Sentara® Health Plans

Commercial

Wearable External Cardioverter Defibrillators, DME 24

Table of Content

Effective Date	10/1/2025
Next Review Date	07/2026
Coverage Policy	DME 24
Version	6

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.

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).
  - 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:
    - 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
    - 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)
- 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
    - 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
      - Family history of premature sudden death
      - 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
      - Inducible sustained (lasting longer than 30 seconds) ventricular tachycardia
      - 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

        - 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
    - 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
- 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
    - No unresolved infection associated with risk for hematogenous seeding
    - No history of significant nonadherence with medical therapy and follow-up

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

Origination Date: March 2010

Coding:

Medically **necessary** with criteria:

Coding	Description
93292	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 are included above for informational purposes only and may not be all inclusive. Additionally, inclusion or exclusion of a treatment, procedure, or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

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:
  - Policy is applicable to Sentara Health Plan Commercial products.
- Authorization requirements:
  - Pre-certification by the Plan is required.
- Special Notes:
  - 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.
  - Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

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).

(LCD) Automatic External Defibrillators L33690 - CGS Administrators. (202, 3). Retrieved 5 2025, from CMS Local Coverage Determination: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33690&ver=20&keyword=Automatic%20External%20Defibrillators&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

28th Edition. (2025). Retrieved 5 2025, from MCG: https://careweb.careguidelines.com/ed28/

Durable Medical Equipment (DME). (2025, 4). Retrieved 5 2025, from DMAS: https://www.dmas.virginia.gov/media/c4hkqkwa/appendix-b-miscellaneous-durable-and-expendable-supplies-f2f-april-2025.pdf

LifeVest System (Asahi Kasei Corp.) Wearable Cardiac Defibrillator for Prevention of Sudden Cardiac Arrest. (2014, 9). Retrieved 5 2025, from Hayes: https://evidence.hayesinc.com/report/htb.lifevest

Wearable cardioverter-defibrillator. (2025, 3). Retrieved 5 2025, from UpToDate: https://www.uptodate.com/contents/wearable-cardioverter-defibrillator?search=Wearable%20cardioverter-defibrillator%20&source=search_result&selectedTitle=1~13&usage_type=default&display_rank=1

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.0000000000000394

Keywords:

SHP Wearable External Cardioverter Defibrillators, SHP Durable Medical Equipment 24, DME 24, cardiac arrest, ventricular fibrillation, ventricular tachycardia, polymorphic ventricular tachycardia, syncope, New York Heart Association, Ischemic cardiomyopathy, heart failure, Arrhythmogenic right ventricular dysplasia, cardiomyopathy, Brugada syndrome, revascularized, ejection fraction, pacemaker, Cardiac sarcoidosis, congenital heart disease, Chagas disease, myotonic dystrophy, amyloidosis, giant cell myocarditis, Peripartum cardiomyopathy, Lifevest