

Wearable Cardioverter-Defibrillator

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| Policy ID: | HHO-DE-MP-1138 |
| Approved By: | Highmark Health Options – Market Leadership |
| Provider Notice Date: | 12/15/2021; 03/01/2023 |
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| Products: | Medicaid |
| Application: | All participating hospitals and providers |
| Page Number(s): | 1 of 5 |

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary wearable cardioverter-defibrillator.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children's Program (DHCP) and Diamond State Health Plan Plus LTSS (DSHP Plus LTSS) members.

Wearable Cardioverter-Defibrillator (WCD) – A temporary, external device. It is intended for temporary use while clinical conditions, for example, infection, preclude permanent implantable cardioverter- defibrillator (ICD) placement

PROCEDURES

A prior authorization is required for items exceeding \$500 dollars.

A WCD may be considered medically necessary for a period of up to three (3) months and when ALL of the following criteria are met:

- At least one (1) year of age or older; and
- Documentation from a cardiovascular disease provider that the individual currently qualifies for an implantable defibrillator but has a current medical contraindication to device implantation; and
- As a bridge to cardiac transplantation, where documentation supports active transplantation listing; or
- Inherited channelopathies or familial Sudden Cardiac Arrest (SCA) with a high risk for life-threatening ventricular tachyarrhythmias where a current medical contraindication to definitive device implantation exists; or
- A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction; or
- Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 35%; or
- Familial or isolated hypertrophic cardiomyopathy with a high risk for life-threatening ventricular tachyarrhythmias where a current medical contraindication to definitive device implantation exists; or
- A previously implanted defibrillator now requires explanation.

WCD implantation should not be secondary to transient or reversible causes including but not limited to the following:

- Transient ischemia or within 48 hours of myocardial infarction; or
- Drug toxicity; or
- Severe hypoxia; or
- Acidosis; or
- Hypokalemia; or
- Hypercalcemia; or
- Hyperkalemia; or
- Systemic infections.

A WCD not meeting the criteria as indicated in this policy is considered not medically necessary.

NEW YORK HEART ASSOCIATION FUNCTIONAL CLASSIFICATION (NYHA) OF HEART DISEASE

| Classification | Characteristics |
|----------------------|--|
| Class I (mild) | No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, rapid/irregular heartbeat (palpitation) or shortness of breath (dyspnea). |
| Class II (mild) | Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, rapid/irregular heartbeat (palpitation), or shortness of breath (dyspnea). |
| Class III (moderate) | Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, rapid/irregular heartbeat (palpitation), and shortness of breath (dyspnea). |
| Class IV (severe) | Inability to carry on any physical activity without discomfort. Symptoms of fatigue, rapid/irregular heartbeat (palpitation) or shortness of breath (dyspnea) are present at rest. If any physical activity is undertaken, discomfort increases. |

MODIFIED ROSS HEART FAILURE CLASSIFICATION FOR CHILDREN

| Classification | Characteristics |
|----------------|-----------------------------|
| Class I | No limitations or symptoms. |

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| Class II | Infants: Mild tachypnea or diaphoresis with feeding. Older children: Mild to moderate dyspnea on exertion. |
| Class III | Infants: Growth failure and marked tachypnea or diaphoresis with feeding. Older children: Marked dyspnea on exertion. |
| Class IV | Symptoms at rest such as tachypnea, retractions, grunting, or diaphoresis. |

*All documentation include daily wear time must be maintained in the medical record and be available upon request. Beginning with the initial date the device was worn for continuous monitoring; the Cardiologist must reevaluate the need for continued use of the WCD at three (3) months and again at 90-day intervals until the device is discontinued. Documentation requirements including but not limited to the following must be maintained in the medical record: the date the device was first worn for continuous monitoring, the initial indication establishing medical necessity, member tolerance and compliance throughout the use of the WCD as documented by Cardiologist evaluations.

The Cardiologist may access the Zoll LifeVest Network on-line patient management system allowing for monitoring of the individual's data reports downloaded from a the LifeVest wearable defibrillator.

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE: OUTPATIENT

WCD is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

COVERED CODES

| CPT code | Description |
|--------------|---|
| 93292 | Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system |
| 93745 | Initial set-up and programming by a physician or other qualified health care professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, 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 |

COVERED DIAGNOSIS CODES FOR PROCEDURE CODES 93292, 93745, K0606:

| Codes | | | | | | |
|--------|--------|--------|--------|--------|--------|--------|
| A18.84 | I21.3 | I21.4 | I21.9 | I21.01 | I21.02 | I21.09 |
| I21.11 | I21.19 | I21.21 | I21.29 | I21.A1 | I21.A9 | I22.0 |

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|----------|----------|----------|----------|----------|----------|----------|
| I22.1 | I22.2 | I22.8 | I22.9 | I25.2 | I40.0 | I40.1 |
| I40.8 | I40.9 | I42.0 | I42.1 | I42.2 | I42.3 | I42.4 |
| I42.5 | I42.6 | I42.7 | I42.8 | I42.9 | I43 | I45.81 |
| I46.2 | I46.8 | I46.9 | I47.0 | I47.1 | I47.2 | I47.9 |
| I49.1 | I49.2 | I49.3 | I49.01 | I49.02 | T82.6XXA | T82.7XXA |
| T82.110A | T82.111A | T82.118A | T82.119A | T82.120A | T82.121A | T82.128A |
| T82.129A | T82.190A | T82.191A | T82.198A | T82.199A | Z82.41 | |

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

Reference

Duncker D, Thorben K€onig T, Hohmann S, Bauersachs J, Veltmann C. Avoiding untimely implantable cardioverter/defibrillator implantation. *J Am Heart Assoc.* 2017;6: e004512.

Reek S, Burri H, Roberts PR, Perings C, Epstein AE, et al. The wearable cardioverterdefibrillator: current technology and evolving indications. *Europace.* 2017;19: 335–345.

Duncker D, Konig T, Hohmann S, Bauersachs J, Veltmann C. Ventricular arrhythmias in patients with newly diagnosed non-ischemic cardiomyopathy: Insights from the PROLONG study. *Clin Cardiol.* 2017;40(8):586-590.

Duncker D, Konig T, Hohmann S, Bauersachs J, Veltmann C. Avoiding untimely implantable cardioverter/defibrillator implantation by intensified heart failure therapy optimization supported by the wearable cardioverter/defibrillator-The PROLONG Study. *J Am Heart Assoc.* 2017;6(1).

Al-Khatib SM, Stevenson WG, Ackerman MJ, Bryant WJ, Callans DJ, 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. *Circulation.* 2018;138(13).

Spar DS, Bianco NR, Knilans TK, et al. The US experience of the wearable cardioverterdefibrillator in pediatric patients. *Circ Arrhythm Electrophysiol.* 2018;11: e006163.

Clark MA, Szymkiewicz SJ, Volosin K. Mortality and costs associated with wearable cardioverterdefibrillators after acute myocardial infarction: A retrospective cohort analysis of Medicare claims data. *J Innovations in Card Rhythm Mgmt.* 2019; 10(10): 3866-3873.

Sandhu U, Rajyaguru C, Cheung C, Morin D, Lee B. The wearable cardioverter-defibrillator vest: Indications and ongoing questions. *Progress CV Dis.* 2019;62: 256-264.

Olgin JE, Pletcher MJ, Vittinghoff E. et al. Wearable cardioverter-defibrillator after myocardial infarction. *NEJM.* 2018; 379(13).

Olgin JE, Lee BK, Vittinghoff E, et al. Impact of wearable cardioverter-defibrillator compliance on outcomes in the VEST trial: As treated and per protocol analyses. *J Cardiovasc Electrophysiol.* 2020; 31:1009-1018.

Mueller_Leisse J, Brunn J, Zormpas C, et al. Extended follow-up after wearable cardioverterdefibrillator person: The PROLONG-II study. ESC Heart Failure. 2021;8(6):5142-5148.

Noriden Healthcare Solutions, LLC. LCD 33690. Effective 1/1/2020.

POLICY UPDATE HISTORY

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|------------|---|
| 10/21/2021 | Approved in medical policy committee |
| 12/2021 | Approved in QI/UM |
| 10/26/2022 | Annual review; approved in medical policy committee |
| 11/2022 | Approved in QI/UM |
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