



AUTOMATED EXTERNAL DEFIBRILLATORS (NON-WEARABLE)

Policy number: 200401-0004

Original effective date: 01/28/2004

Revision date: 11/01/2009

Overview

It has been demonstrated that early defibrillation can result in improved survival from sudden cardiac arrest (SCA). The implantable cardioverter-defibrillator is currently the gold-standard treatment for preventing sudden cardiac death in high risk individuals, including those with a history of SCA and those at risk for ventricular arrhythmias, such as patients with prior myocardial infarction (MI) and reduced ejection fractions.

Estimates of the incidence of SCA in the U.S. vary widely because SCA is not a reportable disease or cause of death. Some experts estimate that sudden death claims 250,000 lives annually in the U.S. The vast majority of such events are due to ventricular fibrillation and ventricular tachycardia. Even though these arrhythmias can be converted if treated promptly, less than 5% of victims of out-of-hospital cardiac arrest survive to hospitalization.

To determine the effect of public access defibrillator (PAD) programs on survival and other outcomes after SCA, the National Heart, Lung and Blood Institute, the American Heart Association, and others, funded a large prospective randomized trial. Volunteers at various locations were randomly assigned to bystander CPR only or to bystander CPR plus AED. More than 11,600 AEDs were placed in public locations, such as recreational facilities and shopping centers. In patients receiving bystander CPR only, 15 of 107 survived to hospital discharge. In patients receiving bystander CPR plus AED, 30 of 128 survived to hospital discharge. These differences are statistically significant. (The Public Access Defibrillation Trial, 2004)

The AED has proven to be safe, reliable, and efficacious in the diagnosis and treatment of ventricular arrhythmias when employed by lay providers/rescuers in a variety of public settings. Society has embraced these data and legislation has been passed that supports the implementation of PAD programs into communities and protects lay rescuers and organizations implementing these programs from liability. (Rho, 2007)

An important issue not addressed in the PAD trial (or in any other prospective, randomized trial), was whether or not AEDs in the home improved survival beyond that achieved with EMS in addition to bystander CPR. An \$18 million trial sponsored by the National Health, Lung and Blood Institute was designed to provide a definitive answer to this question. In this study, 7,000 patients were prospectively randomized to either bystander CPR and EMS (control group) or to bystander CPR, home AED and EMS. The Home Automated External Defibrillator (HAT) study was conducted from January 2003 to October 2005. The results of the HAT study were published April 24, 2008 in the New England Journal of Medicine. Overall, 450 patients died: 228 of 3,506 patients



in the control group, and 222 of 3,495 patients in the AED group. Mortality did not differ significantly in either group, and the availability of an AED in the home did not improve overall survival as compared to the control. (Bardy et al., 2008)

Definitions

Automated external defibrillator (AED) – a portable machine that is designed to analyze a patient's EKG, interpret the rhythm, and automatically deliver an electric shock (fully automated AED), or advise the user to deliver the shock (semi-automated AED). Non-wearable AEDs require the presence of a bystander who is willing and able to use an AED.

Policy

Commercial

Automated external defibrillators (non-wearable) for home use are not covered for commercial plan members because the availability of an AED in the home has not been shown to improve overall survival as compared to the CPR and EMS.

Fallon Senior Plan™

Preauthorization by FCHP is required.

Automatic external defibrillators (non-wearable) are covered for Fallon Senior Plan™ members at high risk for sudden cardiac death (SCD). The plan member must meet both criteria A and B or criteria C, described below:

- A. The patient has one of the following conditions (1-8):
1. A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause.
 2. A sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, either spontaneous or induced during an electrophysiologic (EP) study, not associated with acute myocardial infarction, and not due to a transient or reversible cause.
 3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy.
 4. Coronary artery disease with a documented prior myocardial infarction, with a measured left ventricular ejection fraction less than or equal to 0.35, and inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) during an EP study. To meet this criterion:
 - a. The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription; and,
 - b. The EP test must have been performed more than 4 weeks after the qualifying myocardial infarction.
 5. Documented prior myocardial infarction and a measured left ventricular ejection fraction less than or equal to 0.30. Patients must not have:
 - a. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or
 - b. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months; or
 - c. Had an enzyme-positive MI within past month; or



- d. Clinical symptoms or findings that would make them a candidate for coronary revascularization; or
 - e. Irreversible brain damage from preexisting cerebral disease; or
 - f. Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
6. Patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) \leq 35%.
 7. Patients with nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart failure, and measured LVEF \leq 35%.
 8. Patients who meet one of the previous criteria (1-7) and have NYHA Class IV heart failure.

B. Implantation surgery is contraindicated.

C. A previously implanted defibrillator now requires explantation.

AEDs for Fallon Senior Plan™ members for other indications will be denied as not medically necessary.

The AED must be prescribed by a physician who is experienced in the management of patients at risk for SCD. The physician should ensure that family members who will be responsible for operating the AED are properly trained. An AED operator must know how to recognize the signs of sudden cardiac arrest, when to activate the EMS system, and how to do CPR.

Exclusions

1. Over-the-counter automated external defibrillators, such as the Philips HeartStart Home Defibrillator, Model M5068A (Philips Medical System, Seattle, WA) are not covered.

Codes

AEDs are covered for Fallon Senior Plan™ members only.

Codes	Number	Description
HCPCS	E0617	External Defibrillator with integrated electrocardiogram analysis

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References

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Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

Committee review dates:

Technology Assessment Subcommittee: 03/24/2009

Technology Assessment Committee: 01/28/2004, 06/10/2009

IMPORTANT NOTE

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.