

**Policy: MP121**

**Section: Medical Benefit Policy**

**Subject: Wearable Cardioverter Defibrillators and Automatic External Defibrillators**

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**I. Policy:** Wearable Cardioverter Defibrillators and Automatic External Defibrillators

**II. Purpose/Objective:**

To provide a policy of coverage regarding Wearable Cardioverter Defibrillators and Automatic External Defibrillators

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**Medicaid Business Segment**

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

**ALL Durable Medical Equipment** provided for home use requires advanced determination of coverage. Devices furnished at inpatient or outpatient centers are **NOT SEPARATELY REIMBURSABLE.**

**DEFINITION:**

**Wearable Cardioverter Defibrillator (i.e. LifeVest)** monitors electrocardiogram (ECG) changes through a programmable microprocessor-based device and an electrode belt containing non-adhesive electrodes integrated into the vest. If a life-threatening arrhythmia is detected, the non-adhesive therapeutic electrodes release a conductive gel to the skin and deliver a shock to the heart.

**Automatic External Defibrillators** is a portable automatic device used to restore normal cardiac rhythms to patients in cardiac arrest. An AED is applied outside the body. It automatically analyzes the patient's heart rhythm and advises the rescuer whether or not a shock is needed to restore a normal heart beat. They are often found in public places.

**INDICATIONS:**

The Plan considers a wearable cardioverter defibrillator (e.g. LifeVest) as medically necessary when the following criteria are met:

1. The member must be under the care of, and the device be recommended by a cardiologist sub-specializing in electrophysiology ; **and**
2. The member must meet criteria A; **or** criteria B **or** criteria C;

**Criteria A)** Implanted cardiac defibrillator surgery is medically contraindicated, such as those awaiting a heart transplantation, awaiting ICD reimplantation following infection-related removal, or patients with a systemic infection process or other temporary condition that precludes implantation and the member has one of the following conditions:

1. a documented cardiac arrest due to ventricular fibrillation not due to a transient or reversible cause\*;  
**or**
2. a sustained (30 seconds or longer) ventricular tachyarrhythmia, either spontaneous or induced during electrophysiologic (EP) study, not associated with acute myocardial infarction and not due to a transient or reversible cause; **or**
3. familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias or hypertrophic cardiomyopathy; **or**
4. coronary artery disease with a documented prior myocardial infarction\*\*, a measured left ventricular ejection fraction of 0.35 or less, and inducible sustained ventricular tachycardia or ventricular fibrillation during an EP study;
5. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction of 0.30 or less and a QRS duration of greater than 120 milliseconds; **or**
6. Ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II or III heart Failure, and measured left ventricular ejection fraction of 0.35 or less; **or**
7. Nonischemic dilated cardiomyopathy (NIDCM) less than 3 months, NYHA Class II or III heart failure, and a left ventricular ejection fraction of 0.35 or less; **or**
8. Unexplained syncope and impaired ventricular function, when invasive hemodynamic and EP evaluation fails to reveal a defined and reversible cause; **or**
9. NYHA Class IV heart failure.

**or**

**Criteria B)** A previously implanted cardiac defibrillator now requires removal; **or**

**Criteria C)** As a bridge to ICD implantation when the following criteria are met:

1. Following myocardial infarction (MI) with a history of ventricular tachycardia or ventricular fibrillation after the first 48 hours, **or**
2. For members with a left ventricular ejection fraction less than or equal to 40.

\* Transient or reversible causes include conditions such as, but not limited to drug toxicity, severe hypoxia, acidosis, hypokalemia, hyperkalemia, hypercalcemia, systemic infection and active myocarditis.

\*\* Myocardial infarction must be documented by elevated cardiac enzymes or q-waves on an electrocardiogram. Ejection fraction must be measured by angiography, radionuclide scanning or echocardiography

**LIMITATIONS:** For lines of business with Durable Medical Equipment benefit, coverage will be subject to the limitations or exclusions expressed in the applicable benefit document.

**EXCLUSIONS:** Members must not have:

1. cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; **or**
2. had an enzyme-positive myocardial infarction within the past month; **or**
3. clinical symptoms that would make them a candidate for coronary revascularization; **or**
4. irreversible brain damage from a pre-existing cerebral disease; **or**
5. any disease other than cardiac disease associated with a likelihood of survival less than one year.

The Plan does **NOT COVER** a home-based automatic external defibrillator unit because it is considered to be a precautionary safety device to address a possible cardiac event, and not used for active treatment.

**CODING ASSOCIATED WITH: Automatic External Defibrillators**

***The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements***

93745 Initial set-up and programming by a physician 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

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

E0617 External defibrillator with integrated electrocardiogram analysis

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

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

**LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.**

**REFERENCES:**

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This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 3/04

**Revised:** 4/05, 4/06, 4/08, 7/12, 8/13 (removed indication); 7/16 (gender language) 5/18 (remove PA requirement)

**Reviewed:** 4/07, 7/09, 7/10, 7/11, 8/14; 8/15, 7/17