CLINICAL MEDICAL POLICY	
Policy Name:	Wearable Cardioverter Defibrillators in the Home Setting
Policy Number:	MP-001-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	08/01/2024; 06/01/2023; 06/01/2022; 01/13/2022; 12/21/2020; 11/18/2019; 12/15/2018; 02/15/2018; 08/01/2016
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Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
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Policy History

Date	Activity
09/01/2024	Provider Effective date
05/21/2024	PARP Approval
06/19/2024	QI/UM Committee review
06/19/2024	Annual Review: Added diagnosis code I21.B to the 'Coding Requirements' section. Removed PA DHS TAG determination for HCPCS code K0606. This code no longer requires a Program Exception for approval.
06/01/2023	Provider Effective date
05/18/2023	PARP Approval
04/19/2023	QI/UM Committee review
04/19/2023	Annual Review: No changes to clinical criteria. Removed deleted ICD-10 code I47.2, replaced with the following ICD-10 codes: I47.20, I47.21, & I47.29. Updated 'Summary of Literature' and 'Reference Sources' sections.
07/01/2022	Provider Effective date
05/16/2022	PARP approval
04/20/2022	QI/UM Committee review
04/20/2022	Urgent Review: Policy reinstated after retirement due to transfer to HealthHelp. No changes to clinical criteria. Added TAG determination info.

02/13/2022	Policy Retirement date
05/19/2021	Policy will be retired as codes will now be managed by Health Help.
05/19/2021	QI/UM Committee review
01/18/2021	Provider effective date
10/19/2020	PARP approval
09/16/2020	Annual Review; Updated Summary of Literature and Reference sections. Removed hyperlinks. Added the following ICD-10 codes: I42.2, I42.5, I42.6, I42.7, T82.118A, & T82.6XXA, and removed ICD-10 code I47.9.
09/16/2020	QI/UM Committee review
11/18/2019	Provider Effective Date
02/17/2016	QI/UM Committee approval

Disclaimer

Highmark Wholecare℠ 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 Wholecare℠ 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 Commonwealth of Pennsylvania (PA) Department of Human Services (DHS) and all applicable state and federal regulations.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) – A panel of representatives from within the Pennsylvania Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

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) – is 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.

Myocardial Infarction (MI) - also known as a "heart attack," is caused by decreased or complete cessation of blood flow to a portion of the myocardium. Myocardial infarction may be "silent," and go undetected, or it could be a catastrophic event leading to hemodynamic deterioration and sudden death. Most myocardial infarctions are due to underlying coronary artery disease.

Procedures

1. A wearable cardioverter-defibrillators (WCD) may be considered medically necessary when ALL of the following criteria are met:
   A. The prescribing doctor must be a Cardiologist, Electrophysiologist, or Cardiac Surgeon; AND
   B. The individual is at high risk for sudden cardiac death (SCD); AND
   C. The individual requires the WCD as an interim treatment (for those who meet the criteria for an implantable cardioverter-defibrillator); AND
   D. The WCD is to be fitted on individuals with a chest circumference less than 57 inches (144 cm); or the WCD is to 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
   E. The individual must be able to wear the device for at least 22 hours per day (greater than 90% wear time); AND

F. The individual must be seen by a cardiologist at least two (2) times: one (1) visit in months 0-3 and one (1) visit in 3-6 months post-WCD implementation; AND

G. The individual must experience AT LEAST 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 may be either dysrhythmias 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 MI; OR

2) The individual has a previously implanted defibrillator that requires explanation, OR the individual 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:

i. After a recent acute 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

ii. 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

iii. 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:

i. 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

ii. Individuals 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:

i. Sudden cardiac death in a first-degree relative (e.g., sibling, parent, or child) < 40; OR

ii. Sudden cardiac death in a first-degree relative (e.g., sibling, parent, or child) with hypertrophic cardiomyopathy; OR

iii. Left ventricular/septal thickness > 3 cm; OR

iv. 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

All cardioverter-defibrillator therapy devices are contraindicated for individuals experiencing a tachyarrhythmia with transient or reversible causes including, but not limited to, the following:

- Drug toxicity
- Severe hypoxia
- Acidosis
- Hypokalemia

- Hypercalcemia
- Hyperkalemia
- Systemic infections
- Myocarditis

Note: 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 considered to be not medically necessary
   - A WCD should not be used in individuals with an active implantable ICD or S-ICD.
   - Carrying cases or mounting hardware for the WCD are not covered by Highmark Wholecare℠ because they are not primarily medical in nature and are considered comfort or convenience items.
   - Technological advancements or newly released upgrades to equipment, when the original equipment still functions properly and/or there are no significant changes in the individual's condition.
   - For conditions other than those listed above, scientific evidence has not been established.
   - Any requests for WCD approval that do not meet the guidelines listed above will require a review by a Medical Director on a case-by-case basis.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

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

6. Length of Coverage
   - Initial coverage will be issued for one month.
   - 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.

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.

The FDA provided an update on a recall pertaining to the LifeVest 4000 (Zoll Manufacturing Corporation) and its potential to not deliver treatment to individuals wearing the cardioverter defibrillator on March 3, 2019. The FDA is reminding individuals and healthcare professionals that if the device displays the message "Call for Service – Message Code 102" to contact the manufacturer immediately for a replacement device. Additionally, the FDA approved the manufacturer's new software program that includes a more prominent and persistent alert for Message Code 102. This update is intended to increase awareness and the likelihood of contacting the Zoll Manufacturer Corporation for a replacement device.

The use of the wearable cardioverter defibrillator device outside of listed FDA guidelines will require approval from a Medical Director.

CMS
The Centers for Medicare and Medicaid Services (CMS) has issued the following guidelines on this topic:

- Local Coverage Determination (LCD) Automatic External Defibrillators (L33690)
- Local Coverage Article (LCA) Automatic External Defibrillators - Policy Article (A52458)

Summary of Literature

The American College of Cardiology (ACC) has previously released a report designating sudden cardiac arrest (SCA) as a leading cause of death in the United States (ACC, 2016). 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 an individual for ventricular defibrillation. A WCD detects and delivers timely defibrillation to individuals experiencing sustained VT/VF to prevent SCD. 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 individuals 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."

In March 2018, the ACC concluded a meta-analysis of nearly 20,000 at-risk cardiac patients managed in real-world settings. This meta-analysis found that VT/VF-related mortality occurred infrequently (0.2%) among WCD users (Nguyen et al, 2018). According to the meta-analysis, WCDs are successful in terminating VT/VF in individuals with an elevated risk of SCD and appear to be appropriate while long-term risk management is still being determined (Nguyen et al, 2018).

A 2019 systematic review and meta-analysis, which included 33,242 WCD users from 28 studies (the randomized VEST trial and 27 nonrandomized studies), assessed the likelihood of WCD therapy in a broad range of patient populations, including both primary/secondary prevention and ischemic/nonischemic cardiomyopathy patients. The incidence of appropriate shocks was 5 per 100 persons over three months

(1.67 percent per month) with mortality while wearing the device noted to be 0.7 per 100 persons over three months.

A 2018 review in the New England Journal of Medicine concluded that the wearable cardioverter–defibrillator may protect against sudden death during the immediate period after myocardial infarction, before ICD implantation is indicated under current guidelines (beginning 40 days after myocardial infarction or 90 days if the patient has undergone revascularization). Registries and case series involving high-risk patients have shown that wearable cardioverter–defibrillators are effective in terminating ventricular tachyarrhythmias (Olgin, 2018).

A science advisory was prepared by the American Heart Association which regarding WCDs, and found the use of wearable defibrillators is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care such as infection. WCDs may be appropriate as bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 days of MI (Piccini, Allen, Kudenchuk et al., 2016).

A study of 455 United States pediatric patients <18 years, who wore a WCD, was retrospectively reviewed in 2018. The study concluded the WCD is safe and effective in treating ventricular arrhythmias that can lead to sudden cardiac death in pediatric patients (Spar et al, 2018).

Coding Requirements

Procedure Codes

CPT Code	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, each
K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each

Diagnosis Codes

ICD-10 Code	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
I21.9	Acute myocardial infarction; unspecified (Effective 2018)
I21.A1	Other type of myocardial infarction, myocardial infarction type 2
I21.A9	Other type of myocardial infarction, other myocardial infarction type
I21.B	Myocardial infarction with coronary microvascular dysfunction
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
I42.3	Cardiomyopathy, endomyocardial (eosinophilic) disease
I42.4	Endocardial fibroelastosis, congenital cardiomyopathy, Elastomyofibrosis
I42.5	Other restrictive cardiomyopathy
I42.6	Alcoholic cardiomyopathy
I42.7	Cardiomyopathy due to drug and external agent
I42.8	Other cardiomyopathies [Arrhythmogenic right ventricular dysplasia]
I42.9	Cardiomyopathy, unspecified
I43	Cardiomyopathy in disease classified elsewhere
I45.81	Long QT syndrome
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
I47.20	Ventricular tachycardia, unspecified
I47.21	Torsades de pointes
I47.29	Other ventricular tachycardia
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
T82.118A	Breakdown (mechanical) of other cardiac electronic device, initial encounter

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
T82.6XXA	Infection and inflammatory reaction due to cardiac valve prosthesis, initial encounter
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 Wholecare℠ contract.

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