

Automated External Defibrillators (AED)

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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Purpose:

This policy addresses Automated External Defibrillators (AED) and their accessories.

Description & Definitions:

Automated external defibrillator (AED) also known as a portable cardioverter defibrillator is an electronic device that is attached to the chest area with adhesive electrode pads to deliver a shock when ventricular tachycardia or ventricular fibrillation is detected.

Criteria:

Automated External Defibrillator (AED) is considered medically necessary with **All** of the following:

- Individual has **1 or more** of the following conditions:
 - A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause
 - 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
 - Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy
 - 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 and **All** of the following:
 - The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription

- The EP test must have been performed more than 4 weeks after the qualifying myocardial infarction.
 - Documented prior myocardial infarction and a measured left ventricular ejection fraction less than or equal to 0.30 and **All** of the following:
 - No cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm
 - No coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months
 - No enzyme-positive MI within past month
 - No clinical symptoms or findings that would make them a candidate for coronary revascularization
 - No irreversible brain damage from preexisting cerebral disease
 - No disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year
 - Individual 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%.
 - Individual with nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart failure, and measured LVEF \leq 35%
 - NYHA Class IV heart failure and **1 or more** of the following:
 - A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause
 - 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
 - Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy
 - 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 and **All** of the following:
 - The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription
 - The EP test must have been performed more than 4 weeks after the qualifying myocardial infarction.
 - Documented prior myocardial infarction and a measured left ventricular ejection fraction less than or equal to 0.30 and **All** of the following:
 - No cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm
 - No coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months
 - No enzyme-positive MI within past month
 - No clinical symptoms or findings that would make them a candidate for coronary revascularization
 - No irreversible brain damage from preexisting cerebral disease
 - No disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year
 - Individual 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%.
 - Individual with nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart failure, and measured LVEF \leq 35%
- Automatic implantable cardioverter-defibrillator implantation surgery is currently not possible due to **1 or more** of the following:

- Individual awaiting a heart transplantation. (Individual is on waiting list and meets medical necessity criteria for heart transplantation)
- Individual with a previously implanted cardioverter defibrillator that requires explantation due to infection (e.g., device pocket or lead infection, endocarditis) with waiting period before reimplantation of an implantable cardioverter defibrillator
- Individual with an infectious process or other temporary condition (e.g., recovery from surgery, lack of vascular access) that precludes immediate implantation of an implantable cardioverter defibrillator.

Coding:

Medically necessary with criteria:

Coding	Description
E0617	External defibrillator with integrated electrocardiogram analysis

Considered Not Medically Necessary:

Coding	Description
	None

Document History:

Revised Dates:

Reviewed Dates:

- 2023: August

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- August 2022

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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(2023). Retrieved July 26, 2023, from HAYES:

<https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Automated%2520external%2520defibrillator%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all>

(2023). Retrieved July 26, 2023, from American Heart Association: <https://cpr.heart.org/en/resuscitation-science/cpr-and-ecc-guidelines/search-guidelines#q=home%20use%20Automated%20external%20defibrillators&sort=relevancy>

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https://www.uptodate.com/contents/automated-external-defibrillators?search=Automated%20External%20Defibrillator&topicRef=973&source=see_link#

Code of Federal Regulations Title 21 CFR 870.5310 Automated external defibrillator system. (2023, June 7). Retrieved July 25, 2023, from FDA:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=870.5310&SearchTerm=870%2E5310>

DME Manual - Appendix B. (2023, Jan). Retrieved July 26, 2023, from DMAS DME: <https://www.dmas.virginia.gov/providers/long-term-care/services/durable-medical-equipment/>

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

All medically necessary medical equipment and supplies under the Virginia Administrative Code (12VAC30-50-165) may be covered only if they are necessary to carry out a treatment prescribed by a practitioner. Only supplies, equipment, and appliances that are determined medically necessary may be covered for reimbursement by DMAS. (12VAC30-50-165) The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to DMAS, or its contractor. Medically necessary DME and supplies shall be:

- Ordered by the practitioner on the CMN/DMAS-352;
- A reasonable and medically necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual; • Not furnished for the safety or restraint of the individual, or solely for the convenience of the family, attending practitioner, or other practitioner or supplier;
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational);
- Furnished at a safe, effective, and cost-effective level; and
- Suitable for use, and consistent with 42 CFR 440.70(b)(3), that treats a diagnosed condition or assists the individual with functional limitations.

Keywords:

SHP Automated External Defibrillators (AED), SHP Durable Medical Equipment 63, Implantation surgery, Coronary artery disease, Ischemic dilated cardiomyopathy, Nonischemic dilated cardiomyopathy, NYHA Class IV heart failure