

MEDICAL POLICY – 2.02.506

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

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RELATED MEDICAL POLICIES:

None

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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

| Device | Medical Necessity |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Wearable cardioverter-defibrillator | <p>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 for a period not to exceed 90 days, when any ONE of the following conditions is present:</p> <ul style="list-style-type: none"> • Qualifications for implantation of an ICD are met (see Related Coverage Indications) but implantation of an ICD must be postponed because one of the following temporary contraindications to receiving an ICD placement exists: <ul style="list-style-type: none"> ○ Current systemic infection is being treated, or ○ An ICD was removed due to a concurrent infection or malfunction, and the individual must undergo a waiting period before it can be replaced, or ○ The individual has an ejection fraction (LVEF) $\leq 35\%$; and has ischemic cardiomyopathy due to a recent (< 40 days) myocardial infarction (MI), or ○ The individual has an ejection fraction (LVEF) $\leq 35\%$; and has newly diagnosed non-ischemic dilated cardiomyopathy and guideline-directed medical therapy was initiated (e.g., ACE* inhibitors, ARBs**, beta blockers), or ○ The individual has an ejection fraction (LVEF) $\leq 35\%$; and revascularization was performed (e.g., CABG***, percutaneous coronary intervention) within the past 90 days, or ○ The individual has familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy and is being evaluated for effectiveness of medical therapy, or ○ The individual has a documented episode of ventricular fibrillation or a sustained (lasting 30 seconds or longer) ventricular tachyarrhythmia. These dysrhythmias may be |

| Device | Medical Necessity |
|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <p>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, and are being evaluated for effectiveness of anti-arrhythmia medication,</p> <p>AND</p> <ul style="list-style-type: none"> The ICD placement or an ICD replacement surgery, if appropriate, will be scheduled once one of the temporary contraindications noted above is treated or managed. (See Note below) <p>Note: If the individual responds to the maximal medical treatment and their condition improves after 90 days, the ICD may no longer be necessary and the WCD should be discontinued. However, if there is no improvement in the individual's condition, permanent ICD placement should be implanted.</p> <p>*ACE-Angiotensin-converting enzyme, ** ARB-Angiotensin-receptor blockers, ***CABG-Coronary artery bypass graft</p> <p>Requests for re-authorization beyond the initial 90 days for another 30 days (additional one month rental) must be submitted with physician attestation of ≥90% daily compliance (demonstrated by the individual's data reports downloaded from the manufacturer portal by the treating provider) along with an updated treatment plan documenting the ongoing medical necessity of the WCD from the treating provider.</p> |

| Device | Investigational |
|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Wearable cardioverter-defibrillator | <p>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:</p> <ul style="list-style-type: none"> High-risk individuals awaiting heart transplant Women with peripartum cardiomyopathy |

| Device | Investigational |
|--------|-----------------------------------------------------------------------------|
| | Use of WCDs is considered investigational for all other indications. |

Related Coverage Indications

Temporary Contraindications for ICD placement

It is uncommon for individuals 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 (e.g., 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 individuals 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 individuals who have experienced a life-threatening episode of VT, after reversible causes have been excluded.

Primary Prevention indication 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)

Related Coverage Indications

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) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of individuals 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

OR

- Diagnosis of cardiac sarcoid and considered to be at high risk for sudden cardiac death

Secondary Prevention:

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

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

- Individual has had an acute myocardial infarction (i.e., less than 40 days before ICD treatment)
- Individual has NYHA Class IV congestive heart failure (unless individual 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 individual'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)

Documentation Requirements

- Temporary contraindication(s) to ICD placement

Coding

| Code | Description |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CPT | |
| 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 | |
| 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 |

*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 individuals with coronary artery disease.

Treatment

The ICD has proven effective in reducing mortality for survivors of SCA and for individuals with documented malignant ventricular arrhythmias. More recently, use of ICDs has been broadened by studies reporting a reduction in mortality for individuals at risk for ventricular arrhythmias, such as individuals with prior myocardial infarction (MI) and reduced ejection fraction (EF).

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. Placement of the ICD is a minor surgical procedure. Potential adverse events of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks.

The WCD is an external device intended to perform the same tasks as an ICD, without invasive procedures. It consists of a vest worn continuously underneath the individual'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 individual'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 individual to certain conditions by lights or voice messages, during which time a conscious individual can abort or delay the shock (see [Appendix](#) for graphic).

Food and Drug Administration (FDA) labeled indications for the WCD are adults at risk for (SCA) who either are not candidates for or refuse an implantable ICD.¹ Some experts have suggested that the indications for a WCD should be broadened to include other populations at high risk for SCA.² The potential indications include:

- Bridge to transplantation (i.e., the Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patients at High Risk for Sudden Death [WEARIT] study population)
- Bridge to implantable device or clinical improvement (i.e., the Patients at High Risk for Sudden Death after a Myocardial Infarction or Bypass Surgery not receiving an ICD for up to four months [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.

Summary of Evidence

Overview of Wearable Cardioverter Defibrillator Versus Implantable Cardioverter Defibrillator

One randomized controlled trial (RCT) has compared WCD with usual guideline-based care and found no significant benefit to WCD over usual care. No studies have directly compared the performance of a WCD with a permanent ICD. One small study in an electrophysiology lab demonstrated that the WCD can correctly identify and terminate most induced ventricular arrhythmias. Similarly, a study of the ASSURE WCD in individuals with cardiomyopathy found that the WCD detected all events recorded by an ICD with few false-positive shock alarms in a 30-day period. A cohort study of WCD use estimated that the percentage of successful resuscitations was approximately 70%. Multiple studies have demonstrated suboptimal



adherence. Device failures were largely attributed to incorrect device use and/or nonadherence. A more recent registry study has reported a high compliance rate, although these results may be biased by self-selection. Collectively, this evidence indicates that the WCD can successfully detect and terminate arrhythmias in at least some individuals but that overall performance in clinical practice might be inferior to a permanent ICD.

Temporary Contraindications

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

Immediate Post-Myocardial Infarction

For individuals who are in the immediate post MI period who receive a WCD, the evidence includes an RCT comparing WCD with guideline-based therapy, two cohort studies, and a systematic review. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The RCT reported no benefit of WCD over guideline-based therapy. The cohort study of 8453 individuals showed that 252 shocks successfully terminated VF or VT (82% success rate), but without a control group, interpretation is difficult. Similarly, a retrospective cohort of Medicare data found that WCD use was associated with lower 1-year mortality than no WCD use, but potential biases were noted. Evidence from the systematic review was deemed of low to very low quality, and the reviewers had weak confidence in the reported estimates. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Post–Coronary Artery Bypass Graft Surgery at High Risk for Lethal Arrhythmias

For individuals who are post coronary artery bypass graft (CABG) surgery and are at high risk for lethal arrhythmias, the evidence includes an RCT for ICD and a registry study. 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 OS associated with early ICD placement. The registry study found survival benefits with WCD but had limited interpretation of data. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Awaiting Heart Transplantation at High Risk for Lethal Arrhythmias

For individuals who are awaiting heart transplantation and are at high risk for lethal arrhythmias, the evidence includes analyses of subsets of individuals from the manufacturer registry, a subset from a prospective cohort study, and a case series. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. These studies do not provide sufficient evidence to determine whether a WCD is of benefit compared with usual care. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Newly Diagnosed Nonischemic Cardiomyopathy

For individuals who have newly diagnosed nonischemic cardiomyopathy, the evidence includes an RCT for ICD and several retrospective analyses of WCD registry data. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The RCT found that prophylactic ICD placement for nonischemic cardiomyopathy did not improve mortality compared with usual care. Evidence from the retrospective analysis was not sufficient to determine whether WCD improves outcomes compared with usual care. Given the lack of evidence that ICD improves outcomes, WCD is not expected to improve outcomes under the conditions studied in these trials. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Peripartum Cardiomyopathy



For individuals who have peripartum cardiomyopathy, the evidence includes a retrospective registry data analysis and a small cohort study. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The registry study revealed that no shocks were delivered during use over an average of 124 days. The cohort study identified four episodes of appropriate electric shock over 133 days. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in [Table 1](#).

Table 1 Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|------------------------------------------|---------------------------------------------------------------------------------------------------------|--------------------|---------------------------|
| Ongoing | | | |
| NCT05135403 ^a | ASSURE WCD Clinical Evaluation - Post Approval Study (ACE-PAS) | 5179 | Feb 2025 |
| Ongoing | | | |
| NCT05201495 ^a | A Clinical Evaluation of the Jewel P-WCD in Subjects at High Risk for Sudden Cardiac Arrest | 290 | Nov 2023 |
| NCT02816047 | Indications for and Experience With the Wearable Cardioverter Defibrillator (WCD)–Austrian WCD Registry | 450 | Mar 2022 (unknown status) |
| | EURObservational research programme: Peripartum Cardiomyopathy (PPCM) Registry ^b | | ongoing |

NCT: national clinical trial.
^a Denotes industry sponsored or co-sponsored study ^b Available at: <https://www.escardio.org/Research/registries/global-registries-and-surveys-programme/PeriPartum-CardioMyopathy-PPCM-Registry> Accessed June 4, 2024.

Clinical Input 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 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 individuals 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

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.



American Heart Association et al

In 2018, the American Heart Association (AHA), the American College of Cardiology and the Heart Rhythm Society published a guideline on the management of individuals with ventricular arrhythmias and prevention of SCD.³¹ The guidelines note that "the individuals listed in this recommendation are represented in clinical series and registries that demonstrate the safety and effectiveness of the WCD. Individuals 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 2](#).

Level of evidence class IIa is moderate recommendation, and class IIb is a weak recommendation, and class III is a moderate recommendation for no benefit or a strong recommendation for harm.

Table 2. Guidelines for WCD Therapy

| Recommendation | COR | LOE ^c |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|------------------|
| "In individuals with an ICD and a history of SCA or sustained VA in whom removal of the ICD is required (as with infection), the WCD is reasonable for the prevention of SCD." ^a | IIa | B-NR |
| "In individuals 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 WCD may be reasonable." ^b | IIb | B-NR |

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; VT: ventricular tachycardia; 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 VT/SCD 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%.³² For patients with a history of SCA or sustained ventricular arrhythmia, the WCD may allow the patient to be discharged from the hospital with protection from VT/SCD 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 VT or SCD. 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.

^c B-NR: data derived from ≥1 nonrandomized trials or meta-analysis of such studies.

In 2016, the American Heart Association published a scientific advisory on the WCD.³³ 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 individuals with FDA-approved indications for use." The specific recommendations are summarized in [Table 3](#).

Table 3. Guidelines for WCD Therapy

| Recommendation | COR | LOE ^a |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|------------------|
| "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." | IIa | C |
| "Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation" | IIa | C |
| "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." | IIb | C |
| "WCDs may be appropriate as bridging therapy in situations 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." | IIb | C |
| "WCDs should not be used when nonarrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive >6 mo." | III | C |

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

^a Level C evidence is based on limited data or expert opinion.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In 2001, the Lifecor WCD 2000 system was approved by the 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 LifeVest.

In 2015, the 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.”

In 2021, the FDA approved the ASSURE WCD for adult patients at risk for SCA who are not candidates for (or refuse) an ICD.

FDA product code: MVK.

References

1. Food and Drug Administration. Summary of Safety and Effectiveness Data, P010030, Lifecor, Inc. WCD 2000 System. 2001; https://www.accessdata.fda.gov/cdrh_docs/pdf/p010030b.pdf. Accessed June 5, 2024.
2. Beauregard LA. Personal security: Clinical applications of the wearable defibrillator. *Pacing Clin Electrophysiol*. Jan 2004; 27(1): 1-3. PMID 14720147
3. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Wearable cardioverter-defibrillator as a bridge to implantable cardioverter-defibrillator treatment. *TEC Assessments*. 2010;Volume 25:Tab 2.
4. Auricchio A, Klein H, Geller CJ, et al. Clinical efficacy of the wearable cardioverter-defibrillator in acutely terminating episodes of ventricular fibrillation. *Am J Cardiol*. May 15 1998; 81(10): 1253-6. PMID 9604964
5. Chung MK, Szymkiewicz SJ, Shao M, et al. Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. *J Am Coll Cardiol*. Jul 13 2010; 56(3): 194-203. PMID 20620738
6. Goetz G, Wernly B, Wild C. Wearable cardioverter defibrillator for preventing sudden cardiac death in patients at risk: An updated systematic review of comparative effectiveness and safety. *Int J Cardiol Heart Vasc*. Apr 2023; 45: 101189. PMID 37025482
7. Tanawuttiwat T, Garisto JD, Salow A, et al. Protection from outpatient sudden cardiac death following ICD removal using a wearable cardioverter defibrillator. *Pacing Clin Electrophysiol*. May 2014; 37(5): 562-8. PMID 24762055
8. Mitrani RD, McArdle A, Slane M, et al. Wearable defibrillators in uninsured patients with newly diagnosed cardiomyopathy or recent revascularization in a community medical center. *Am Heart J*. Mar 2013; 165(3): 386-92. PMID 23453108



9. Kao AC, Krause SW, Handa R, et al. Wearable defibrillator use in heart failure (WIF): results of a prospective registry. *BMC Cardiovasc Disord.* Dec 12 2012; 12: 123. PMID 23234574
10. Feldman AM, Klein H, Tchou P, et al. Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD. *Pacing Clin Electrophysiol.* Jan 2004; 27(1): 4-9. PMID 14720148
11. Kutiyfa V, Moss AJ, Klein H, et al. Use of the wearable cardioverter defibrillator in high-risk cardiac patients: data from the Prospective Registry of Patients Using the Wearable Cardioverter Defibrillator (WEARIT-II Registry). *Circulation.* Oct 27 2015; 132(17): 1613-9. PMID 26316618
12. Poole JE, Gleva MJ, Birgersdotter-Green U, et al. A wearable cardioverter defibrillator with a low false alarm rate. *J Cardiovasc Electrophysiol.* May 2022; 33(5): 831-842. PMID 35174572
13. Gregoratos G, Cheitlin MD, Conill A, et al. ACC/AHA guidelines for implantation of cardiac pacemakers and antiarrhythmia devices: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Pacemaker Implantation). *J Am Coll Cardiol.* Apr 1998; 31(5): 1175-209. PMID 9562026
14. Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. *N Engl J Med.* Dec 09 2004; 351(24): 2481-8. PMID 15590950
15. Steinbeck G, Andresen D, Seidl K, et al. Defibrillator implantation early after myocardial infarction. *N Engl J Med.* Oct 08 2009; 361(15): 1427-36. PMID 19812399
16. Olgin JE, Pletcher MJ, Vittinghoff E, et al. Wearable Cardioverter-Defibrillator after Myocardial Infarction. *N Engl J Med.* Sep 27 2018; 379(13): 1205-1215. PMID 30280654
17. Uyei J, Braithwaite RS. Effectiveness of wearable defibrillators: systematic review and quality of evidence. *Int J Technol Assess Health Care.* Apr 2014; 30(2): 194-202. PMID 24893969
18. Epstein AE, Abraham WT, Bianco NR, et al. Wearable cardioverter-defibrillator use in patients perceived to be at high risk early post-myocardial infarction. *J Am Coll Cardiol.* Nov 19 2013; 62(21): 2000-2007. PMID 23916930
19. Clark MA, Szymkiewicz SJ, Volosin K. Mortality and Costs Associated with Wearable Cardioverter-defibrillators after Acute Myocardial Infarction: A Retrospective Cohort Analysis of Medicare Claims Data. *J Innov Card Rhythm Manag.* Oct 2019; 10(10): 3866-3873. PMID 32477706
20. Bigger JT. Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary-artery bypass graft surgery. *Coronary Artery Bypass Graft (CABG) Patch Trial Investigators.* *N Engl J Med.* Nov 27 1997; 337(22): 1569-75. PMID 9371853
21. Zishiri ET, Williams S, Cronin EM, et al. Early risk of mortality after coronary artery revascularization in patients with left ventricular dysfunction and potential role of the wearable cardioverter defibrillator. *Circ Arrhythm Electrophysiol.* Feb 2013; 6(1): 117-28. PMID 23275233
22. Opreanu M, Wan C, Singh V, et al. Wearable cardioverter-defibrillator as a bridge to cardiac transplantation: A national database analysis. *J Heart Lung Transplant.* Oct 2015; 34(10): 1305-9. PMID 26094085
23. Wäbnig NK, Günther M, Quick S, et al. Experience With the Wearable Cardioverter-Defibrillator in Patients at High Risk for Sudden Cardiac Death. *Circulation.* Aug 30 2016; 134(9): 635-43. PMID 27458236
24. Rao M, Goldenberg I, Moss AJ, et al. Wearable defibrillator in congenital structural heart disease and inherited arrhythmias. *Am J Cardiol.* Dec 01 2011; 108(11): 1632-8. PMID 21890075
25. Kadish A, Schaechter A, Subacius H, et al. Patients with recently diagnosed nonischemic cardiomyopathy benefit from implantable cardioverter-defibrillators. *J Am Coll Cardiol.* Jun 20 2006; 47(12): 2477-82. PMID 16781376

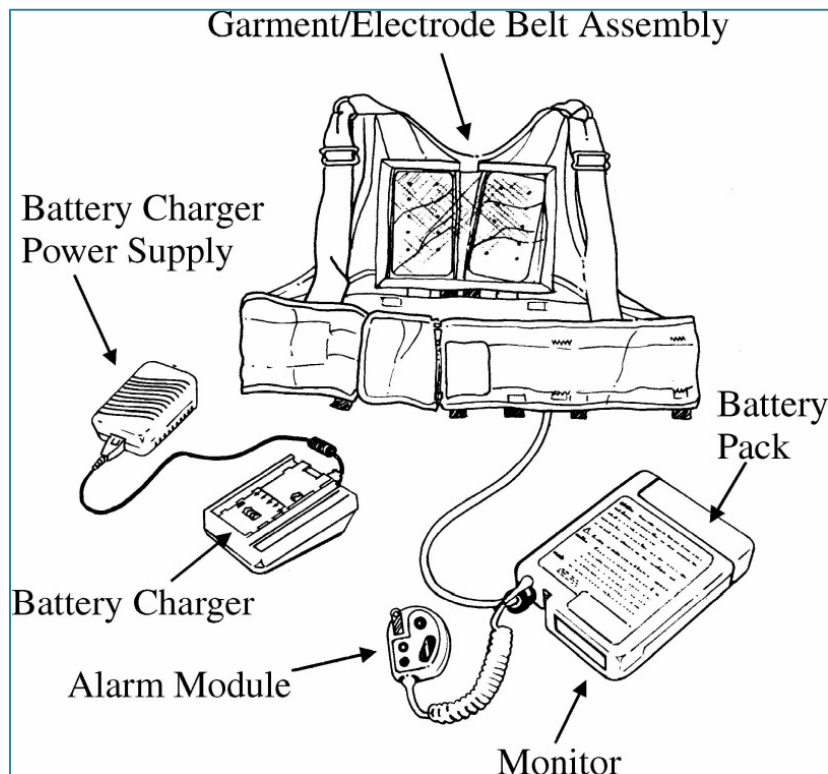


26. Salehi N, Nasiri M, Bianco NR, et al. The Wearable Cardioverter Defibrillator in Nonischemic Cardiomyopathy: A US National Database Analysis. *Can J Cardiol.* Oct 2016; 32(10): 1247.e1-1247.e6. PMID 26975224
27. Duncker D, König T, Hohmann S, et al. Ventricular arrhythmias in patients with newly diagnosed nonischemic cardiomyopathy: Insights from the PROLONG study. *Clin Cardiol.* Aug 2017; 40(8): 586-590. PMID 28333373
28. Duncker D, König T, Hohmann S, et al. Avoiding Untimely Implantable Cardioverter/Defibrillator Implantation by Intensified Heart Failure Therapy Optimization Supported by the Wearable Cardioverter/Defibrillator-The PROLONG Study. *J Am Heart Assoc.* Jan 17 2017; 6(1). PMID 28096098
29. Saltzberg MT, Szymkiewicz S, Bianco NR. Characteristics and outcomes of peripartum versus nonperipartum cardiomyopathy in women using a wearable cardiac defibrillator. *J Card Fail.* Jan 2012; 18(1): 21-7. PMID 22196837
30. Duncker D, Haghikia A, König T, et al. Risk for ventricular fibrillation in peripartum cardiomyopathy with severely reduced left ventricular function-value of the wearable cardioverter/defibrillator. *Eur J Heart Fail.* Dec 2014; 16(12): 1331-6. PMID 25371320
31. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation.* Sep 25 2018; 138(13): e272-e391. PMID 29084731
32. Klein HU, Meltendorf U, Reek S, et al. Bridging a temporary high risk of sudden arrhythmic death. Experience with the wearable cardioverter defibrillator (WCD). *Pacing Clin Electrophysiol.* Mar 2010; 33(3): 353-67. PMID 19889186
33. Piccini JP, Allen LA, Kudenchuk PJ, et al. Wearable Cardioverter-Defibrillator Therapy for the Prevention of Sudden Cardiac Death: A Science Advisory From the American Heart Association. *Circulation.* Apr 26 2016; 133(17): 1715-27. PMID 27022063

Appendix



Figure 1.



Selected components of the wearable cardioverter-defibrillator¹

History

| Date | Comments |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11/13/12 | 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. |
| 12/09/13 | Replace policy. Policy updated with literature review. References 6, 7, 13, 15 added. No change to policy statement. |
| 03/25/14 | Replace policy. Policy statement unchanged. References 5, 6 added. ICD-9 and ICD-10 diagnosis codes removed; these are not utilized in adjudication. |

| Date | Comments |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 05/12/14 | Interim review. Added primary prevention criteria found in 7.01.44 to the Policy Guidelines section. |
| 12/01/14 | Update Related Policies. Remove 2.02.10 as it was archived. |
| 03/31/15 | Annual Review. Policy statements unchanged. References 8,17,23,26,27,28 added. |
| 06/09/15 | 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. |
| 12/15/15 | Update Related Policies. Remove 7.01.44 as it is archived. |
| 04/01/16 | Update Related Policies Removed 2.02.505 as it was archived. |
| 08/01/16 | Annual Review, approved July 12, 2016. Policy updated with literature review through March 22, 2016; references added. Policy statements unchanged. |
| 10/07/16 | Minor formatting update. Updated hyperlink in reference number 1. |
| 07/01/17 | Annual Review, approved June 22, 2017. Updated 2016 ACC -AHA guidelines. Policy moved into new format. |
| 08/01/18 | 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. |
| 04/01/19 | Minor update, added Documentation Requirements section. |
| 08/01/19 | Annual Review, approved July 25, 2019. Policy updated with literature review through March 2019; reference 31 added. Policy statements unchanged. |
| 04/01/20 | Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020. |
| 07/02/20 | Delete policy. |
| 11/01/20 | Policy reinstated effective February 5, 2021, approved October 13, 2020. Annual review. Policy updated with literature review through March, 2020; reference added. Policy statements unchanged. |
| 08/01/21 | Annual Review, approved July 9, 2021. Policy updated with literature review through April 10, 2021; reference added. Policy statements unchanged. |
| 06/01/22 | Interim Review, approved May 10, 2022. Added "for a period not to exceed 90 days" to medically necessary statement for use of a WCD as interim treatment as a bridge to permanent implantable (internal) cardioverter-defibrillator (ICD) surgery for greater clarity. This becomes effective for dates of service on or after September 2, 2022. Policy intent unchanged. |



| Date | Comments |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 08/01/22 | Annual Review, approved July 11, 2022. Policy updated with literature review through March 16, 2022; reference added. Policy statements unchanged. |
| 01/01/23 | Interim Review, approved December 13, 2022. Added additional criteria for ICD placement: The individual has LVEF < 35% and has ischemic cardiomyopathy due to a recent (< 40 days) myocardial infarction (MI); or has newly diagnosed non-ischemic dilated cardiomyopathy and guideline-directed medical therapy initiated (e.g., ACE inhibitors, ARBs, beta blockers); or revascularization was performed (e.g., CABG, percutaneous coronary angioplasty and/or stenting within the past 90 days, or the individual has familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy, or the individual has 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. Added documentation requirements for reauthorization of WCD beyond initial 90 days for another 30 days (one month rental). Changed the wording from "patient" to "individual" throughout the policy for standardization. |
| 08/01/23 | Annual Review, approved July 10, 2023. Policy updated with literature review through March 14, 2023; no references added. Minor editorial refinements to policy statement; intent unchanged. |
| 01/01/24 | Interim Review, approved December 26, 2023. Policy criteria reorganized and clarifying language added for greater clarity, policy intent unchanged. |
| 08/01/24 | Annual Review, approved July 8, 2024. Policy updated with literature review through March 27, 2024; references added. Policy statements reformatted for greater clarity with minor edits; policy statements unchanged. |

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). ©2024 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.

