

Wearable External Cardioverter Defibrillators, DME 24

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| | | |

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Coverage Policy DME 24

<u>Version</u> 6

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 by 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.*.

Description & Definitions:

Wearable external cardioverter defibrillators are worn outside the body as a vest like garment rather than implanted in the chest, like an implantable cardioverter defibrillator (ICD). This device is to be worn 24 hours per day (except when bathing, showering or submersion into water) to continuously monitor the individual's heart with dry, non-adhesive sensing electrodes to detect life-threatening abnormal heart rhythms, acts as a loop recorder, does not provide backup pacing. A wearable external cardioverter defibrillators delivers a shock if ventricular tachycardia (VT) or Ventricular fibrillation (VF) are sensed. This device is meant to be used temporarily as a bridge to implantation of implantable ICD (for example as a patient completes an antibiotic course for infection, or during the required waiting periods after MI or revascularizing).

Criteria:

Wearable external cardioverter defibrillator is considered medically necessary with ALL of the following:

- Individual meets indications for **1 or more** of the following:
 - Systemic infectious process or other temporary medical condition that precludes implantation of an implantable cardioverter defibrillator (MCG mentions existing one requires removal due to infection).
 - o Individual is awaiting implantable cardioverter defibrillator reimplantation following the removal of a previous implantable cardioverter defibrillator- as in the case of a device infection
 - Individual at increased risk of sudden cardiac death, but not immediately able to have implantable cardioverter defibrillator placed due to required waiting periods (i.e. revascularization in past 90 days, myocardial infarct in past 40 days, newly diagnosed CMO with newly initiated GDMT
 - Individual awaiting cardiac transplant
- Individual has cardiac condition that requires Implantable Cardioverter-Defibrillator (ICD) placement as indicated by 1 or more of the following:
 - Cardiac arrest due to ventricular fibrillation or ventricular tachycardia without known treatable precipitating cause (eg, myocardial ischemia, electrolyte disorder, myocarditis)
 - Ventricular fibrillation or polymorphic ventricular tachycardia within 48 hours of MI and 1 or more of the following:

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- Revascularization of infarct vessel not feasible
- Inducible sustained ventricular tachycardia or ventricular fibrillation at electrophysiologic study performed 4 or more days after revascularization
- Individual within 40 days of MI and 1 or more of the following:
 - Syncope presumed to be due to ventricular arrhythmia and inducible sustained (lasting more than 30 seconds) ventricular tachycardia
 - New York Heart Association class I heart failure with ALL of the following:
 - Left ventricular ejection fraction less than or equal to 30%
 - · Recovery of left ventricular function not expected
 - Individual having permanent pacemaker placed
 - New York Heart Association class II or III heart failure with ALL of the following:
 - Left ventricular ejection fraction less than or equal to 35%
 - Recovery of left ventricular function not expected
 - Individual having permanent pacemaker placed
 - Left ventricular ejection fraction less than 40% and ALL of the following:
 - Nonsustained ventricular tachycardia
 - Inducible sustained ventricular tachycardia
 - New York Heart Association class IV heart failure with ALL of the following:
 - Individual is ambulatory (not bed bound)
 - Individual is a candidate for cardiac transplant, left ventricular assist device, or cardiac resynchronization therapy
 - Sustained (lasting more than 30 seconds) or hemodynamically significant (eg, Hypotension) ventricular tachycardia not believed to be due to reversible etiology (eg, myocardial ischemia, severe electrolyte abnormality)
- Individual who has been revascularized (with bypass surgery or percutaneous intervention) within last
 90 days and is not within 40 days of acute MI with 1 or more of the following:
 - Individual requires permanent pacemaker and ALL of the following:
 - Left ventricular ejection fraction less than or equal to 35%
 - Recovery of left ventricular ejection fraction not expected
 - Syncope presumed to be due to ventricular arrhythmia and inducible sustained (lasting more than 30 seconds) ventricular tachycardia
 - Left ventricular ejection fraction less than 40% and ALL of the following:
 - Nonsustained ventricular tachycardia
 - Inducible sustained ventricular tachycardia
 - Sustained (lasting more than 30 seconds) or hemodynamically significant (eg, Hypotension) ventricular tachycardia not believed to be due to reversible etiology (eg, myocardial ischemia, severe electrolyte abnormality)
- Individual with history of MI (more than 40 days ago, not revascularized in last 90 days) and 1 or more of the following:
 - Sustained (lasting more than 30 seconds) or hemodynamically significant (eg, Hypotension)
 ventricular tachycardia not believed to be due to reversible etiology (eg, myocardial ischemia,
 severe electrolyte abnormality)
 - Syncope presumed to be due to ventricular arrhythmia and inducible sustained (lasting more than 30 seconds) ventricular tachycardia
 - New York Heart Association class I heart failure with left ventricular ejection fraction less than or equal to 30%
 - New York Heart Association class II or III heart failure with left ventricular ejection fraction less than or equal to 35%
 - Left ventricular ejection fraction less than 40% and ALL of the following:
 - Nonsustained ventricular tachycardia
 - Inducible sustained ventricular tachycardia

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- Left ventricular ejection fraction less than or equal to 40%, and individual having permanent pacemaker placed
- Ischemic cardiomyopathy (known coronary artery disease) and 1 or more of the following:
 - New York Heart Association class I heart failure with left ventricular ejection fraction less than or equal to 30%
 - New York Heart Association class II or III heart failure with left ventricular ejection fraction less than or equal to 35%
 - Syncope presumed to be due to ventricular arrhythmia and inducible sustained (lasting more than 30 seconds) ventricular tachycardia
 - Left ventricular ejection fraction less than 40% and ALL of the following:
 - Nonsustained ventricular tachycardia
 - Inducible sustained ventricular tachycardia
- Sustained (lasting more than 30 seconds) or hemodynamically significant (eg, Hypotension)
 ventricular tachycardia not believed to be due to reversible etiology (eg, myocardial ischemia, severe electrolyte abnormality)
- Sustained (lasting 30 seconds or longer) ventricular tachycardia and left ventricular ejection fraction less than or equal to 35%
- Syncope presumed to be due to ventricular arrhythmia with 1 or more of the following:
 - Inducible sustained ventricular tachycardia
 - Left ventricular ejection fraction less than or equal to 35%
 - Cardiac amyloidosis
 - Arrhythmogenic right ventricular dysplasia or cardiomyopathy
 - Hypertrophic obstructive cardiomyopathy
 - Advanced structural heart disease (eg, valvular heart disease, congenital heart disease)
- o Nonischemic cardiomyopathy and **1 or more** of the following:
 - Syncope presumed to be due to ventricular tachycardia
 - Stable ventricular tachycardia not due to reversible causes
 - Induced or spontaneous ventricular tachycardia that is hemodynamically significant (eg, Hypotension) or sustained (lasting 30 seconds or longer)
 - New York Heart Association class I to III heart failure and ALL of the following:
 - Left ventricular ejection fraction less than or equal to 35%
 - Individual treated for at least 3 months with guideline-directed medical therapy
 - Survival is reasonably expected to be greater than 1 year
 - New York Heart Association class IV heart failure and 1 or more of the following:
 - Heart transplant candidate
 - Left ventricular assist device candidate or implanted
 - Candidate for cardiac resynchronization therapy (ie, device will incorporate both pacing and defibrillation capabilities)
 - History of Chagas disease
 - History of myotonic dystrophy
 - History of heart failure due to amyloidosis
 - History of giant cell myocarditis
 - Peripartum cardiomyopathy persisting more than 3 months post partum
 - Arrhythmogenic right ventricular cardiomyopathy with risk factors for ventricular arrhythmia
- Individual has genetic condition that increases risk of sudden cardiac death as indicated by 1 or more
 of the following:
 - Long QT syndrome and 1 or more of the following:
 - History of cardiac arrest (eg, resuscitated ventricular fibrillation)
 - Corrected QT interval greater than 500 milliseconds while receiving beta-blocker
 - Beta-blocker therapy ineffective (eg, persistent symptoms) or not tolerated
 - Syncope presumed to be due to ventricular arrhythmia
 - Genotypes LQT2 or LQT3

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- Female with genotype LQT2
- Age younger than 40 years
- Onset of symptoms at age younger than 10 years
- Arrhythmogenic right ventricular dysplasia or cardiomyopathy and 1 or more of the following:
 - Sustained (lasting 30 seconds or longer) or hemodynamically significant (eg, Hypotension) ventricular tachycardia
 - Right or left ventricular ejection fraction less than or equal to 35%
 - Syncope presumed to be due to ventricular arrhythmia
 - Risk factors for sudden cardiac death indicated by 1 or more of the following:
 - Frequent premature ventricular contractions
 - o Family history of premature sudden death
 - o Inducible ventricular tachycardia
- Brugada syndrome and 1 or more of the following:
 - Individual has spontaneous type 1 Brugada syndrome ECG pattern and 1 or more of the following:
 - Sustained (lasting 30 seconds or longer) or hemodynamically significant (eg, Hypotension) ventricular tachycardia
 - o Inducible sustained (lasting longer than 30 seconds) ventricular tachycardia
 - o History of cardiac arrest (eg, resuscitated ventricular fibrillation)
 - Syncope presumed to be due to ventricular arrhythmia
 - Individual with other than spontaneous type 1 Brugada syndrome ECG pattern with response to pharmacologic challenge (eg, procainamide, flecainide, ajmaline) of 1 or more of the following:
 - Ventricular arrhythmia
 - Marked QRS widening
 - o Type 1 Brugada syndrome ECG pattern
- Catecholaminergic polymorphic ventricular tachycardia and **1 or more** of the following:
 - Sustained (lasting longer than 30 seconds) ventricular tachycardia while receiving beta-blocker therapy
 - Syncope presumed to be due to a ventricular arrhythmia while receiving beta-blocker therapy
- Hypertrophic cardiomyopathy and 1 or more of the following:
 - Ventricular tachycardia that is sustained (lasting longer than 30 seconds) or hemodynamically significant (eg, Hypotension)
 - Syncope presumably due to ventricular arrhythmia
 - Maximum left ventricle wall thickness of 30 mm or greater
 - Family history of sudden death due to ventricular arrhythmia, presumably caused by hypertrophic cardiomyopathy
 - Nonsustained ventricular tachycardia and 1 or more of the following:
 - Age younger than 30 years
 - Late gadolinium enhancement on cardiac MRI
 - Left ventricular outflow tract obstruction
 - Left ventricular aneurysm
 - Abnormal blood pressure response to exercise (20 mm Hg decrease in blood pressure, or failure to increase blood pressure by 20 mm Hg during exertion) and 1 or more of the following:
 - Age younger than 30 years
 - Late gadolinium enhancement on cardiac MRI
 - Left ventricular outflow tract obstruction
 - Left ventricular aneurysm
- Short QT syndrome
- Noncompaction of left ventricle

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- Lamin A/C mutation and 2 or more of the following:
 - Male sex
 - Left ventricular ejection fraction less than or equal to 45%
 - Nonsustained ventricular tachycardia
 - Lamin A/C mutation and indication for permanent pacemaker is present
- Phospholamban cardiomyopathy and 1 or more of the following:
 - Left ventricular ejection fraction of less than 45%
 - Nonsustained ventricular tachycardia
- Filamin-C cardiomyopathy and left ventricular ejection fraction of less than 45%
- Other familial cardiomyopathy associated with sudden death
- o Cardiac sarcoidosis and 1 or more of the following:
 - Ventricular tachycardia that is hemodynamically significant (eg, Hypotension) or sustained (lasting 30 seconds or longer)
 - Left ventricular ejection fraction less than or equal to 35% after treatment with optimal medical therapy for heart failure and immunosuppression (if active inflammation is present)
 - Left ventricular ejection fraction of 36% to 49% and right ventricular ejection fraction less than 40% despite treatment with optimal medical therapy for heart failure and immunosuppression (if active inflammation is present)
 - Evidence of myocardial scar by cardiac MRI or PET scan
 - Permanent pacemaker required
 - Syncope presumably due to ventricular arrhythmia
 - Inducible sustained ventricular arrhythmia
- Congenital heart disease and 1 or more of the following:
 - Sustained (lasting 30 seconds or longer) or hemodynamically significant ventricular tachycardia without identified reversible etiology (eg, myocardial ischemia, severe electrolyte abnormality)
 - Inducible sustained (lasting 30 seconds or longer) ventricular tachycardia
 - Single ventricle or systemic right ventricle with ejection fraction less than or equal to 35%
 - Left ventricular ejection fraction 35% or less
 - Awaiting heart transplant
 - Syncope presumably due to ventricular arrhythmia
 - Tetralogy of Fallot and 1 or more of the following:
 - Left ventricular systolic or diastolic dysfunction
 - QRS duration of 180 milliseconds or more
 - Right ventricular scarring
 - Other risk for sudden cardiac death (eg, impaired systolic or diastolic function, nonsustained ventricular tachycardia)
- Left ventricular assist device with ventricular tachycardia that is sustained (lasting longer than 30 seconds)
- Post heart transplant with ALL of the following:
 - Left ventricular dysfunction
 - Severe allograft vasculopathy
- Individual without contraindication to ICD placement as indicated by ALL of the following:
 - No condition limiting life expectancy to less than 1 year (eg, advanced malignancy)
 - No treatment-refractory class IV heart failure in individual who is not candidate for cardiac transplant or left ventricular assist device
 - No significant psychiatric illness that may be aggravated by device implantation or that may preclude regular follow-up
 - No ongoing IV drug abuse
 - o No unresolved infection associated with risk for hematogenous seeding
 - No history of significant nonadherence with medical therapy and follow-up

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Coding:

Medically **necessary** with criteria:

| Coding | Description |
|--------|---|
| 92392 | Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per individual encounter; wearable defibrillator system |
| 93745 | Initial set-up and programming by a physician of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, individual instruction in wearing system and individual reporting of problems or events |
| K0606 | Automatic external defibrillator, with integrated electrocardiogram analysis, garment type |
| K0607 | Replacement battery for automated external defibrillator, garment type only, each |
| K0608 | Replacement garment for use with automated external defibrillator, each |
| K0609 | Replacement electrodes for use with automated external defibrillator, garment type only, each |

Considered **not medically** necessary:

| Coding | Description |
|--------|-------------|
| | None |

The preceding codes for treatments and procedures applicable to this policy are included above for informational purposes only. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy.

Document History:

Revised Dates:

- 2022: July
- 2021: August
- 2020: August
- 2019: November
- 2016: March
- 2015: February
- 2014: March, April
- 2013: November
- 2011: February

Reviewed Dates:

- 2025: July Implementation date of October 1, 2025. No changes references updated.
- 2024: July Annual review completed. No changes. References and coding updated.
- 2023: July
- 2019: April
- 2018: July
- 2017: November
- 2016: February
- 2014: February
- 2013: February
- 2012: March

Effective Date: March 2010

Policy Approach and Special Notes: *

- Coverage:
 - See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.
- Application to products:

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- Policy is applicable to Sentara Health Plan Virginia Medicaid products.
- Authorization requirements:
 - o Pre-certification by the Plan is required.
- 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 by 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.
 - Documentation Requirements <u>DME Chapter IV (updated 5.23.25) Final.pdf</u> <u>appendix-b-21-excel-version-with-all-categories-of-appendix-b-july-2025.xlsx</u>
 - All durable medical equipment (DME) and supplies must be ordered by a practitioner on the form: CMN/DMAS-352 (revised 2017) and must be medically necessary to treat a health condition. The CMN/DMAS352 may be completed by the practitioner, DME provider, or other health care professionals, but the practitioner must sign and date the completed Certification of Medical Necessity (CMN).
 - The CMN and any supporting verifiable documentation must be completed (signed and dated by the practitioner) within 60 days.
 - The CMN shall be valid for a maximum period of six (6) months for Medicaid individuals under 21 years of age. The CMN shall be valid for a maximum period of twelve (12) months for Medicaid individuals 21 years and older.

Repair vs. Replacement Guidelines

- If individual owned equipment needs to be replaced prior to the service limit (Per Appendix B) expiring the provider will be required to justify and obtain service authorization.
- Documentation for service authorization should include the required information as stated in this manual and the provider shall also include additional documentation as stated below:
 - What equipment the individual is currently using and why that equipment is no longer appropriate for the individual. This description shall include the reason why repairs could not be done or why the option to repair the equipment was not cost effective.
 - The provider shall include a breakdown of what items need to be repaired and include the cost to repair the items to justify why the purchase of new equipment would be more cost effective; and

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If the item is no longer appropriate due to a change in medical condition, limitations
and symptoms, or if the equipment was provided inappropriately, the provider shall
give justification to describe the circumstances.

Rental vs. Purchase Guideline

- When determined to be cost effective by SHP, payment may be made for rental of the equipment in lieu of purchase. (12 VAC 30-50-165)
- When usage is anticipated to be long-term, and the individual's need or condition is not expected to change, the items must be considered for purchase

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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Wearable Cardioverter-Defibrillator Therapy for the Prevention of Sudden Cardiac Death: A Science Advisory From the American Heart Association. (2016). Retrieved 5 2025, from American Heart Association (AHA): https://www.ahajournals.org/doi/10.1161/cir.000000000000000394

Keywords:

Endometrial Ablation, SHP Surgical 15, uterine bleeding, Menorrhagia, Hormonal therapy, Dilation and curettage, D&C, Pap smear, gynecologic examination, cervical disease, endometrial resection, electrosurgical ablation, thermoablation, hydrothermal endometrial ablation (HTEA), Thermal balloon endometrial ablation (TBEA), Microwave Endometrial Ablation (MEA), cryoablation, electrosurgical ablation, laser

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