



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

**Number:** *200401-0004*

Effective date: 01/28/2004

Revision date(s): 12/23/2003

**Important note**

Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the *Evidence of Coverage* to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy and Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. The Centers for Medicare and Medicaid's *Coverage Issues Manual* can be found on the following Web site:

<http://www.cms.hhs.gov/manuals/nub06ndf/nub06ndf.asp>

**Overview**

**Automatic external defibrillators (AEDs)** are devices that can monitor or assess cardiac rhythms, detecting dysrhythmias, and deliver a shock to the heart when appropriate, without any user decision-making. The **Wearable Cardioverter Defibrillator (WCD)** is used for adults at risk for sudden cardiac arrest and who are not candidates for or refuse an implantable cardioverter defibrillator. If a life-threatening rhythm is detected and the patient loses consciousness, the device delivers an electrical shock to restore normal rhythm. If the device alarms and the patient is conscious, the patient can disable the electrical charge.

**Policy and criteria**

**Policy:**

Based on the assessment of peer-reviewed literature, the AED and WCD have not demonstrated a benefit to patient outcomes. The Fallon Community Health Plan (FCHP) Technology Assessment Committee has determined these devices are still investigational and experimental.

However, coverage may be considered for those patients who meet criteria for an implantable cardiac defibrillator (ICD) device *and* who have medical contraindications to implanting the ICD device, such as a single ventricle, *or* when urgent/imminent cardiac transplantation is anticipated and the AED/WCD is a bridge to the transplant.

A plan Medical Director will review the request for an AED or WCD to determine coverage. Individual consideration will depend on the general condition of the patient and the frequency, severity and duration of the arrhythmias.

These devices are considered durable medical equipment (DME) and would apply toward the Prosthetic/Orthotic and DME benefit's annual limit. If authorized, the plan Medical Director will determine whether the device is rented or purchased.

**Criteria:**

The following Criteria must be met for coverage to be considered:

- The specific reason why an implantable cardiac defibrillator (ICD) is contraindicated is stated; or
  - The AED/WCD is a bridge to a heart transplant that is urgent and/or imminent; and
  - The patient meets the criteria for an ICD. At least **one** of the following conditions exists and has been appropriately documented:
    - Episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause; or
    - A sustained ( $\geq 30$  seconds) ventricular tachyarrhythmia (VT), either spontaneous or induced during an electrophysiologic (EP) study, not associated with acute myocardial infarction (MI), and not due to a transient or reversible cause; or
    - Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy; or
    - Coronary artery disease with a documented prior myocardial infarction, with a measured left ventricular ejection fraction  $\leq 0.35$ , and inducible, sustained VT or VF during an EP study. To meet this criterion:
      - The MI must have occurred more than four weeks prior to the external defibrillator prescription; and
      - The EP test must have been performed more than four weeks after the qualifying MI.
- or
- Documented prior MI and a measured left ventricular ejection fraction  $\leq 0.30$  and a QRS duration of greater than 120 milliseconds. Patients must not have:
    - New York Heart Association classification IV; or
    - Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or
    - Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past three months; or
    - Had an enzyme-positive MI within past month; or
    - Clinical symptoms or findings that would make them a candidate for coronary revascularization.

***When services are not covered:***

We **do not cover** services when the above criteria are not met *or* for any procedures or devices not listed above.

We **do not cover** services when any of the following *contraindications* exist:

- Irreversible brain damage from preexisting cerebral disease; or
- Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year.

**Codes:**

Codes	Number	Description
CPT	None	
HCPCS	K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
	K0607	Replacement battery for automated external defibrillator, each
	K0608	Replacement garment for use with automated external defibrillator, each
	K0609	Replacement electrodes for use with automated external defibrillator, each

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**FCHP products to which this policy applies:**

Automatic External Defibrillator and Wearable Cardioverter Defibrillator

- ⊕ FCHP Direct and FCHP Select Care (HMO)
- ⊕ FCHP Flex Care Direct and Select (POS)
- ⊕ Fallon Preferred Care (PPO)
- ⊕ FCHP MassHealth
- ⊕ Non-Group: FCHP Independent Care, Direct enrollment and Bill-at-home

Medicare plan – *reminder* to refer to CMS for policy and criteria

**References**

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**Mandated benefit/Regulatory issues**

- Ø Federal
- Ø Commonwealth of Massachusetts
- Ø Medicare – National policy
- Ø Medicare – Local medical review policy
- ⊕ Not applicable

**Committee review dates:**

**Technology Assessment Committee:** mm/yyyy

Approved by:	<i>Signature on file</i>	1/28/2004
	Dennis A. Batey, M.D.	Date
	Vice President and Chief Medical Officer	