STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Wearable Automatic External Defibrillator
DME-019

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	9/1/2020
Revision Number:	5	**Last Rev Date:**	10/20/2023
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	10/18/2024
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	7/1/2020

Descriptive Narrative

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease. When a person's heart rhythm goes into an uncoordinated electrical activity called ventricular fibrillation, the heart twitches and cannot pump blood efficiently. This condition often accompanies severe heart attacks when the patient's heart appears to have stopped beating.

Defibrillators work by giving the heart a controlled electric shock, hopefully jolting it back into a regular rhythm. The implantable cardioverter defibrillator (ICD) has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, the use of ICDs has been potentially broadened by studies reporting a reduction in mortality for patients at risk for ventricular arrhythmias, such as patients with prior myocardial infarction (MI) and reduced ejection fraction.

ICDs consist of implantable leads in the heart that connect to a pulse generator implanted beneath the skin of the chest or abdomen. ICD placement is a minor surgical procedure, with the ICD device placed under the skin on the chest wall and the cardiac leads placed percutaneously. Potential adverse effects of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks.

The wearable cardioverter-defibrillator is an external device that is intended to perform the same tasks as an ICD, without requiring invasive procedures. It consists of a vest that is worn continuously underneath the patient's clothing. Part of this vest is the 'electrode belt' that contains the cardiac monitoring electrodes, and the therapy electrodes that deliver a counter shock. The vest is connected to a monitor with a battery pack and alarm module that is worn on the patient's belt. The monitor contains the electronics that interpret the cardiac rhythm and determines when a counter shock is necessary. The alarm module alerts the patient to certain conditions by lights or voice messages, during which time a conscious patient can abort or delay the shock.

Criteria

Prior authorization is required.

The wearable automatic external defibrillator device is considered medically necessary when **ALL** the following are met:

1. Member is 18 years of age or older; **AND**
2. Is at high-risk of SCA and meets criteria for placement of a defibrillator; **AND**
3. Member has **ONE** of the following contraindications to an ICD:
   a. Is on a waiting list and meets medical necessity criteria for heart transplantation; **OR**
   b. Had previously undergone placement of an ICD which had to be removed (explanted) due to infection (such as device pocket, lead failure, or endocarditis) and is waiting until a new device can be safely placed; **OR**
   c. Has an infectious process or other temporary condition (such as, but not limited to recovery from surgery or lack of vascular access) that prevents immediate placement of an ICD; **OR**
   d. Member is a candidate for a "bridge" to resolution of elevated risk or to ICD placement due to findings of reduced left ventricular (LV) systolic function (LVEF ≤35%) resulting from a myocardial infarction within the past 40 days; **OR** newly diagnosed dilated cardiomyopathy with severely reduced LV systolic function (LVEF ≤35%) that is potentially reversible.

For sudden cardiac death prevention in individuals younger than 18 years of age, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit versus harm; additional research is recommended.

Coding

The following list of codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

HCPCS	Description
93745	Initial set-up and programming by a physician or other qualified health care professional of WCD includes initial programming of system, establishing baseline electronic electrocardiogram, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events.
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type.

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

EncoderPro.

Zoll Life Vest https://lifevest.zoll.com/.

Automatic External Defibrillators. LCD L33690. Medicare Coverage Database. For services performed on or after January 1, 2020.

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33690.

Chung MK. Wearable Cardioverter-Defibrillator. UpToDate. Last updated: February 22, 2023.

Al-Khatib SM. Stevenson WG. Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2018; 72:e91.

Piccini JP Sr. Allen LA, Kudenchuk PJ. et al. Wearable Cardioverter-Defibrillator Therapy for the Prevention of Sudden Cardiac Death: A Science Advisory from the American Heart Association. Circulation 2016; 133:1715.

European Society of Cardiology. ESC Guidelines for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. ESC Practice Guidelines. August 26, 2022.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version

Signature

Change Date	Changed By	Description of Change	Version

Signature

Change Date	Changed By	Description of Change	Version
10/21/2023	CAC	Criteria (added bullets e, f, and g under criterion #3 and criterion 4 and 5. References updated.	5

Signature
William (Bill) Jagiello, DO 

Change Date	Changed By	Description of Change	Version
7/21/2023	CAC	Annual review.	4

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William (Bill) Jagiello, DO 

Change Date	Changed By	Description of Change	Version
7/15/2022	CAC	Annual review.	3

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William (Bill) Jagiello, DO 

Change Date	Changed By	Description of Change	Version
7/16/2021	CAC	Annual review. Added Compliance section. Formatting changes.	2

Signature
William (Bill) Jagiello, DO 

Change Date	Changed By	Description of Change	Version
7/17/2020	CAC	Criteria implementation.	1

Signature
William (Bill) Jagiello, DO