ND

Medical Policies

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Policy Number:	E-9003		
Policy Name:	Automated External Defibrillators for Home Use		
Policy Type:	Medical	**Policy Subtype:**	Durable Medical Equipment (DME)
Effective Date:	09-15-2025	**End Date:**	11-02-2025

Description

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 United States Food and Drug Administration (U.S. 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 U.S. 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" (U.S. 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 U.S. FDA Premarket Approval (PMA) (U.S.FDA, 2019). There are additional devices for home use that have also been cleared by the U.S.FDA, (for example, the HeartSine Samaritan® PAD [HeartSine Technologies, Inc., San Clemente, CA]).

On January 25, 2010, the Circulatory System Devices Panel of the U.S. 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 U.S. 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 U.S. FDA issued a Final Order which now requires all AED devices to meet PMA protocols; AED manufacturers must now submit PMA applications for U.S. 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 (U.S. 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.

Policy Application

All claims submitted for this policy will be processed according to the policy effective date and associated revision effective dates in effect on the date of processing, regardless of service date.

Diagnosis Codes

Not Applicable

CURRENT CODING

HCPCS:

E0617	Automatic ext defibrillator	Commercial
E0617	Automatic ext defibrillator	Medicaid Expansion

References

Peer Reviewed Publications:

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Government Agency, Medical Society, and Other Authoritative Publications:

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ND Committee Review

Internal Medical Policy Review 07-22-2021 New Policy for ND **Effective 9-6-2021**

Internal Medical Policy Review 07-21-2022 Annual Review - no changes in criteria **Effective 9-5-2022**

Internal Medical Policy Committee 7-26-2023 Annual Review - no changes in criteria **Effective 9-4-2023**

Internal Medical Policy Committee 7-16-2024 Annual Review - no changes in criteria **Effective 9-2-2024**

- **Added** Policy Application

Disclaimer

Current medical policy is to be used in determining a Member's contract benefits on the date that services are rendered. Contract language, including definitions and specific inclusions/exclusions, as well as state and federal law, must be considered in determining eligibility for coverage. Members must consult their applicable benefit plans or contact a Member Services representative for specific coverage information. Likewise, medical policy, which addresses the issue(s) in any specific case, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and the Company reserves the right to review and update medical policy periodically.