KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Wearable Automatic Defibrillators

- Automated External Defibrillators (AED) for Home Use by Pediatric Patients
- Heartstream FR2 AED for Home Use by Adult Patients

Criteria

For Medicare Members

Medical necessity review is no longer required.

For Non-Medicare Members

Medical necessity review is no longer required.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Sudden cardiac death (SCD) is a major cause of mortality in industrialized countries and is thought to account for 50% of deaths related to heart disease. In the majority of cases cardiac arrest caused by a ventricular tachyarrhythmia precedes sudden cardiac death (Reek 2003).

The implantable cardioverter defibrillator (ICD) introduced in the 1980s, proved to improve survival of patients with a history of a previous episode of sudden cardiac arrest, left ventricular dysfunction, and/or ventricular tachyarrhythmia induced by electrophysiological testing (Feldman 2004). The aim of the device is to continuously monitor the heart, identify malignant ventricular tachyarrhythmias, and deliver an electric counter shock to restore normal rhythm. It was reported that most patients experiencing cardiac arrest have no history of severe cardiac disease, and sudden cardiac death is frequently the first manifestation of a cardiovascular disease. Many others with considerable risk of SCD or those with temporary increased risk may not meet the current guidelines for ICD implantation. This has led to the development of automated external cardioverter defibrillators (AEDs) for individual use.

There are two types of AEDs: 1) The automated external defibrillator with integrated electrocardiogram analysis. This is similar to the manual defibrillator except that it detects and analyzes heart rhythms automatically. This AED requires an operator to initiate the delivery of shock, and 2) The wearable cardioverter defibrillator (WCD) which is also an external defibrillator with integrated electrocardiogram analysis, but in a garment type.

The WCD has defibrillation features similar to the ICD and does not require an operator to defibrillate. It consists of a vest-like device worn under the patient’s clothing and is sized to accommodate the chest size and weight of the patient. The device holds a monitor, electrodes, battery and a small alarm module. The monitor is designed to automatically sense abnormal heart rhythms and deliver a series of shocks through the electrodes. When arrhythmia is detected, the device displays a message to the patient to press and hold two response buttons to prevent unnecessary shocks. If the device continues to detect the abnormal rhythm and the patient loses consciousness, he / she involuntarily releases the response buttons and an electrical shock therapy is

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automatically delivered to restore the heart rhythm. Non-wearable components of the device include a battery charger, a computer modem, modem cable, computer cable, WCNET, and the diagnostic test. The WCNET is a web based data storage and retrieval system that allows the physician to access the patient's ECG data stored in the WCD monitor. The WCD has the advantage of allowing the patient to ambulate freely, and does not require assistance from a bystander when the life threatening arrhythmic event occurs (Reek 2003). It may have limited use among patients who are unable to wear the WCD vest due to obesity, or due to skin irritation from wearing the electrode 24 hours per day.

The LIFECOR Wearable Cardioverter Defibrillator (WCD ®)2000 system, is FDA approved for its use 24 hours a day by patients at risk of a sudden cardiac arrest, and an implantable defibrillator is not wanted or not practical. It should not be used if the patient has or needs an implantable ICD, is under 18 years of age, pregnant or breast feeding, has a vision or hearing problem or taking medications that would interfere with pushing the response button on the alarm module, is unwilling or unable to wear the device continuously, is of childbearing age and not attempting to prevent pregnancy, or is exposed to excessive electromagnetic interference (FDA Web page).

Medical Technology Assessment Committee(MTAC)

Wearable Automatic Defibrillators

02/05/2007: MTAC REVIEW

Evidence Conclusion: The literature search on the wearable cardioverter defibrillators revealed only small observational studies with no control or comparison groups. Two small studies (Auricchio et al, 1998, and Reek et al, 2003) tested the efficacy of the device in the electrophysiology lab among very small numbers of patients (N=15, and 12 respectively). The largest study (N=289) published by Feldman et al 2004, combined the results of two case series (WEARIT and BIROAD). They were begun as separate studies but were combined at the request of the FDA. The authors did not indicate at what stage they were grouped, but noted that they tracked the results of each group as a subpopulation. The two studies had different inclusion criteria, and different population characteristics with different implications. The WEARIT participants were patients with NYHA class III or IV heart failure and an ejection fraction <30% while BIROAD included a more heterogeneous group of patients considered at high risk after an MI or CABG surgery or were candidates of an ICD but refused the implant. The BIROAD population used the wearable defibrillator (WCD) for 4 months after which they discontinued therapy or received an ICD. The WEARIT population continued in the study until they developed a terminal heart failure requiring bed confinement, became unable to interact with the device, or experienced a definitive event as ICD implant, heart transplantation, or hospitalization for terminal heart failure. Patients in both groups could discontinue participation at any time during therapy. The follow-up duration with a mean of 3.1 months was too short, as only 8 defibrillation attempts were made, six of which were successful, 2 in the WEARIT population occurring the same patient, and four in the BIROAD population and again two occurred in the same patient. Six sudden deaths occurred in patients who were not wearing the device at the time of the event or were improperly wearing it despite the training they received and the 24-hour support they had. Over one fifth of the participants withdrew prematurely from the study, mainly due to discomfort and life style issues or due to receiving an ICD implant. In conclusion the published studies do not provide sufficient evidence to determine the efficacy and safety of the wearable cardioverter defibrillator for patients at high risk for sudden cardiac death.

Articles: The search yielded 95 articles on the automated external defibrillators. The majority were reviews, opinion pieces, studies on the non-wearable AEDs, and other articles not directly related to the current review. Three studies on the wearable cardioverter defibrillators were identified. All were observational, and two were very small (N=12-15). The largest study by Feldman and colleagues was selected for critical appraisal. Feldman AM, Klein H, Tchou P, et al. Use of wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of WEARIT/BIROAD. Pacing Clin Electrophysiol 2004; 27:4-9. See Evidence Table.

The use of Wearable Automatic Defibrillators in the prevention of sudden cardiac death does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Automated External Defibrillators (AED) for Home Use by Pediatric Patients

BACKGROUND

Approximately half of the deaths from cardiovascular disease in the United States are sudden and unexpected. Defibrillation immediately after a witnessed ventricular fibrillation (VF) has been shown to increase survival rates from cardiac arrest. Each minute of delaying defibrillation is associated with about a 10% reduction in survival and survival rates after 10 minutes of VF are low (Marenco et al., 2001) The use of automated external defibrillators (AEDs) by lay people can reduce the time to defibrillation compared to waiting for the arrival of emergency medical personnel. AEDs, which were first introduced in 1979, are portable devices designed both to analyze cardiac

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rhythms via a heart rhythm analysis algorithm and to deliver shocks. Shock treatment is appropriate when the patient is in ventricular fibrillation. The devices indicate to the operator via text and/or voice prompts whether shock treatment is recommended. AEDs were first approved by the FDA for use in adults. In May, 2001, the FDA approved the Heartstream FR2 with attenuated defibrillation pads (Agilent Technologies, Seattle, WA) for use in infants and children with ventricular fibrillation. The Heartstream FR2 is specifically designed for children who are 8 years old or younger, weigh 55 pounds or less, and are not responsive and not breathing. The attenuated pads deliver a shock that is about one-third the strength delivered to adults FDA Web site).
There is interest in having the Heartstream FR2 available at home at school for children with known heart disease. In order to be effective, the pediatric AED device must accurately detect shockable and non-shockable rhythms and must deliver an appropriate level of shock. Moreover, the device must be able to be used properly by parents and school personnel. In addition, AEDs are only applicable when patients are in ventricular fibrillation. Children in cardiac arrest may be less likely than adults to be in VF, although data are few and conflicting. The largest study, an analysis of 10,992 non-traumatic cardiac arrests in Seattle/King County between 1976 and 1992 (Appleton et al., 1995), found that VF was the first recorded rhythm in only 12/412 (3%) of patients 0-7 years old. In adults 30 years or older, the rate of VF was 42%. In another report of Seattle/King County data (Mogayzel et al., 1995), VF was the initial rhythm in 12 out of the 24 emergency medical services patients under 20 years old whose arrest was due to a cardiac cause and 2 out of 8 patients with congenital heart disease. Evidence on the technical accuracy of the Heartstream FR2 and the ability of AEDs to reduce mortality in practice will be reviewed.

12/11/2002: MTAC REVIEW
Automated External Defibrillators (AED) for Home Use by Pediatric Patients
Evidence Conclusion: The findings from a study by Cecchin et al suggest that the Heartstream FR2 AED can effectively distinguish between shockable and non-shockable rhythms in children. Limitations of this study are possible bias in selecting children for inclusion, variability in data collection and the first author being a consultant to the device manufacturer. Shocks were not actually delivered in the Cecchin study, so the appropriateness of the intensity of shock could not be examined. No evidence was available on the effectiveness of the device at reducing mortality in practice.
Articles: The search yielded 28 articles. Many of the articles were reviews, dealt with technical issues or addressed the use of AEDs in public places. There were no articles on clinical outcomes (e.g. mortality) of pediatric patients or on the actual use of AEDs for pediatric patients at home or at school. There was one article on the ability of the Heartstream FR2 to accurately detect arrhythmias in children (Cecchin et al., 2001) and no articles on the appropriateness of the shock delivered by the device to pediatric patients. The Cecchin article was critically appraised: Ceccin F, Jorgenson DB, Berul CI et al. Is arrhythmia detection by automatic external defibrillator accurate for children? *Circulation* 2001; 103: 2483-2488. See Evidence Table.

The use of AED in the prevention of sudden death in the home from ventricular fibrillation does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Medical Necessity Review not required:

CPT® or HCPC Codes	Description
E0617	External defibrillator with integrated electrocardiogram analysis
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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

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Date Created	Date Reviewed	Date Last Revised
04/19/2007	9/7/2010[MDCRPC], 7/5/2011[MDCRPC], 5/1/2012[MDCRPC], 3/5/2013[MDCRPC], 1/7/2014[MDCRPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/02/2021[MPC] , 02/01/2022[MPC], 02/07/2023[MPC]	07/19/2018

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
07/19/2018	No medical necessity review was added for Medicare members.

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