Medical Policy Manual

Durable Medical Equipment, Policy No. 61

Wearable Cardioverter-Defibrillators

Effective: July 7, 2017

Next Review: June 2018
Last Review: June 2017

IMPORTANT REMINDER

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

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

DESCRIPTION

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

MEDICAL POLICY CRITERIA

Notes:

- This policy does not address pediatric patients, which may be considered medically necessary. For the purposes of this policy, adult patient is defined as age 18 years and older.
- For implantable cardioverter defibrillators (ICD), please see Medical Policy, Surgery No. 17 (see Cross References).

1. Use of wearable cardioverter defibrillators (WCDs) for the prevention of sudden cardiac death is considered **medically necessary** as interim treatment when any of the following criteria are met:
A. For patients who require an ICD and have been scheduled for ICD placement but have a temporary contraindication which is expected to resolve, such as a current systemic infection; OR

B. If risk of arrhythmic death is present and clinically documented (e.g., low ejection fraction, syncope, non-sustained ventricular tachycardia (VT) on telemetry, polymorphous VT on telemetry, or short bursts of ventricular fibrillation); OR

C. As a bridge to definitive therapy (e.g., cardiac transplant).

II. Use of WCDs for the prevention of sudden cardiac death is considered investigational for all other indications including but not limited to the following when they are the sole indication for a WCD:

A. Patients in the immediate (e.g., <40 days) period following an acute myocardial infarction; or

B. Patients post coronary artery bypass graft surgery; or

C. Patients with newly diagnosed nonischemic cardiomyopathy; or

D. Women with peripartum cardiomyopathy; or

E. High-risk patients awaiting heart transplant, who meet implant criteria for an implantable cardioverter-defibrillator.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Implantable Cardioverter Defibrillator, Surgery, Policy 17

BACKGROUND

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

WEARABLE CARDIOVERTER-DEFIBRILLATOR (WCD)

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

Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is intended as treatment for patients who require an implantable cardioverter defibrillator (ICD) but have a temporary or permanent contraindications for ICD placement. In addition, the American Heart Association (AHA) published a science advisory (2016) stating the device is FDA approved for selected patients at risk for sudden cardiac arrest.[2] Relative contraindications include patients who cannot respond to testing stimuli and those needing pacing capabilities.

REGULATORY STATUS

The Wearable Cardioverter Defibrillator (WCD)® 2000 “LifeVest” (Zoll® Medical Corporation) received U.S. Food and Drug Administration (FDA) premarket approval (PMA) for "adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator.”[3] In 2015, the FDA extended the indications for LifeVest® and approved its use “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.”

EVIDENCE SUMMARY

WEARABLE CARDIOVERTER DEFIBRILLATORS (WCDS) AS AN INTERIM TREATMENT TO IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) PLACEMENT

Technology Assessments

The 2010 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment of Wearable Cardioverter-Defibrillators (WCD) identified no controlled trials that specifically evaluated the efficacy of the WCD in comparison to alternatives for patients at high risk of sudden cardiac death.[4] The available evidence consisted of two uncontrolled studies that evaluated the ability of the WCD to detect and abort ventricular arrhythmias:

The first study included 15 patients who were survivors of sudden cardiac arrest (SCA) and scheduled to receive an ICD.[5] During the procedure to implant a permanent ICD or to test a previously inserted ICD, patients wore the WCD while clinicians attempted to induce ventricular arrhythmias. Of the 15 patients, 10 developed ventricular tachycardia or ventricular fibrillation. The WCD correctly detected the arrhythmia in nine of 10 cases and successfully terminated the arrhythmia in all nine cases.

The prospective WEARIT/BIROAD registry study evaluated the WCD in 289 patients at high risk for sudden cardiac death who did not meet criteria for an ICD or who could not receive an ICD for several months.[6] During the main follow-up time of 3.1 months, there were eight documented episodes of arrhythmia requiring shock in six separate patients. Six of the eight episodes were successfully resuscitated by the WCD (successful resuscitation = 69%). In the two cases of unsuccessful defibrillation, the authors reported that the WCD was placed incorrectly (electrodes reversed and not directed to the skin). In addition, the high study dropout rate (22%) was due to the inconvenience and discomfort associated with wearing the device.
Although limited, the TEC Assessment found the evidence sufficient to conclude that WCD can successfully identify and terminate malignant ventricular arrhythmias because:

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

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

Nonrandomized Studies

Since the 2010 TEC assessment, the prospective WEARIT-II registry study enrolled 2000 patients with ischemic (n=805, 40%), or nonischemic cardiomyopathy (n=927, 46%), or congenital/inherited heart disease (n=268) prescribed WCD between August 2011 and February 2014.[7] At three months, the median daily use of the WCD was 22.5 hours. The high compliance in this study may have been related to greater compliance in patients who volunteered to participate in the registry. During the WCD trial period there were 120 sustained ventricular tachyarhythmias in 41 patients. Ninety of the events were withheld from shock therapy by the patients and 30 required shock therapy. Appropriate shock was received for 54% of the 41 patients, while 10 patients (0.5%) received inappropriate shock. Three patients died while wearing the WCD, all from asystole. No patients died from VT/VF while wearing the WCD. At the end of the evaluation period, 42% of patients received an ICD and 40% of patients were no longer considered to need an ICD, most frequently from an improvement in ejection fraction. Long-term follow-up on clinical outcomes for this study are expected.

WCD USE IMMEDIATELY FOLLOWING AN ACUTE MYOCARDIAL INFARCTION (MI)

Systematic Reviews and Technology Assessments

Uyei (2014) reported results of a systematic review (SR) conducted with the goal of evaluating the effectiveness of WCD use in several clinical situations, including for individuals early (≤40 days) post-MI with a LVEF less than or equal to 35%. The authors identified 36 articles and conference abstracts, most of which (N=28; 78%) were conference abstracts. Four studies (Chung et al [2010],[9] Epstein et al [2013][10], and 2 conference abstracts) assessed the effectiveness of WCD use in post-MI patients. Outcomes reported were heterogeneous. For two studies that reported ventricular tachycardia/ventricular fibrillation (VT/VF)-related mortality, on average 0.52 percent (2/384) of the study population died of VF or VT over 58.3 mean days of WCD use. For two studies that reported on VT/VF incidence, on average 2.8 percent (11/384) of WCD users experienced a VT and/or VF event over the course 58.3 (range, 3–146) mean days of WCD use. Among those who experienced a VT/VF event, on average 82 percent (9/11) experienced successful termination of one or more arrhythmic events. Although authors reported an absolute risk reduction of approximately 1% in VT/VF associated death, the quality of evidence was reported as “low to very low quality,” calling into question the clinical utility of WCD immediately following an MI. Furthermore, overall survival of treated patients in the Epstein study was 73% compared to 96% of non-treated patients at
three-month follow-up. These results highlight the need for RCTs to isolate the independent contribution of WCD and control for biases inherent in manufacturer sponsored registry studies.\textsuperscript{[11]}

The 2010 TEC Assessment also evaluated whether treatment with a defibrillator (WCD or ICD) improved overall survival in patients who were at high risk for SCA immediately following an acute MI, or in other high risk patients, when used as a bridge to permanent ICD placement.\textsuperscript{[12]}

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

Two RCTs that evaluated immediate post-MI patients did not support the hypothesis that early ICD implantation post-MI improves overall survival.\textsuperscript{[12,13]} Taken together, the trials offered compelling evidence that immediate ICD placement post-MI did not improve mortality compared with delayed placement. However, the main limitation of these trials in extrapolating this data to the WCD as a bridge to permanent ICD placement is that the time frame of the trials did not correspond precisely to the period of time for which the WCD was intended. The ICD was implanted within 30 or 40 days in these trials, but follow-up continued for 2-3 years and results were analyzed over this entire time period. This is considerably longer than the 1-2-month period that might be expected for WCD use.

The trial in high-risk post-CABG patients also found no improvement in mortality and no trends toward improvement associated with early ICD placement.\textsuperscript{[14]}

The TEC Assessment identified no other clinical trials on the use of defibrillators for other bridging purposes.

**Randomized Control Trials**

No RCTS were identified after the above SR.

**PATIENTS AWAITING HEART TRANSPLANTATION AT HIGH RISK FOR LETHAL ARRHYTHMIAS**

There were no SRs or RCTs identified.

**Nonrandomized Studies**

Many patients awaiting heart transplantation are at high risk for lethal arrhythmias. A WCD can be used to reduce risks associated with ICD placement or when ICD placement is contraindicated. Opreanu (2015) analyzed a manufacturer’s database to identify patients prescribed a WCD as a bridge to heart transplantation.\textsuperscript{[15]} The registry included 121 patients, 12\% with New York Heart Association (NYHA) functional class II heart failure, 32\% with NYHA class III heart failure, 34\% with NYHA class IV heart failure, and 21\% unknown. Of the 121 patients, 73\% were being evaluated for heart transplantation or were on a transplantation waiting list, and 27\% were awaiting retransplantation following rejection of a prior heart transplantation. Patients wore the WCD for a median of 20 hours per day for a median of 39 days. Seven (6\%) patients received appropriate WCD shocks during this period and survived. Two patients received inappropriate shocks. Thirteen (11\%) patients ended WCD use after heart transplantation, 42\% ended WCD use after ICD placement, and 15\% ended WCD use...
after EF improved. There were 11 (9%) deaths; nine of these patients were not wearing a WCD at the time of death. The two patients who died while wearing the WCD had asystole.

Rao (2011) published a case series of 162 patients with congenital structural heart disease or inherited arrhythmias treated with WCD. Approximately one-third of these patients had a permanent ICD, which was explanted due to infection or malfunction. The remaining patients used the WCD either as a bridge to heart transplantation, during an ongoing cardiac evaluation, or in the setting of surgical or invasive procedures that increased the risk of arrhythmias. Four patients died during a mean WCD treatment duration of approximately one month, but none was related to cardiac causes. Two patients received three appropriate shocks for VT or VF, and four patients received seven inappropriate shocks. The results of this series suggested that the WCD can be worn safely and can detect arrhythmias in this population, but the rate of inappropriate shocks was relatively high.

**WCD USE FOR OTHER INDICATIONS**

There were no SRs or RCTs identified.

**Nonrandomized Studies**

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

WCDs may be used in situations where the cardiomyopathy is reversible, but temporary protection against arrhythmias is needed, such as in patients with alcoholic cardiomyopathy who abstain from alcohol. Salehi et al. identified 127 patients from the LifeVest® manufacturer’s database with nonischemic cardiomyopathy possibly related to alcohol use. The mean ejection fraction was 19.9% upon presentation. Patients wore the WCD for a median of 51 days and a median of 18.0 h per day. During this period, seven patients received nine appropriate shocks and 13 patients received 18 inappropriate shocks. At the end of WCD use 33% of patients had an improvement in ejection fraction and did not require ICD placement and 24% received an ICD. There were four deaths during this period, one of which occurred while wearing the WCD and was due to ventricular asystole.

Duncker (2014) reported outcomes for 12 prospectively-enrolled women with peripartum cardiomyopathy who were treated at a single center and followed over a median of 12 months. A WCD was recommended for 9 patients with LVEF less than or equal to 35% and 7 of the 9 consented to wear the WCD. For these 7 patients, the median WCD wearing time was 81 days (mean 133 days). In three patients, four episodes of VF were detected that led to delivery of a shock, which successfully terminated the arrhythmia in all cases. No inappropriate shocks were delivered. Among the 5 patients without WCD, no episodes of syncope, ventricular arrhythmias, or deaths occurred.

Tanawuttiwat (2013) reported the results of a retrospective, evaluation of 97 patients who received a WCD after their ICD was explanted due to device infection. Subjects wore the device for a median of 21 days; and during the study period, two patients had four episodes of arrhythmia that were appropriately terminated by the WCD, one patient experienced two inappropriate treatments, and three patients experienced sudden death outside the hospital while not wearing their WCD device. Similar to the previous nonrandomized studies mentioned above, this study is limited by a lack of controlled comparison group. In addition, this study adds to the body of evidence regarding suboptimal compliance associated with WCD use.
Mitrani and colleagues published a study of 259 patients with newly diagnosed cardiomyopathy who were consecutively prescribed a WCD.\textsuperscript{[20]} The study was limited by a high rate of lost to follow-up (35\%) and non-randomized design, which precluded conclusions regarding the usefulness of WCDs for the detection and treatment of arrhythmias within this group.

In another registry study, 809 patients with WCD were compared to 4149 patients who were discharged without a defibrillator after coronary revascularization for left ventricular ejection fraction \( \leq 35\% \).\textsuperscript{[21]} Early mortality, within 90 days of surgery, was higher among the non-defibrillator group compared to the WCD group, (post-coronary artery bypass graft surgery 7\% versus 3\%, \( P=0.03 \); post-percutaneous coronary intervention (PCI) 10\% versus 2\%, \( P<0.0001 \)). In addition, an adjusted lower risk of long-term mortality in the total cohort (39\%, \( P<0.0001 \)) was observed across the entire WCD group.

Kao and colleagues published an observational study of 82 patients who were either listed for cardiac transplantation, diagnosed with dilated cardiomyopathy, or receiving inotropic medications and were prescribed a WCD.\textsuperscript{[22]} Although no sudden cardiac deaths or arrests were reported, this study was limited by a lack of comparison group, variable application of the device and mixed patient demographic.

In 2012, a retrospectively matched registry study evaluated WCD in peripartum cardiomyopathy patients.\textsuperscript{[23]} The study included 107 women with peripartum cardiomyopathy treated with a WCD device and 159 matched women with nonischemic dilated cardiomyopathy, during the period of 2003 through 2009. Patients were identified from a registry of WCD use maintained by the manufacturer of the device. The average length of time that the WCD was used was 124+123 days in the peripartum group and 96+83 days in the matched nonischemic group. There were no appropriate shocks or patient deaths during the time of WCD treatment in the peripartum group compared to two appropriate shocks and 11 deaths in the nonischemic group. Following discontinuation of the WCD, there were three deaths over a mean follow-up of 3.0+1.2 years in the peripartum group. Ultimately, authors suggest further study is needed to help determine the usefulness of WCD in patients with peripartum cardiomyopathy.

Use of WCDs in patients with congenital structural heart disease (CSHD) and inherited arrhythmias (IAs) was described in one registry-based, observational study of 162 patients (CSHD = 43, IA = 119).\textsuperscript{[24]} The main indication for a WCD was transplant listing in the CSHD group and pending genetic testing in IA group. Although the study suggests that a WCD could be safely used, this study was limited by short-term follow-up and observational design which is not considered a sufficient level of evidence for establishing the safety and effectiveness of WCD use in patients with CSHD or IA.

A report based on data from a nationwide WCD registry corroborated the conclusion of the 2010 TEC Assessment that device compliance was a significant limitation to WCD effectiveness.\textsuperscript{[9]} Of more than 3,500 patients enrolled in the registry, full compliance with treatment (defined as wearing the WCD for at least 90\% of the day) was achieved in only 52\% of patients. The device was discontinued by 14.2\% of patients, primarily due to discomfort and/or inconvenience.
HEART RHYTHM SOCIETY, AMERICA COLLEGE OF CARDIOLOGY, AND THE AMERICAN HEART ASSOCIATION

The American Heart Association (AHA) (2016) published a scientific advisory on the WCD.[2] The science advisory states that without published RCTs, the recommendations below provide direction but are not evidence-based.

**AHA Recommendations for Wearable Cardioverter Defibrillator Therapy**

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<thead>
<tr>
<th>Recommendation</th>
<th>Class</th>
<th>LOE</th>
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<tr>
<td>“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.”</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>“Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation”</td>
<td>IIa</td>
<td>C</td>
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<tr>
<td>“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.”</td>
<td>IIb</td>
<td>C</td>
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<tr>
<td>“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.”</td>
<td>IIb</td>
<td>C</td>
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<tr>
<td>“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.”</td>
<td>IIc</td>
<td>C</td>
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AHA: American Heart Association; ICD: implantable cardioverter defibrillator; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator; LOE: level of evidence; LVAD: left ventricular assist device; MSSD: mechanical circulatory support device.

In 2014, the Heart Rhythm Society, American College of Cardiology, and the American Heart Association issued a consensus statement on the use of ICD therapy in patients who are not included or not well-represented in clinical trials.[25] The statement does not contain formal recommendations regarding WCD use, but states, “The wearable cardioverter-defibrillator (WCD) may be an option as a ‘bridge to ICD’ for selected patients at high risk of sudden cardiac death due to ventricular arrhythmias, although the data are scant.”

**AMERICAN COLLEGE OF CARDIOLOGY AND THE AMERICAN HEART ASSOCIATION**

In 2014, the American College of Cardiology and the American Heart Association issued guidelines on the management of non-ST-elevation acute coronary syndrome (NSTE-ACS).[26] These guidelines do not make specific recommendations regarding the use of WCDs, but do state the following:

“Life-threatening ventricular arrhythmias that occur >48 hours after NSTE-ACS are usually associated with LV [left ventricular] dysfunction and signify poor prognosis. RCTs in patients with ACS have shown consistent benefit of implantable cardioverter-defibrillator therapy for survivors of VT or VF arrest. For other at-risk patients, especially those with significantly reduced LVEF, candidacy for primary prevention of sudden cardiac death with an implantable
cardioverter-defibrillator should be readdressed ≥40 days after discharge. A life vest may be considered in the interim.”

**SUMMARY**

There is enough research to show that wearable cardioverter-defibrillators (WCDs) as an interim treatment improves health outcomes for patients who require an implantable cardioverter defibrillator (ICD), but who have a temporary contraindication for ICD placement. Practice guidelines recommend WCDs as an interim treatment. Therefore, the use of wearable cardioverter defibrillators for the prevention of sudden cardiac death may be considered medically necessary for patients who require an ICD but have a temporary contraindication for ICD placement.

There is enough research to show that wearable cardioverter-defibrillators (WCDs) improve health outcomes for patients at risk for arrhythmic death or for certain patients needing a bridge to definitive therapy (e.g., cardiac transplant). Clinical guidelines recommend WCDs for patients at risk for arrhythmic death and for patients needing a bridge to definitive therapy (e.g., cardiac transplant). Therefore; the use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death or as a bridge to definitive therapy may be considered medically necessary for certain patients when policy criteria are met.

There is not enough research to show that wearable cardioverter-defibrillators improve health outcomes for any other indications including but not limited to the following when they are the sole indication for a WCD: patient is in the immediate (e.g., <40 days) period following an acute myocardial infarction; post coronary artery bypass graft surgery; newly diagnosed nonischemic cardiomyopathy; women with peripartum cardiomyopathy; or high-risk patients awaiting heart transplant who meet implant criteria for an implantable cardioverter-defibrillator. Therefore, use of WCDs for prevention of sudden cardiac death is considered investigational for all indications not meeting the policy criteria.

**REFERENCES**


20. Mitrani, RD, McArdle, A, Slane, M, Cogan, J, Myerburg, RJ. Wearable defibrillators in uninsured patients with newly diagnosed cardiomyopathy or recent revascularization in


27. BlueCross BlueShield Association Medical Policy Reference Manual "Wearable Cardioverter-Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator Placement." Policy No. 2.02.15

### CODES

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<tbody>
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<td>CPT</td>
<td>93292</td>
<td>Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system</td>
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<td></td>
<td>93745</td>
<td>Initial set-up and programming by a physician or other qualified health care professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events</td>
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<td>Replacement garment for use with automated external defibrillator, each</td>
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<tr>
<td></td>
<td>K0609</td>
<td>Replacement electrodes for use with automated external defibrillator, each</td>
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*Date of Origin: February 2003*