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Nonwearable Automatic External Defibrillators

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

A nonwearable automatic defibrillator **may be considered medically necessary** for individuals who meet either: 1) both criteria A and B, **OR** 2) criteria C, as described below.

A. The individual has **one or more** 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, that is:
      a. NOT associated with acute myocardial infarction (MI), and
      b. 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 MI with a measured left ventricular ejection fraction (LVEF) ≤ 0.35, and **ALL** of the following:
      a. Inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) during an EP study;

b. MI occurred more than 4 weeks prior to the external defibrillator prescription;
c. EP study was performed more than 4 weeks after the qualifying MI.

5. Documented prior MI and a measured LVEF ≤ 0.30 and **ALL** of the following:
    a. No cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
    b. No coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within the past 3 months;
    c. No enzyme-positive MI within the past month;
    d. No clinical symptoms or findings that would make the individual a candidate for coronary revascularization;
    e. No irreversible brain damage from preexisting cerebral disease; or
    f. No disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
6. Ischemic dilated cardiomyopathy (IDCM) and **ALL** of the following:
    a. Documented prior MI;
    b. New York Heart Association (NYHA) Class II or III heart failure;
    c. Measured LVEF ≤ 35%.
7. Nonischemic dilated cardiomyopathy (NIDCM) > 3 months and **ALL** of the following:
    a. NYHA Class II or III heart failure;
    b. Measured LVEF ≤ 35%.
8. 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.

Nonwearable automatic defibrillators for other indications **are considered not medically necessary.**

Policy Guidelines

Myocardial infarctions are defined by elevated cardiac enzymes or Q-waves on an electrocardiogram.

Ejection fraction must be measured by angiography, radionuclide scanning, or echocardiography.

Transient or reversible dysrhythmia causes include conditions such as drug toxicity, severe hypoxia, acidosis, hypokalemia, hypercalcemia, hyperkalemia, systemic infections, and myocarditis (not all-inclusive).

Description

Sudden cardiac arrest (SCA) and sudden cardiac death (SCD) refer to the sudden cessation of cardiac activity with hemodynamic collapse, typically due to sustained ventricular tachycardia/ventricular fibrillation (VF), pulseless electrical activity (PEA), or asystole. These events mostly occur in patients with structural heart disease (that may not have been previously diagnosed), particularly coronary heart disease (CHD). The event is referred to as SCA (or aborted SCD) if an intervention (e.g., defibrillation) or spontaneous reversion restores circulation and the event is called SCD if the patient dies.

The specific causes of SCA vary with the population studied and patient age. Hayashi et al. (2015) notes that SCD most often develops in older adults with acquired structural heart disease, but it also rarely occurs in the young, where it is more commonly because of inherited disorders. Coronary heart disease is known to be the most common pathology underlying SCD, followed by cardiomyopathies, inherited arrhythmia syndromes, and valvular heart disease. (2) The outcome following SCA depends upon numerous factors including the underlying cause and the rapidity of resuscitation. Most individuals suffering from SCA become unconscious within seconds to minutes as a result of insufficient cerebral blood flow. There are usually no premonitory symptoms. If symptoms are present, they are nonspecific and include chest discomfort, palpitations, shortness of breath, and weakness.

Several interventions can improve the likelihood of VF resuscitation, the single most important is early delivery of an external electric shock to reset the cardiac rhythm and restore spontaneous circulation. Early defibrillation is consistently associated with a greater likelihood of survival, which decreases by approximately five to ten percent with each additional minute from collapse to defibrillation. (3)

An automatic external defibrillator (AED) is a portable device designed to analyze a patient's electrocardiogram (EKG), the heart rhythm in people who are experiencing cardiac arrest. When appropriate, the AED automatically delivers a defibrillation shock (fully automated AED) or advises the user to deliver a defibrillation shock (semi-automated AED) in an attempt to restore a normal heart rhythm. There are two main types of AEDs: public access and professional use. Public access AEDs can be found in airports, community centers, schools, government buildings, hospitals, and other public locations. They are intended to be used by laypeople who have received minimal training. Professional use AEDs are used by first responders, such as emergency medical technicians (EMTs) and paramedics, who receive additional AED training. (4)

The U.S. Food and Drug Administration (FDA) regulates AEDs as medical devices. In addition, the FDA notes that AEDs are not difficult to use, but training in the use of AEDs is highly recommended. (6)

Regulatory Status

The FDA requires manufacturers to obtain premarket approval for all nonwearable AEDs and AED accessories. (4)

The HeartStart Home Defibrillator (Model M5068A) received FDA Premarket approval on June 6, 2019. (5) It is indicated for use on potential victims of sudden cardiac arrest with the following symptoms:

- Unconsciousness; and
- Absence of normal breathing.

The HeartStart Home Defibrillator (Model M5068A) is indicated for adults over 55 pounds (25 kg). This device is also indicated for infants and children under 55 lbs (25 kg) or 8 years old when used with the optional infant/child SMART pads (Model M5072A).

The HeartStart Home device when used with the Adult SMART Pads Cartridges are for over-the-counter use. The sale and distribution of the Infant/Child SMART Pads Cartridges for use with the HeartStart Home device are restricted to prescription use.

Please note, this list is not all inclusive. Please see the U.S. FDA website at <https://www.fda.gov> for a current list of U.S. FDA-approved AEDs.

Rationale

This policy is based on a review of coverage guidance from the Centers for Medicare and Medicaid Services (CMS) specific to automatic external defibrillators. (1)

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	E0617

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

Local Coverage Determination

1. Centers for Medicare and Medicaid Services. Local Coverage Determination for Automatic External Defibrillators (L33690) (January 1, 2020) (Revision 7). Available at <https://www.cms.gov> (accessed April 24, 2025).

Other

2. Hayashi M, Shimizu W, Albert CM. The spectrum of epidemiology underlying sudden cardiac death. Circ Res. 2015 Jun 5; 116(12):1887-1906. PMID 26044246
3. Rea TD. Automated external defibrillators. In: UpToDate, Page RL and Botkin NF (Eds), UpToDate, Waltham, MA. Available at: <https://www.uptodate.com> (accessed April 24, 2025).
4. U.S. Food and Drug Administration (FDA). Automatic External Defibrillators (AEDs). Content current as of: October 22, 2024. Available at: <https://www.fda.gov> (accessed May 22, 2025).
5. U.S. Food and Drug Administration (FDA). HeartStart OnSite Defibrillator (Model M5066A), HeartStart Home Defibrillator (Model M5068A), SMART Pads Cartridges (Adult Model M5071A) and Infant/Child (Model M5072A). (P160029) June 6, 2019. Available at <https://www.accessdata.fda.gov> (accessed April 24, 2025).
6. U.S. Food and Drug Administration (FDA). How AEDs in Public Places Can Restart Hearts. November 17, 2022. Available at: <https://www.fda.gov> (accessed May 22, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/01/2025	Document updated. Coverage criteria revised to be consistent with coverage guidance from the Centers for Medicare and Medicaid Services. Added references 1 and 6, others removed. Title changed from: Nonwearable Automatic External Defibrillator (AED) for Home Use.
07/01/2024	Document updated with literature review. Coverage changed from experimental, investigational and/or unproven to medically necessary for home use of a U.S. Food and Drug Administration (FDA)-approved nonwearable automatic external defibrillator when the conditional criteria are met. Added “NOTE 1: See medical policy SUR707.003 Implantable Cardioverter Defibrillators (ICDs) for indications for ICD devices”. References 1, 4, 5 and 9 were added. Some references were removed.
03/15/2023	Document updated with literature review. Coverage unchanged. No new references added; some were updated.

08/15/2022	Reviewed. No changes.
01/01/2022	Document updated with literature review. Coverage unchanged. Added references 7 and 11; others were updated.
01/15/2021	Reviewed. No changes.
08/15/2020	Document updated with literature review. Coverage unchanged. Added/updated references 1, 4 and 8.
10/15/2019	Reviewed. No changes.
11/15/2018	Document updated with literature review. Coverage unchanged. Added references 6-10.
08/15/2017	Document updated with literature review. Coverage unchanged.
10/01/2016	Reviewed. No changes.
06/15/2015	Document updated with literature review. Entire document revised to remove any reference to wearable defibrillators. This medical policy will now address only nonwearable external defibrillators. Title changed from “Automatic External Defibrillators (AEDs) (Wearable and Nonwearable)”.
04/15/2014	Document updated with literature review. The following 2 indications were added to the coverage criteria: 1) As a bridge to permanent AICD placement and 2) As a bridge for patients with severe heart failure awaiting transplantation. In addition, clarification added to bulleted criteria of "documented prior MI” adding the following: "(>48 hours post MI)".
12/15/2013	Document updated with literature review. Coverage unchanged.
09/15/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
09/01/2006	Revised/updated entire document
02/27/2004	Revised/updated entire document
03/01/1998	Revised/updated entire document
05/01/1990	New medical document