HIGHMARK Delaware
HEALTH OPTIONS

CLINICAL MEDICAL POLICY	
Policy Name:	Wearable Cardioverter-Defibrillators in the Home Setting
Policy Number:	MP-001-MD-DE
Responsible Department(s):	Medical Management
Provider Notice Date:	01/15/2019; 04/15/2018
Issue Date:	02/18/2019; 05/15/2018
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Annual Approval Date:	12/11/2019
Revision Date:	12/11/2018; 01/26/2018; 10/23/2017; 08/09/2017
Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 10

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 as a Durable Medical Equipment (DME) benefit of the Company's Medicaid products for a medically necessary wearable cardioverter-defibrillator (WCD) as a treatment in the home setting. A prescription for the device must be from a professional provider that will provide usage instructions, and the device must be from a DME provider.

This policy is designed to address medical 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 on 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

Sudden Cardiac Death (SCD) — the sudden stop in effective blood flow due to the failure of the heart to contract successfully. The blood stops flowing to the brain and other vital organs during sudden cardiac arrest (SCA). SCD is a life-threatening medical emergency that can cause brain damage or death without immediate treatment.

Wearable Cardioverter-Defibrillator (WCD) — a wearable cardioverter-defibrillator (K0606) is a temporary external device that is an alternative to an implantable cardioverter-defibrillator (ICD). It is primarily intended for temporary conditions for which an implantable device is contraindicated or for a period of time during which the need for a permanent implantable device is uncertain.

Implantable Cardioverter-Defibrillator (ICD) — a device that is implanted inside the chest or abdomen to help treat and monitor irregular heart arrhythmias 24 hours a day. The device is transversely inserted into the heart chambers by wires with electrodes. If the device detects a heart arrhythmia, an electrical shock is sent out to correct the arrhythmia.

Ventricular Tachycardia (VT) — a type of heart rhythm disorder (arrhythmia) in which the lower chambers of the heart (ventricles) beat very quickly because of a problem in the heart's electrical system.

Hypertrophic Cardiomyopathy (HCM) — a condition that occurs when heart muscle cells become enlarged and cause the walls of the ventricles to thicken.

Long QT Syndrome — a rare inherited disorder of the heart's electrical activity, in which delayed repolarization of the heart following a heartbeat increases the risk of episodes of torsades de pointes (TdP).

Left Ventricular Ejection Fraction (LVEF) — the fraction of outbound blood pumped from the heart with each heartbeat. It is commonly measured by an echocardiogram and serves as a general measure of a person's cardiac function. A normal LVEF is 50% to 75%. A decreased LVEF is a result of cardiomyopathy, cardiac arrest, or heart failure.

PROCEDURES

1. A WCD is considered medically necessary when the following criteria are met:
   A. The prescribing doctor must be a Cardiologist, Electrophysiologist or Cardiac Surgeon; AND
   B. The patient is at high risk for sudden cardiac death (SCD); AND
   C. The patient requires the WCD as an interim treatment for those who meet the criteria for an implantable cardioverter-defibrillator; AND
   D. The WCD can only be fitted on patients with a chest circumference less than 57 inches (144 cm); OR
   E. The WCD can only be used in pediatric patients with a chest circumference of 26 inches (66 cm) or greater and a weight of 18.75 kilograms (41.3 pounds) or greater; AND
   F. The patient must be able to wear the device for at least 22.5 hours per day (greater than 90% wear time); AND
   G. The patient must be seen by a cardiologist at least two times: one visit in months 0–3 and one visit in 3–6 months post-WCD implementation; AND

H. The patient must experience ONE of the following criteria (1 through 4):
   1) A documented episode of ventricular fibrillation or a sustained ventricular tachyarrhythmia (lasting 30 seconds or longer). 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 are not occurring during the first 48 hours of an acute myocardial infarction; OR
   2) The patient has a previously implanted defibrillator that requires explanation, or the patient has a delay in implantation of an ICD; OR
   3) As a bridge to left ventricular improvement for any ONE of the following indications:
      a. LVEF is less than or equal to 35% after cardiac events such as:
         1. After a recent acute myocardial infarction (MI) during the 40-day period under which an ICD implantation is not indicated or deferred. Reevaluation of LVEF should occur no later than three months after an MI. If the LVEF remains at 35% or less, an ICD is indicated; OR
         2. Coronary revascularization procedures such as before and after coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) during the 90-day ICD waiting period; OR
         3. Recently diagnosed with non-ischemic cardiomyopathy during the three-month to nine-month waiting period awaiting LV improvement or ICD implantation; OR
      b. Heart Transplantation:
         1. As an alternative to an implantable cardioverter-defibrillator (ICD) in an individual who has a documented contraindication to an ICD (e.g., systemic infection, lack of vascular access); OR
         2. Patients who refuse implant-device therapy;

      OR
   4) Inherited or familial conditions with a high risk for life-threatening ventricular tachyarrhythmia. High-risk factors as evidenced by ANY ONE of the following:
      a. Hypertrophic cardiomyopathy, OR
      b. Long QT Syndrome, OR
      c. A family history of any one of the following:
         1. Sudden cardiac death in a first-degree relative (e.g., sibling, parent, or child) < 40; OR
         2. Sudden cardiac death in a first-degree relative (e.g., sibling, parent, or child) with hypertrophic cardiomyopathy; OR
         3. Left ventricular/septal thickness > 3 cm; OR
         4. Abnormal exercise blood pressure including failure of blood pressure to rise > 25 mmHg from baseline or decrease < 10 mmHg from the maximal blood pressure during exercise.

2. Contraindications
   A. All cardioverter-defibrillator therapy devices are contraindicated for patients experiencing a tachyarrhythmia with transient or reversible causes including, but not limited to, the following:
      1) Drug toxicity; OR
      2) Severe hypoxia; OR
      3) Acidosis; OR
      4) Hypokalemia; OR
      5) Hypercalcemia; OR

6) Hyperkalemia; OR
7) Systemic infections; OR
8) Myocarditis

B. Cardioverter-defibrillators are not considered medically necessary when other disease processes are present that clearly and severely limit the patient's life expectancy.

3. When the WCD is not covered
   A. A WCD should not be used in patients with an active implantable ICD or S-ICD.
   B. Carrying case or mounting hardware for the WCD are not covered by Highmark Health Options because they are not primarily medical in nature and are considered comfort or convenience items.
   C. Technological advancements or newly release upgrades to equipment, when the original equipment still functions properly and/or there are no significant changes in the individual's condition.
   D. For conditions other than those listed above, scientific evidence has not been established.

4. 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.

5. Place of Service
   The place of service for the administration of the device is outpatient.

6. Length of Coverage
   A. Initial coverage will be issued for one month.
   B. Reauthorization will be issued at one month intervals.

GOVERNING BODIES APPROVAL

The Zoll® Medical LifeVest® received FDA premarket approval (P010030) on December 18, 2001. The device is indicated for adult patients who are at risk for sudden cardiac arrest and either are not candidates for or refuse an implantable defibrillator. Additional information is available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm458494.htm. Accessed on January 11, 2016.

The U.S. Food and Drug Administration (FDA) approved the Lifecor WCD® 2000 system via premarket application approval in December 2001 for "adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator." The vest was renamed and is now called the Zoll® LifeVest; FDA product code: MVK.

The FDA approved the Zoll Lifecor LifeVest WCD on December 17, 2015. The LifeVest WCD provides a new treatment option for pediatric patients and adult patients who are at risk of SCD and are not candidates for the implantable defibrillator.

Pediatric patients must have a chest circumference of 26 inches (66 cm) or greater and a weight of 18.75 kilograms (41.3 pounds) or greater. Accessed on January 19, 2016 and available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/p010030s056b.pdf.

CODING REQUIREMENTS

Procedure Codes

HCPCS Codes	Description
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, garment type only, each
K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each

Diagnosis Codes

ICD-10 Codes	Description
A18.84	Tuberculosis of heart
I21.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery
I21.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery
I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery
I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery
I21.29	ST elevation (STEMI) myocardial infarction involving other sites
I21.3	ST elevation (STEMI) myocardial infarction involving
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
I22.1	Subsequent ST elevation (STEMI) myocardial infarction of interior wall
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site
I25.2	Old myocardial infarction
I42.0	Dilated cardiomyopathy, congestive cardiomyopathy
I42.1	Obstructive hypertrophic cardiomyopathy, Hypertrophic subaortic stenosis (idiopathic)
I42.2	Other hypertrophic cardiomyopathy, nonobstructive hypertrophic cardiomyopathy
I42.3	Cardiomyopathy, endomyocardial (eosinophilic) disease
I42.4	Endocardial fibroelastosis, congenital cardiomyopathy, Elastomyofibrosis
I42.8	Other cardiomyopathies [Arrhythmogenic right ventricular dysplasia]
I42.9	Cardiomyopathy, unspecified
I43	Cardiomyopathy in disease classified elsewhere
I45.81	Long QT syndrome
I45.89	Other specified conduction disorders [Atrioventricular (AV) dissociation]
I45.9	Conduction disorder, unspecified
I46.2	Cardiac arrest due to underlying cardiac condition (code first underlying cardiac condition)

I46.8	Cardiac arrest due to other underlying condition
I46.9	Cardiac arrest, cause unspecified
I47.0	Re-entry ventricular arrhythmia
I47.2	Ventricular tachycardia
I47.9	Paroxysmal tachycardia, unspecified
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
T82.110A	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of cardiac electrode
T82.111A	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of cardiac pulse generator (battery), initial encounter
T82.111D	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of cardiac pulse generator (battery), subsequent encounter
T82.111S	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of cardiac pulse generator (battery), sequela
T82.119A	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of unspecified cardiac electronic device, initial encounter
T82.119D	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of, unspecified cardiac electronic device, subsequent encounter
T82.119S	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of, unspecified cardiac electronic device, sequela
T82.120A	Mechanical complication of cardiac electronic device, displacement of cardiac electrode, initial encounter
T82.120D	Mechanical complication of cardiac electronic device, displacement of cardiac electrode, subsequent encounter
T82.120S	Mechanical complication of cardiac electronic device, displacement of cardiac electrode, sequela
T82.121A	Mechanical complication of cardiac electronic device, displacement of cardiac pulse generator (battery), initial encounter
T82.121D	Mechanical complication of cardiac electronic device, displacement of cardiac pulse generator (battery), subsequent encounter
T82.121S	Mechanical complication of cardiac electronic device, displacement of cardiac pulse generator (battery), sequela
T82.128A	Mechanical complication of cardiac electronic device, displacement of other cardiac electronic device, initial encounter
T82.128D	Mechanical complication of cardiac electronic device, displacement of cardiac pulse generator (battery), subsequent encounter
T82.128S	Mechanical complication of cardiac electronic device, displacement of cardiac pulse generator (battery), sequela
T82.129A	Mechanical complication of cardiac electronic device, displacement of unspecified cardiac device, initial encounter
T82.190A	Mechanical complication of cardiac electronic device, other mechanical complication of cardiac electrode, initial encounter
T82.190D	Mechanical complication of cardiac electronic device, other mechanical complication of cardiac electrode, subsequent encounter
T82.190S	Mechanical complication of cardiac electronic device, sequela

T82.191A	Mechanical complication of cardiac electronic device, other mechanical complication of cardiac pulse generator (battery), initial encounter
T82.191D	Mechanical complication of cardiac electronic device, other mechanical complication of cardiac pulse generator (battery), subsequent encounter
T82.191S	Mechanical complication of cardiac electronic device, other mechanical complication of cardiac pulse generator (battery), sequela
T82.198A	Mechanical complication of cardiac electronic device, other mechanical complication of other cardiac electronic device, initial encounter
T82.198D	Mechanical complication of cardiac electronic device, other mechanical complication of other cardiac electronic device, subsequent encounter
T82.198S	Mechanical complication of cardiac electronic device, other mechanical complication of other cardiac electronic device, sequela
T82.199A	Mechanical complication of cardiac electronic device, other mechanical complication of unspecified cardiac device, initial encounter
T82.199D	Mechanical complication of cardiac electronic device, other mechanical complication of unspecified cardiac device, subsequent encounter
T82.199S	Mechanical complication of cardiac electronic device, other mechanical complication of unspecified cardiac device, sequela
T82.7XXA	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter
T82.7XXD	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, subsequent encounter
T82.7XXS	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, sequela
T82.827A	Fibrosis due to cardiac and vascular prosthetic devices, implants and grafts, initial encounter
T82.827D	Fibrosis due to cardiac and vascular prosthetic devices, implants and grafts, subsequent encounter
T82.827S	Fibrosis due to cardiac and vascular prosthetic devices, implants and grafts, sequela
T82.837A	Hemorrhage due to cardiac and vascular prosthetic devices, implants and grafts, initial encounter
T82.837D	Hemorrhage due to cardiac and vascular prosthetic devices, subsequent encounter
T82.837S	Hemorrhage due to cardiac and vascular prosthetic devices, sequela
T82.847A	Pain due to cardiac and vascular prosthetic devices, initial encounter
T82.847D	Pain due to cardiac and vascular prosthetic devices, subsequent encounter
T82.847S	Pain due to cardiac and vascular prosthetic devices, sequela
T82.867A	Thrombosis due to cardiac and vascular prosthetic devices, initial encounter
T82.867D	Thrombosis due to cardiac and vascular prosthetic devices, subsequent encounter
T82.867S	Thrombosis due to cardiac and vascular prosthetic devices, sequela
T82.897A	Other specified complication of cardiac and vascular prosthetic devices, initial encounter
T82.897D	Other specified complication of cardiac and vascular prosthetic devices, subsequent encounter
T82.897S	Other specified complication of cardiac and vascular prosthetic devices, sequela
Z82.41	Family history of sudden cardiac death
Z82.49	Family history of ischemic heart disease and other diseases of the circulatory system
Z84.81	Family history of genetic disease

Z86.74	Personal history of sudden cardiac arrest

REIMBURSEMENT

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

SUMMARY OF LITERATURE

The American College of Cardiology released a report (2016) designating sudden cardiac arrest (SCA) as a leading cause of death in the United States. SCA is the abrupt loss of heart function and leads to sudden cardiac death (SCD). A wearable cardioverter-defibrillator (WCD) is an automatic external defibrillator which monitors and treats a patient for ventricular defibrillation. The device is intended to be worn in home or hospital settings as prescribed and overseen by a physician.

Guidelines from the major cardiology specialty societies do not make specific recommendations for the use of WCD (Zipes, 2006). For example, the most recent ACC/AHA guidelines on the treatment of patients with ventricular arrhythmias includes the following statement on WCD but does not include a formal recommendation: "The wearable automatic defibrillator has been approved in the United States by the FDA for cardiac patients with a transient high risk for VF [ventricular fibrillation] such as those awaiting cardiac transplantation, those at very high risk after a recent MI [myocardial infarction] or an invasive cardiac procedure, or those requiring temporary removal of an infected implanted defibrillator for antibiotic therapy."

POLICY SOURCE(S)

American College of Cardiology. New Report Outlines Ten Measures for the Prevention of Sudden Cardiac Death: American Heart Association/American College of Cardiology Clinical Performance and Quality Measures; December 19, 2016. Accessed on 01/20/2017.

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Policy History

Date	Activity
06/07/2016	QI/UM Committee approval
12/01/2016	Provider effective date
02/03/2017 02/15/2017	Revisions: There were revisions made to the WCD policy, including: formatting, criteria revision and additions, definition additions, face sheet updates, and reference revisions
03/14/2017	QI/UM Annual Review Approval
08/09/2017	Format Change: in opening announcement box added issue date; Added Health Options Disclaimer before Policy Statement; Revised title for procedure and diagnosis code tables to read 'Covered' Procedure Codes and 'Covered' Diagnosis Codes. Operational Guidelines revised to reflect policy direction. Procedure and Diagnosis Codes tables retitled.
10/23/2017	Clinical Review: No changes
01/26/2018	Coding Revisions; 2018 ICD-10 Revisions – Added new codes: I21.9, I21.A1; I21.A9
03/13/2018	QI/UM Annual Review Approval
04/25/2018	Revision: Removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C
05/15/2018	New Effective Date
12/11/2018	Annual Review Revisions: Added related policy MP-057-MD-PA to Pg. 1 table; removed duplicate definition from Pg. 1: Policy Statement; Added updated literature to Attachment A; Removed interrogation CPT codes 93745 and 93292 due to lack of specificity; Removed references to citations in Attachment D; Added new references
12/11/2018	QI/UM Annual Review Approval
02/18/2019	New Effective Date