CLINICAL MEDICAL POLICY and PRIOR-AUTHORIZATION POLICY	
Policy Name:	Wearable Cardioverter-Defibrillators in the Home Setting
Policy Number:	MP-001-MD-PA
Approved By:	Medical Management
Provider Notice Date:	08/01/16
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Products:	Pennsylvania Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 6

Disclaimer

Gateway Health℠ (Gateway) clinical medical policies and/or prior-authorization policy is intended to serve only as a general reference resource regarding payment and 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:

Gateway provides coverage as durable medical equipment (DME) benefit under the medical benefits of the Company's Medicaid products for medically necessary wearable a cardioverter-defibrillator (WCD) as temporary 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. 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. 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.

This medical policy does not address the use of a wearable cardioverter-defibrillator in the treatment of acutely ill or hospitalized patients. 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 warrants individual consideration, based on review of applicable medical records.

(Current applicable PA 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 PA 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.

PROCEDURES

1) The following medical necessity criteria must be met:
   a) Are at high risk for sudden cardiac death (SCD); AND
   b) Requires the WCD as an interim treatment for those who meet the criteria for an implantable cardioverter-defibrillator; AND
   c) Must be able to wear the device for at least 22.5 hours per day (greater than 90% wear time); AND
   d) Must be seen by a cardiologist two times; one visit in months 0–3 and one visit in 3–6 months post WCD implementation; AND

2) Any ONE of the following criteria must be met (A through D):
   a) 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 electro physiologic (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. Transient or reversible causes include but are not limited to:
      - Drug toxicity, or
      - Severe hypoxia, or
      - Acidosis, or
      - Hypokalemia, or
      - Hypercalcemia, or
      - Hyperkalemia, or
      - Systemic infections, or
      - Myocarditis

   OR

   b) A previously implanted defibrillator now requires explanation.

   OR

   c) As a bridge to left ventricular improvement for any ONE of the following indications:
      i) LVEF is less than or equal to 35% after cardiac events such as:
         - 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 implantable cardioverter is indicated; OR
         - 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
         - Recently diagnosed with non-ischemic cardiomyopathy during the three month to nine month awaiting period awaiting LV improvement or ICD implantation; or
      ii) Heart Transplantation:
         - 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).
         - Patients who refuse implant device therapy

   OR

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

3) Contraindications
   a) Cardioverter-defibrillators are not considered medically necessary when other disease processes are present that clearly and severely limit the member's life expectancy.

4) Wearable Cardioverter-Defibrillators are not covered for indications other than those listed above scientific evidence has not been demonstrated.

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

6) The Place of Service for the administration of the device is outpatient.

7) Length of Coverage
   a) Initial coverage will be issued for one month
   b) Reauthorization will be issued at one month interval

8) U.S. Food and Drug Administration (FDA)
   A wearable cardioverter-defibrillator 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.

   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

   On December 17, 2015 the FDA issued premarket approval of the LifeVest® (P010030/S056) for patients under the age of 18 who are at risk for sudden cardiac arrest and are not candidates for or refuse an 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. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/p010030s056b.pdf. Accessed on January 19, 2016

9) 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."

AUTHORIZATION and CODING REQUIREMENTS:

Procedure Codes

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 ECG, transmission of data to data repository, patient instruction in wearing the system and patient reporting of problems or events.
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement batter 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

Carrying case or mounting hardware for the WCD are not covered by Gateway Health Plan® because they are not primarily medical in nature and are considered comfort or convenience items.

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.

Diagnosis Codes

I21.01	I21.02	I21.09	I21.11	I21.19	I21.21
I21.29	I21.3	I21.4	I22.0	I22.1	I22.2
I22.8	I22.9	I25.2	I42.0	I42.1	P42.3
I42.4	I42.5	I42.6	I42.7	I42.8	I42.9
I43	I45.81	I46.2	I46.8	I46.9	I47.0
I47.0	I47.2	I47.9	I49.01	I49.02	T82.110A
T82.111A	T82.111D	T82.111S	T82.119A	T82.119D	T82.119S
T82.120A	T82.120D	T82.120S	T82.121A	T82.121D	T82.121S
T82.128A	T82.128D	T82.128S	T82.129A	T82.190A	TT82.190D
T82.190S	T82.191A	T82.191D	T82.191S	T82.198A	T82.198D
T82.198S	T82.199A	T82.199D	T82.199S	T82.7XXA	T82.7XXD
T82.7XXS	T82.827A	T82.827D	T82.827S	T82.837A	T82.837D

T82.837S	T82.847A	T82.847D	T82.847S	T82.867A	T82.867D
T82.867S	T82.897A	T82.897D	T82.897S		

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