Anthem

Medical Policy

Subject: Automated External Defibrillators for Home Use
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Description/Scope

This document addresses automated external defibrillators (AEDs) for home use. An AED is a portable machine that uses an algorithm to distinguish ventricular fibrillation (VF) from other cardiac rhythms, advises the rescuer that a shockable rhythm is present, and then allows for the delivery of the appropriate amplitude shock to "restart" the individual's normal heart rhythm. This document does not address wearable or implantable cardioverter defibrillators.

Note: Please see the following related documents for additional information:

- MED.00055 Wearable Cardioverter Defibrillators

Position Statement

Investigational and Not Medically Necessary:

Automated external defibrillators for home use are considered **investigational and not medically necessary.**

Rationale

The implantable cardioverter defibrillator (ICD) is currently the "gold-standard" treatment for preventing sudden cardiac death (SCD) in high-risk individuals, including those with a previous history of sudden cardiac arrest (SCA) and those at risk for ventricular arrhythmias, such as individuals with prior myocardial infarction (MI) and reduced ejection fraction.

Clinical studies suggest that AED use in public locations, such as airports and casinos, improves survival from SCA. The Public Access Defibrillation (PAD) trial, sponsored by the National Institutes of Health (NIH), was a multicenter study in which community-based AED training was employed in "high-risk" settings, that included 1260 community sites and residential locations with more than 250 persons older than age 50 years on site for most of the day, or sites where a cardiac arrest had occurred within the 2 years prior to the study. Sites were randomized to rescuers trained in cardiopulmonary resuscitation (CPR) alone or those trained in CPR and defibrillator use. Approximately 20,000 lay volunteers were trained, representing almost 10 volunteers per available defibrillator. The primary endpoint of the study was the number of subjects who survived to hospital discharge. More cardiac arrests occurred in the CPR-defibrillator locations (n=129) than in the CPR-alone locations (n=103). A total of 29 individuals in the CPR-defibrillator group survived to hospital discharge (22.5%), compared with only 15 in the CPR alone group (14.6%) (p=0.042). Notably, there was only 1 survival to hospital discharge in each group when SCA occurred in a residential unit. Investigators drew the following conclusions from the study results:

- Trained laypersons can use AEDs safely to provide early defibrillation;
- Survival rate almost doubles when AEDs are added to CPR-trained response systems in public facilities with predefined increased risk;
- The survival rate in multi-unit residential facilities is very low (Hallstrom, 2004).

An important issue not addressed in the PAD study is whether or not AED use in the home setting improves health outcomes and survival beyond that achieved with the standard emergency response (EMS call, in addition to CPR). The Home Use of Automatic External Defibrillators to Treat Sudden Cardiac Arrest Trial (HAT), sponsored by the National Heart, Lung and Blood Institute (NHLBI), enrolled an estimated 7000 individuals who were randomized, following anterior MI, into either a group that received standard lay response to SCA (call EMS and begin CPR) or to a group that received home AED and the standard response. The primary endpoint was all-cause mortality in the two arms of the trial with secondary endpoints of survival free from post-arrest neurological impairment and diminished quality of life (QOL) for affected individuals and spouses. This Phase III trial enrolled participants for more than 2 years and followed them for an additional 2 years at 200 cardiology clinics. Results of this study were published in 2008 and concluded that for survivors of anterior-wall MI who were not candidates for implantation of a cardioverter-defibrillator, access to a home AED did not significantly improve overall survival, as compared with reliance on conventional resuscitation methods (Bardy, 2008; Mark, 2010).

A large randomized controlled trial (RCT) (n=2589) conducted by Rubertsson and colleagues (2014) compared mechanical chest compressions and simultaneous defibrillation with conventional CPR in individuals who are undergoing SCA outside of a hospital (LUCAS in Cardiac Arrest Study [LINC]). The primary outcome measure was 4-hour survival and the secondary outcome measure was survival up to 6 months with a favorable neurological outcome. Neurological outcomes were assessed using the Cerebral Performance Category (CPC) score; a score of 1 or 2 was classified as a "good" outcome. Final results showed that there were no statistically significant differences in 4-hour survival between participants treated with conventional CPR and those treated with mechanical chest compressions and simultaneous AED. At 6 months of follow-up, participants in both groups demonstrated good neurological outcomes. Mechanical chest compression and AED did not demonstrate a net improvement in effectiveness when compared with manual CPR techniques.

Background/Overview

Sudden cardiac arrest (SCA) is estimated to account for over 250,000 deaths annually. Although all known heart diseases can lead to SCA, the life-threatening arrhythmia of ventricular fibrillation (VF) is the leading cause. Early recognition of arrhythmia and subsequent defibrillation is the most important factor in survival from a cardiac arrest due to VF. Approximately 80 percent of people who suffer SCA are at home when it happens.

An automated external defibrillator, or AED, is a portable machine that is designed to use an algorithm to distinguish VF from other cardiac rhythms, advise the rescuer that a shockable rhythm is present, and then allow for the delivery of the appropriate amplitude shock to restore the individual's normal heart rhythm. AEDs are designed to be used by lay rescuers or first responders.

The U.S. Food and Drug Administration (FDA) cleared the HeartStart Home OTC Defibrillator (Philips Medical Systems, Seattle, WA) for home use through the 510(k) approval process on September 16, 2004. The FDA cleared indication for use is, "For the termination of ventricular fibrillation and pulseless ventricular tachycardia. These devices are intended to be used on suspected victims of sudden cardiac arrest" (FDA, 2004). The previous version of this device required a prescription. However, this device is available without a prescription. On June 06, 2019, HeartStart Home OTC Defibrillator received FDA Premarket Approval (PMA) (FDA, 2019). There are additional devices for home use that have also been cleared by the FDA, (for example, the HeartSine Samaritan® PAD [HeartSine Technologies, Inc., San Clemente, CA]). On January 25, 2010 the Circulatory System Devices Panel of the FDA Center for Devices and Radiological Health (CDRH) issued a recommendation that, "AEDs be classified as Class III medical devices and be subject to the regulations in accordance with [PMA] applications." According to the FDA, AED devices, although historically classified as Class III devices, have not been subject to the requirement of submitting a PMA application to demonstrate affirmatively a reasonable assurance of safety and effectiveness. Instead, they have been allowed to enter the market following FDA clearance of a 510(k) submission, usually reserved for lower-risk devices. On February 3, 2015 the FDA issued a Final Order which now requires all AED devices to meet PMA protocols; AED manufacturers must now submit PMA applications for FDA approval for all previously cleared AED devices. In addition, this new order requires that all new AED devices and accessories have an approved PMA in effect before being placed in commercial distribution (FDA, 2015). This order is based on the reports of 45,000 adverse events and 88 recalls received by the FDA between 2005 and 2013, many due to battery failure and improper maintenance. The FDA maintains an updated list of approved AEDs on their website (FDA, 2023).

Definitions

Cardiac arrhythmia: A disturbance in the electrical activity of the heart that manifests as an abnormality in the heart rate or heart rhythm. Individuals with arrhythmias may experience a wide variety of symptoms ranging from palpitations to fainting to death.

Coronary artery: Vessels that supply blood to the myocardium (middle layer of the walls of the heart). Coronary arteries subdivide into branched vessels that travel down the length of the heart supplying oxygenated blood to the myocardium.

Coronary artery disease: This condition refers to narrowing of the coronary arteries sufficient to prevent adequate blood supply to the myocardium.

Defibrillation: A process in which an electronic device sends an electric shock to the heart to attempt to restore the normal heart rhythm.

Ejection fraction: The ejection fraction is the percentage of blood that is pumped out with each heartbeat: a measure of ventricular contractility.

Fibrillation: Very rapid contractions or twitching of small muscle fibers in the heart.

Tachycardia: An abnormally rapid heartbeat.

Ventricle: One of two lower chambers of the heart.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

HCPCS

E0617	External defibrillator with integrated electrocardiogram analysis

ICD-10 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

1. Bardy GH, Lee KL, Mark DB, et al.; HAT Investigators. Home use of automated external defibrillators for sudden cardiac arrest. N Engl J Med. 2008; 358(17):1793-1804.
2. Cecchin F, Jorgenson DB, Berul CI, et al. Is arrhythmia detection by automatic external defibrillator accurate for children: sensitivity and specificity of an automatic external defibrillator algorithm in 696 pediatric arrhythmias. Circulation. 2001; 103(20):2483-2488.
3. Fukuda T, Ohashi-Fukuda N, Kobayashi H, et al. Public access defibrillation and outcomes after pediatric out-of-hospital cardiac arrest. Resuscitation. 2017; 111:1-7.
4. Hallstrom AP, Ornato JP, Weisfeldt M, et al. Public Access Defibrillation (PAD) Trial Investigators. Public-access defibrillation and survival after out-of-hospital cardiac arrest. N Engl J Med. 2004; 351(7):637-646.
5. Kadish A. Public-access defibrillation: advances and controversies. Primary Care Perspectives. Medscape Primary Care. 2004; Volume 6(1).
6. Koster RW. Automatic external defibrillator: key link in the chain of survival. J Cardiovasc Electrophysiol. 2002; 13(1 Suppl):S92-S95.
7. Lee BK, Olgin JE. Role of wearable and automatic external defibrillators in improving survival in patients at risk for sudden cardiac death. Curr Treat Options Cardiovasc Med. 2009; 11(5):360-365.
8. Marenco JP, Wang PJ, Link MS, et al. Improving survival from sudden cardiac arrest: the role of the automatic external defibrillator. JAMA. 2001; 285(9):1193-1200.
9. Mark DB, Anstrom KJ, McNulty SE, et al. Quality of life effects of automatic external defibrillators in the home: results from the Home Automatic External Defibrillator Trial (HAT). Am Heart J. 2010; 159(4):627-634.e7.
10. McLeod KA, Fern E, Clements F, McGowan R. Prescribing an automated external defibrillator for children at increased risk of sudden arrhythmic death. Cardiol Young. 2017; 27(7):1271-1279.
11. Meischke H, Diehr P, Phelps R, et al. Psychologic effects of automated external defibrillator training: a randomized trial. Heart Lung. 2011; 40(6):502-510.
12. Pundi KN, Bos JM, Cannon BC, Ackerman. Automated external defibrillator rescues among children with diagnosed and

treated long QT syndrome. Heart Rhythm. 2015; 12(4):776-781.
13. Rubertsson S, Lindgren E, Smekal D, et al. Mechanical chest compressions and simultaneous defibrillation vs conventional cardiopulmonary resuscitation in out-of-hospital cardiac arrest: the LINC randomized trial. JAMA. 2014; 311(1):53-61.
14. Sanna T, La Torre G, de Waure C, et al. Cardiopulmonary resuscitation alone vs. cardiopulmonary resuscitation plus automated external defibrillator use by non-healthcare professionals: a meta-analysis on 1583 cases of out-of-hospital cardiac arrest. Resuscitation. 2008; 76(2):226-232.
15. Solomon SD, Zelenkofske S, McMurray JJ, et al.; Valsartan in Acute Myocardial Infarction Trial (VALIANT) Investigators. Sudden death in patients with myocardial infarction and left ventricular dysfunction, heart failure, or both. NEJM. 2005; 352(25):2581-2588. Erratum in: NEJM. 2005; 353(7):744.
16. Sparks KE. Owning a home defibrillator: security blanket or excuse to do nothing? Primary Care Perspectives. Medscape Primary Care. 2004; Volume 6(1).
17. Stokes NA, Scapigliati A, Trammell AR, Parish DC. The effect of the AED and AED programs on survival of individuals, groups and populations. Prehosp Disaster Med. 2012; 27(5):419-424.
18. Weisfeldt ML, Everson-Stewart S, Sitlani C, et al.; Resuscitation Outcomes Consortium Investigators. Ventricular tachyarrhythmias after cardiac arrest in public versus at home. N Engl J Med. 2011; 364(4):313-321.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Association for Respiratory Care (AARC) Clinical Practice Guideline: Resuscitation and Defibrillation in the Health Care Setting. 2004 revision and update to 1995 Guideline on defibrillation during resuscitation and the 1993 Guideline on resuscitation in acute care hospitals. Available at: http://rc.rcjournal.com/content/respcare/49/9/1085.full.pdf. Accessed on December 30, 2023.
2. Emergency Cardiovascular Care (ECC) Committee, Subcommittees and Task Forces of the American Heart Association. 2005 American Heart Association Guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation. 2005; 112(24 Suppl):IV1-203.
3. Epstein AE, DiMarco JP, Ellenbogen KA, et al. American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS) 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices) developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. May 2008. J Am Coll Cardiol. 2008; 51(21):e1-e62. Available at: https://www.ahajournals.org/doi/10.1161/CIRCUALTIONAHA.108.189742. Accessed on December 30, 2023.
4. Hazinski MF, Idris AH, Kerber RE, et al. Lay rescuer automated external defibrillator (public access defibrillation) programs: lessons learned from an international multi-center trial. Advisory statement from the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology. Circulation. 2005; 111(24):3336-3340.
5. Kushner FG, Hand M, Smith SC Jr, et al. 2009 focused updates: ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction (updating the 2004 guideline and 2007 focused update) and ACC/AHA/SCAI guidelines on percutaneous coronary intervention (updating the 2005 guideline and 2007 focused update): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2009; 54(23):2205-2241. Available at: https://www.jacc.org/doi/abs/10.1016/j.jacc.2009.10.015. Accessed on December 30, 2023.
6. Masoudi FA, Ponirakis A, de Lemos JA, et al. Executive Summary: Trends in U.S. Cardiovascular Care: 2016 Report From 4 ACC National Cardiovascular Data Registries. J Am Coll Cardiol. 2017; 69(11):1424-1426.
7. Myerburg RJ, Estes NA 3rd, Fontaine JM, et al. Task Force 10: automated external defibrillators. J Am Coll Cardiol. 2005; 45(8):1369-1371.
8. O'Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013; 61(4):e78-140.
9. Ontario Ministry of Health and Long-term Care, Medical Advisory Secretariat (MAS). Use of automated external defibrillators in cardiac arrest. An evidence-based analysis. Toronto, ON: MAS; December 2005; 5(19).
10. Priori SG, Bossaert LL, Chamberlain DA, et al. ESC-ERC recommendations for the use of automated external defibrillators (AEDs) in Europe. The European Society of Cardiology (ESC) and the European Resuscitation Council (ERC) Policy Conference: December 2002. Eur Heart J. 2004; 25(5):437-445.
11. Samson RA, Berg RA, Bingham R. Use of automated external defibrillators for children: an Advisory Statement from the Pediatric Advanced Life Support Task Force, International Liaison Committee on Resuscitation. Circulation. 2003; 107(25):3250-3255. Available at: https://www.ahajournals.org/doi/10.1161/01.cir.0000074201.73984.fd. Accessed on December 30, 2023.
12. Tracy CM, Epstein AE, Darbar D, et al. 2012 ACCF/AHA/HRS focused update of the 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2012; 60(14):1297-1313. Available at: https://www.ahajournals.org/doi/full/10.1161/cir.0b013e3182618569. Accessed on December 30, 2023.
13. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health 510(k) Premarket Notification Database. New device clearance: Philips HeartStart Home OTC Defibrillator (Seattle, WA) Summary of Safety and Effectiveness. No. K040904. September 16, 2004. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf4/k040904.pdf. Accessed on December 30, 2023.
14. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health Premarket Approval Application (PMA). Philips HeartStart Home OTC Defibrillator (Seattle, WA). Summary of Safety and Effectiveness. PMA Number: P160029. June 06, 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160029B.pdf. Accessed on December 23, 2022.
15. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health 510(k) Premarket Notification Database. HeartSine Samaritan® PAD (HeartSine Technologies, Inc., San Clemente, CA) Summary of Safety and Effectiveness. No. K041067. May 25, 2004. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf4/K041067.pdf. Accessed on December 30, 2023.
16. US. and Drug Administration (FDA). Automated External Defibrillators (AEDs). July 2023. Available at: https://www.fda.gov/medical-devices/cardiovascular-devices/automated-external-defibrillators-aeds#check. Accessed on January 06, 2024.
17. U.S. Food and Drug Administration (FDA). Automated External Defibrillators (AEDs). Final Order. February 3, 2015. Available at: https://www.federalregister.gov/articles/2015/02/03/2015-02049/effective-date-of-requirement-for-premarket-approval-for-automated-external-defibrillator-systems. Accessed on December 30, 2023.
18. Weisfeldt ML, Sitlani CM, Ornato JP, et al.; ROC Investigators. Survival after application of automatic external defibrillators before arrival of the emergency medical system: evaluation in the resuscitation outcomes consortium population of 21 million. J Am Coll Cardiol. 2010; 55(16):1713-1720.

19. Zipes DP, Camm AJ, Borggrefe M, et al. ACC/AHA/ESC 2006 guidelines 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 and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to develop guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death). J Am Coll Cardiol. 2006; 48(5):e247-346. Available at: https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.106.178104. Accessed on December 30, 2023.

Websites for Additional Information

1. American Heart Association. Available at: http://www.americanheart.org. Accessed on December 30, 2023.
2. National Heart, Lung and Blood Institute. Health Topics. Available at: https://www.nhlbi.nih.gov/health-topics/defibrillators. Accessed on December 30, 2023.
    - How to use an automated external defibrillator.
    - When should an automated external defibrillator be used?

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Background/Overview and References sections.
Reviewed	02/16/2023	MPTAC review. Updated References section.
Reviewed	02/17/2022	MPTAC review. Background/Overview and References sections were updated.
Reviewed	02/11/2021	MPTAC review. Background/Overview and References sections were updated.
Reviewed	02/20/2020	MPTAC review. Background/Overview and References were updated.
Revised	03/21/2019	MPTAC review. An acronym (AED) was removed from the Position Statement. References were updated.
Reviewed	03/22/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated References section.
Reviewed	05/04/2017	MPTAC review. Updated References section.
Reviewed	05/05/2016	MPTAC review. The Background section and References were updated. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated Rationale and References.
Reviewed	05/15/2014	MPTAC review. Description/Scope, Rationale, Background/Overview and References were updated.
Reviewed	05/09/2013	MPTAC review. Definitions and References were updated.
Reviewed	05/10/2012	MPTAC review. References were updated.
Reviewed	05/19/2011	MPTAC review. The Background and References were updated.
Reviewed	05/13/2010	MPTAC review. The Background section and References were updated.
Reviewed	05/21/2009	MPTAC review. The Rationale, Background and References sections were updated.
Reviewed	05/15/2008	MPTAC review. References and Background sections were updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	05/17/2007	MPTAC review. References were updated.
Reviewed	06/08/2006	MPTAC review. Document was renumbered from former MED.00049 to DME.00032. References were updated.
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	07/28/2004	MED.00049	Automatic External Defibrillators and Wearable Cardioverter-Defibrillators
WellPoint Health Networks, Inc.	06/24/2004	9.04.05	Automated External Defibrillators for Home Use

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Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.