonsustained VT, and a LVEF of 35% or less. Results of this trial did not show a significant reduction in mortality with ICD regardless of duration since diagnosis (HR=0.65; 95% CI, 0.40 to 1.06; p=0.08). A post hoc analysis of the same trial by Kadish
et al (2006) evaluated use of an ICD in patients with nonischemic dilated cardiomyopathy and examined the benefit of ICD use by time since diagnosis (<3 months and >9 months). This trial excluded patients with a clinical picture consistent with a reversible cause of cardiomyopathy and thus may differ from the population considered for a WCD. The difference in survival was of borderline significance for the ICD group compared with controls, both for the recently diagnosed subgroup (HR=0.38; 95% CI, 0.14 to 1.00; p=0.05) and the remotely diagnosed subgroup (HR=0.43; 95% CI, 0.22 to 0.99; p=0.046).

Study characteristics and results are summarized in Tables 3 and 4, respectively. In the WEARIT-II Registry study (discussed previously), 46% (n=927) of patients were prescribed WCD for nonischemic cardiomyopathy. After three months of follow-up, the rate of sustained VTs was 1% among those with nonischemic cardiomyopathy. However, outcomes data (appropriate and inappropriate shocks) were not reported separately for patients with nonischemic cardiomyopathy.

Another potential indication for the WCD is alcoholic cardiomyopathy where cardiomyopathy is reversible but temporary protection against arrhythmias is needed. Salehi et al (2016) reported on the results of analysis of a subset of patients identified from manufacturer registry. Mean EF was 19.9% on presentation. Patients wore the WCD for a median of 51 days and a median of 18.0 hours a day. At the end of WCD use, 33% of patients had improved EF and did not require ICD placement; 24% received an ICD. Four deaths occurred during this period, with one death in a patient wearing WCD (due to ventricular asystole).

Wässnig et al (2016) reported on the results of a national German registry of 6043 patients with multiple etiologies including dilated cardiomyopathy, myocarditis, and ischemic and nonischemic cardiomyopathies who were prescribed WCD. Overall 7 (1%) of 735 patients with nonischemic cardiomyopathy were appropriately shocked for sustained VT or VF.

Duncker et al (2017) reported on the results of the Avoiding Untimely Implantable Cardioverter/Defibrillator Implantation by Intensified Heart Failure Therapy Optimization Supported by the Wearable Cardioverter/Defibrillator (PROLONG) study of 156 patients of whom 111 with nonischemic cardiomyopathy with a newly diagnosed LVEF of 35% or less were prescribed WCD and analyzed separately from the full cohort.

The Uyei and Braithwaite (2014) systematic review also identified 4 studies (Saltzberg et al [2012], Chung et al [2010], 2 conference abstracts) that assessed WCD use in newly diagnosed nonischemic cardiomyopathy. In the 3 studies that reported VT and VF incidences, on average, 0.57% (5/871) subjects experienced VT and/or VF over a mean duration of 52.6 days. Among those who experienced a VT or VF event, on average, 80% had successful event termination.
In summary, for patients with newly diagnosed nonischemic cardiomyopathy, the evidence includes an RCT for ICD and multiple retrospective analyses of registry data for WCD. The RCT found that prophylactic ICD placement in nonischemic cardiomyopathy did not improve mortality compared with usual clinical care. The retrospective analysis did not provide sufficient evidence to determine whether a WCD improves outcomes compared with usual care. Thus, given the lack of evidence that a permanent ICD improves outcomes, a WCD is not expected to improve outcomes under the conditions studied in this trial.

Table 3: Key Nonrandomized Trial Characteristics for Newly Diagnosed Nonischemic Cardiomyopathy

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Dates</th>
<th>Participants</th>
<th>Treatment</th>
<th>FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEARIT-II Registry</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duncker et al (2017)</td>
<td>Retrospective cohort</td>
<td>Germany</td>
<td>2012-2016</td>
<td>Newly diagnosed LVEF ≤35%</td>
<td>WCD</td>
<td>11 mo</td>
</tr>
<tr>
<td>PROLONG</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wässnig et al (2016)</td>
<td>Retrospective cohort</td>
<td>Germany, multiple sites</td>
<td>2010-2013</td>
<td>Patients with multiple etiology</td>
<td>WCD</td>
<td>NR</td>
</tr>
</tbody>
</table>

FU: follow-up; LVEF: left ventricular ejection fraction; NR: not reported; WCD: wearable cardioverter defibrillator.

Table 4: Key Nonrandomized Trial Results for Newly Diagnosed Nonischemic Cardiomyopathy

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Appropriate Shocka</th>
<th>Inappropriate Shocka</th>
<th>Nonadherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kutyifa et al (2015)</td>
<td>927</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WEARIT-II Registry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study: Trial</td>
<td>Appropriate Shock&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Inappropriate Shock&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Nonadherence</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------------------------</td>
<td>--------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>WCD</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>Salehi et al (2016)&lt;sup&gt;22&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WCD</td>
<td>7/127 (6%)</td>
<td>13/127 (10.2%)</td>
<td></td>
</tr>
<tr>
<td>Duncker et al (2017)&lt;sup&gt;23,24&lt;/sup&gt;, PROLONG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WCD</td>
<td>8/117 (7%)</td>
<td>None</td>
<td>Of 156 (entire cohort), 48 terminated WCD treatment before 3-mo follow-up. Of the 48, 24 (50%) discontinued due to incompliance</td>
</tr>
<tr>
<td>Wässnig et al (2016)&lt;sup&gt;19&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WCD</td>
<td>7/735 (1%)</td>
<td>Stratified data not reported</td>
<td>Stratified data not reported</td>
</tr>
</tbody>
</table>

WCD: wearable cardioverter defibrillator.
<sup>a</sup> Appropriate WCD therapy was classified as ventricular tachycardia or ventricular fibrillation episodes detected and treated by a WCD shock and inappropriate if not.

### Summary of Evidence

**Temporary Contraindications**

For individuals who have a temporary contraindication for an implantable cardioverter defibrillator (ICD) who receive a wearable cardioverter defibrillator (WCD), the evidence includes prospective cohort studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. A small number of patients meet established criteria for an ICD but have a transient contraindication for an implantable device, most commonly an infectious process. The available data established that the WCD device can detect lethal arrhythmias and can successfully deliver a countershock in most cases. In patients scheduled for ICD placement, the WCD will improve outcomes as an interim treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Immediate Post Myocardial Infarction**

For individuals who are in the immediate post myocardial infarction (MI) period who receive a WCD, the evidence includes randomized controlled trials (RCTs) and a technology assessment.
that assess ICD devices, given the absence of evidence on WCD devices. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. Two RCTs have reported that overall survival did not improve after treatment with a permanent ICD. While both trials reported a decrease in sudden cardiac death (SCD), there was a corresponding increase in non-SCD events, resulting in no net survival benefit. Analysis of data from a retrospective postmarket registry with WCD reported a success rate of 82% but interpretation of registry data is limited in absence of a control group. Given the lack of evidence that a permanent ICD improves outcomes in the immediate post myocardial infarction period, a WCD would not be expected to improve outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Other High-Risk Conditions**

For individuals who are post coronary artery bypass graft (CABG) surgery and are at high risk for lethal arrhythmias, awaiting heart transplantation and at high risk for lethal arrhythmias, have newly diagnosed nonischemic cardiomyopathy, or have peripartum cardiomyopathy who receive a WCD, the evidence includes an RCT evaluating early ICD placement after CABG, and case series and registry data for other indications that assess ICD devices, given the absence of evidence on WCD devices. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. For high-risk post CABG patients, an RCT reported no difference in overall survival associated with early ICD placement. For other indications, there are no RCTs that demonstrate benefit of an ICD placement. Because of the absence of any benefit of ICD and lack of any RCTs to demonstrate benefit of a WCD, the evidence does not currently permit conclusions that a WCD will improve patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 5.
Table 5: Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01446965</td>
<td>Prevention of Sudden Death After Myocardial Infarction Using a LifeVest Wearable Cardioverter-defibrillator</td>
<td>1900</td>
<td>July 2019</td>
</tr>
<tr>
<td></td>
<td>EURObservational research programme: Peripartum Cardiomyopathy (PPCM) Registry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial

b Available at: https://www.escardio.org/Research/Registries-&-surveys/Observational-research-programme/PeriPartum-CardioMyopathy-PPCM-Registry Accessed July 2019

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests, further input was received from two physician specialty societies and seven academic medical centers and while this policy was under review in 2014. Input related to the role of WCDs in preventing SCD among high-risk patients awaiting a heart transplant. Overall, input on the use of WCDs in this patient population was mixed. Some reviewers indicated that it may have a role among certain patients awaiting heart transplant, but there was no consensus on specific patient indications for use.

2013 Input

In response to requests, input was received from three physician specialty societies and eight academic medical centers while this policy was under review in 2013. Overall, the input was
mixed. Most, but not all, providing comments suggested that the WCD may have a role in select high-risk patients following acute MI or in newly diagnosed cardiomyopathy. However, reviewers acknowledged the lack of evidence for benefit and that available evidence was not consistent in defining high-risk subgroups that may benefit.

Practice Guidelines and Position Statements

American Heart Association et al

The American Heart Association, the American College of Cardiology and the Heart Rhythm Society (2018) published a guideline on the management of patients with ventricular arrhythmias and prevention of sudden cardiac death.27 The guidelines note that "the patients listed in this recommendation are represented in clinical series and registries that demonstrate the safety and effectiveness of the wearable cardioverter-defibrillator. Patients with recent MI, newly diagnosed NICM, recent revascularization, myocarditis, and secondary cardiomyopathy are at increased risk of VT/SCA. However, the wearable cardioverter-defibrillator is of unproven benefit in these settings, in part because the clinical situation may improve with therapy and time." The specific recommendations are summarized in Table 6. Class IIa is moderate recommendation, and class IIb is a weak recommendation.

Table 6. Guidelines for WCD Therapy

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;In patients with an ICD and a history of SCA or sustained VA in whom removal of the ICD is required (as with infection, the wearable cardioverter-defibrillator is reasonable for the prevention of SCD.&quot;</td>
<td>IIa</td>
<td>B-NR</td>
</tr>
<tr>
<td>&quot;In patients at an increased risk of SCD but who are not ineligible for an ICD, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed, NICM, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, the wearable cardioverter-defibrillator may be reasonable.&quot;</td>
<td>IIb</td>
<td>B-NR</td>
</tr>
</tbody>
</table>

B-NR: Level B - nonrandomized; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NICM: non-ischemic cardiomyopathy; SCA: sudden cardiac arrest; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

The American Heart Association (2016) published a scientific advisory on the WCD.28 The AHA stated that "because there is a paucity of prospective data supporting the use of the WCD, particularly in the absence of any published, randomized, clinical trials, the recommendations
provided in this advisory are not intended to be prescriptive or to suggest an evidence-based approach to the management of patients with FDA-approved indications for use." The specific recommendations are summarized in Table 7.

Table 7. Guidelines for WCD Therapy

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Use of WCDs is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care such as infection.&quot;</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>&quot;Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation&quot;</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>&quot;Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time or with treatment of left ventricular dysfunction/for example, in ischemic heart disease with recent revascularization, newly diagnosed nonischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc) in which the underlying cause is potentially treatable.&quot;</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>&quot;WCDs may be appropriate as bridging therapy in situation associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 D of MI.&quot;</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>&quot;WCDs should not be used when nonarrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive &gt;6 mo.&quot;</td>
<td>III</td>
<td>C</td>
</tr>
</tbody>
</table>

COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; MI: myocardial infarction; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

American College of Cardiology et al

The American College of Cardiology, American Heart Association, and the Heart Rhythm Society jointly published guidelines on the management of adults who have ventricular arrhythmias or who are at risk for sudden cardiac death, including diseases and syndromes associated with a risk of sudden cardiac death, including diseases and syndromes associated with a risk of sudden cardiac death from ventricular arrhythmias. Recommendations related to the use of WCDs are provided in Table 8.

Table 8. Guidelines for WCD Therapy

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>In patients with an implantable cardioverter defibrillator and a history of sudden cardiac arrest or</td>
<td>IIa</td>
<td>B-NR</td>
</tr>
</tbody>
</table>

Page | 16 of 22
Recommendation | COR | LOE
--- | --- | ---
sustained ventricular arrhythmia in whom removal of the implantable cardioverter defibrillator is required (as with infection), the wearable cardioverter defibrillator is reasonable for the prevention of sudden cardiac death.a | IIb | B-NR

In patients at an increased risk of sudden cardiac death but who are not ineligible for an implantable cardioverter defibrillator, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed nonischemic cardiomyopathy, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, wearable cardioverter defibrillator may be reasonable.b

B-NR: data derived from ≥1 nonrandomized trials or meta-analysis of such studies; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; MI: myocardial infarction; WCD: wearable cardioverter defibrillator.

a Removal of an ICD for a period of time, most commonly due to infection, exposes the patient to risk of untreated ventricular tachycardia/sudden cardiac death unless monitoring and access to emergency external defibrillation is maintained. In 1 series of 354 patients who received the WCD, the indication was infection in 10%. For patients with a history of sudden cardiac arrest or sustained ventricular arrhythmia, the WCD may allow the patient to be discharged from the hospital with protection from ventricular tachycardia/sudden cardiac death until the clinical situation allows reimplantation of an ICD.

b The patients listed in this recommendation are represented in clinical series and registries that demonstrate the safety and effectiveness of the WCD. Patients with recent MI, newly diagnosed nonischemic cardiomyopathy, recent revascularization, myocarditis, and secondary cardiomyopathy are at increased risk of ventricular tachycardia or sudden cardiac death. However, the WCD is of unproven benefit in these settings, in part because the clinical situation may improve with therapy and time. In patients awaiting transplant, even with anticipated survival <1 year without transplant, and depending on clinical factors such as use of intravenous inotropes and ambient ventricular arrhythmia, a WCD may be an alternative to an ICD.

**International Society for Heart and Lung Transplantation**

The International Society for Heart and Lung Transplantation (2006) issued guidelines on the care of cardiac transplant candidates that addressed use of ICDs or WCDs. Recommendations on the use of WCDs are provided in Table 9:

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“An implanted or wearable ICD should be provided for Status 1B patients [ie, dependent on intravenous medications or a mechanical assist device] who are discharged home given that the wait for transplantation remains significant.”</td>
<td>I</td>
<td>C</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“It is reasonable to consider placement of a defibrillator in patients with Stage D failure who are candidates for transplantation or LVAD destination therapy (see subsequent considerations for</td>
<td>IIa</td>
<td>C</td>
</tr>
</tbody>
</table>
Medicare National Coverage

There is no national coverage determination.

Noridian Healthcare Solutions, LLC

Noridian Healthcare Solutions, LLC the contractor for jurisdiction D has an LCD for Automatic External Defibrillators (L33690) that includes coverage criteria for beneficiaries at high risk for sudden cardiac death (SCD) due to one of the conditions described in the coverage guideline. 33

Regulatory Status

In 2001, the Lifecor WCD® 2000 system was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process 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 the Zoll® LifeVest®.

In 2015, FDA approved the LifeVest® “for certain children who are at risk for sudden cardiac arrest but are not candidates for an implantable defibrillator due to certain medical conditions or lack of parental consent.”

FDA product code: MVK.

References


Appendix
Figure 1.

Selected components of the wearable cardioverter-defibrillator

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/13/12</td>
<td>New Policy. Premera policy created to include in the policy statement, information about when coverage for the WCD will stop; and to maintain the allowance of newly diagnosed nonischemic cardiomyopathy (as explained in the Policy Guidelines) as an indication for the temporary use of the WCD. The Policy Guidelines statement on nonischemic cardiomyopathy was changed to investigational in the October 2012 version of BCBSA policy 2.02.15. Therefore, Policy 2.02.15 is deleted.</td>
</tr>
<tr>
<td>12/09/13</td>
<td>Replace policy. Policy updated with literature review. References 6, 7, 13, 15 added. No change to policy statement.</td>
</tr>
<tr>
<td>03/25/14</td>
<td>Replace policy. Policy statement unchanged. References 5, 6 added. ICD-9 and ICD-10 diagnosis codes removed; these are not utilized in adjudication.</td>
</tr>
<tr>
<td>05/12/14</td>
<td>Interim review. Added primary prevention criteria found in 7.01.44 to the Policy</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>12/01/14</td>
<td>Update Related Policies. Remove 2.02.10 as it was archived.</td>
</tr>
<tr>
<td>03/31/15</td>
<td>Annual Review. Policy statements unchanged. References 8, 17, 23, 26, 27, 28 added.</td>
</tr>
<tr>
<td>06/09/15</td>
<td>Interim review. Policy statement and policy guidelines rewritten for clarification. Reference 28 the Noridian LCD on WCD for jurisdiction D added; others renumbered. Policy statements revised as noted, intent is unchanged.</td>
</tr>
<tr>
<td>12/15/15</td>
<td>Update Related Policies. Remove 7.01.44 as it is archived.</td>
</tr>
<tr>
<td>04/01/16</td>
<td>Update Related Policies Removed 2.02.505 as it was archived.</td>
</tr>
<tr>
<td>08/01/16</td>
<td>Annual Review, approved July 12, 2016. Policy updated with literature review through March 22, 2016; references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>10/07/16</td>
<td>Minor formatting update. Updated hyperlink in reference number 1.</td>
</tr>
<tr>
<td>08/01/18</td>
<td>Annual Review, approved July 10, 2018. Policy updated with literature review through March 2018; reference 28 added; Policy statements edited for clarity. Added “patients post coronary artery bypass graft (CABG) surgery, high-risk patients awaiting heart transplant, patients with newly diagnosed nonischemic cardiomyopathy and women with peripartum cardiomyopathy” as indications that are considered investigational.</td>
</tr>
<tr>
<td>04/01/19</td>
<td>Minor update, added Documentation Requirements section.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible
electronic formats, other formats)

- Provides free language services to people whose primary language is not
  English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or
discriminated in another way on the basis of race, color, national origin, age,
disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help
filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important
information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action
by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.
Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):

يحتوي هذا الإشعار على معلومات مهمة. قد تحتوي هذه المعلومات على داخل
معلومات مشابهة لحياتك. ستكون هناك ترجمة مهنية.

Premera Blue Cross. هذه المعلومات ومساعدتك بIGHL MATHOON ICHI
800-722-1471 (TTY: 800-842-5357) معلومات.

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的
申請或保險的重要訊息。本通知可能有重要日期。您可能需要在截止日期
之前採取行動。以保留您的健康保險或費用補貼。您有權利免費以您的母
語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Beekisini kun odefeannoo barbarachisaa qaaba. Beekisiti kun sagantaa
yooan karaa Premera Blue Cross tiin tajaajila keessaan ilaachishe
odefeannoo barbarachisaa qabaachuu danda’a. Guyyaaawan murteessa
ta’an beekisita kana keessatti ilaali. Tarii kaffaltidhaan deeggarmuuf
yooan tajaajila fayyaa keessanif guyyaa dhumaa irritti wanti rawaawat
jiracchuu danda’a. Kaffaltii irraa bilisa haala ta’an afaan keessanin
odefeannoo aragchu fi deeggersa aragchuuf miga ni qabattaantu.
Lakkoofsa biliibii 800-722-1471 (TTY: 800-842-5357) tii biliibii.

Français (French):

Cet avis a d’importantes informations. Cet avis peut avoir d’importantes
informations sur votre demande ou la couverture par l’intermédiaire de
Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous
devrez peut-être prendre des mesures par certains délais pour maintenir
votre couverture de santé ou d’aide avec les coûts. Vous avez le droit
d’obtenir cette information et de l’aide dans votre langue à aucun coût.
Appelez le 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Diese Benachrichtigung enthält wichtige Informationen. Diese
Benachrichtigung enthält unter Umständen wichtige Informationen
bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera
Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser
Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln
müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten
zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen
in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471
(TTY: 800-842-5357).

Italiano (Italian):

Questo avviso contiene informazioni importanti. Questo avviso può contenere
informazioni importanti sulla tua domanda o copertura attraverso Premera
Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe
essere necessario un tuo intervento entro una scadenza determinata per
consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto
di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.
Chiama 800-722-1471 (TTY: 800-842-5357).
This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information.

Spanish (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Thai (Thai):
ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมู...