

**NEW YORK STATE MEDICAID
WEARABLE AUTOMATIC EXTERNAL
DEFIBRILLATOR GUIDELINES**

October 2015

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Introduction

The purpose of these guidelines is to provide detailed coverage criteria for wearable automatic external defibrillators (WAED) to all stakeholders so that medically necessary equipment is provided to Medicaid beneficiaries in a timely manner. Written comments and feedback on this document may be directed to:

Office of Health Insurance Programs
Division of Utilization Management and Provider Relations
150 Broadway, Suite 6E, Albany, NY 12204
(Attn: DME/WAED Guidelines)

I. General Definitions

18 NYCRR 505.5, states that **durable medical equipment (DME)** are devices and equipment, other than prosthetic or orthotic appliances, which have been ordered by a practitioner in the treatment of a specific medical condition and which have all the following characteristics:

- Can withstand repeated use for a protracted period of time;
- Are primarily and customarily used for medical purposes;
- Are generally not useful in the absence of an illness or injury;
- Are not usually fitted, designed or fashioned for a particular individual's use;
- Where equipment is intended for use by only one beneficiary, it may be either custom-made or customized.

A **WAED** is a vest-like device that is worn by the patient and is capable of monitoring cardiac rhythms, detecting dysrhythmias and delivering a defibrillation shock to the heart when appropriate without any patient decision making. WAED's are categorized as DME and are covered under the Home Health Benefit of the Medicaid (MA) State Plan.

II. Criteria for Coverage

The WAED (K0606) is covered for patients at high risk of sudden cardiac death (SCD) who meet the criteria 1 through 4:

1.
 - A) A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be spontaneous; and/or must be reproducible during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction, first 72 hours post coronary bypass, or within 5 days of a transplant; or
 - B) Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
 - C) Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; and
2.
 - A) Implantation surgery is contraindicated (systemic infectious process) or a temporary condition that precludes initial implantation; or
 - B) A previously implanted defibrillator now requires explanation due to infection or inflammatory process due to implant graft with waiting period before ICD reinsertion with documentation that severe infection is not due to poor patient compliance; and
3. The provider and ordering practitioner have assured that all less costly medically appropriate alternatives have been explored. If the alternatives are not adequate the ordering practitioner is required to provide clear documentation as to why the alternatives are not adequate (per 18NYCRR513.4); and
4. The ordering practitioner of the wearable defibrillator is a cardiologist and experienced in the management of patients at risk for SCD.

III. Non-Covered Indications

The wearable cardioverter defibrillator (WCD) is considered **investigational, not medically necessary, medically contraindicated** and **not covered** for all other indications, including but not limited to, the following:

- Patients with a history of an acute myocardial infarction (MI) within 30 days;
- Patients with drug-refractory class IV congestive heart failure (CHF) who are not candidates for heart transplantation;
- Patients with a history of psychiatric disorders that interfere with the necessary care and follow-up;
- Patients in whom a reversible triggering factor (by drug therapy, definitive therapy, ablation) for VT/VF can be definitely identified, such as ventricular tachyarrhythmias in evolving acute myocardial infarction or electrolyte abnormalities;
- Patients with terminal illnesses other disease processes that clearly and severely limits the patient's life expectancy.

IV. General Requirements

Department regulations and policies regarding ordering and provision of DME are available at: <http://www.nyhealth.gov/nysdoh/phforum/nycrr18.htm>, and in the DME Provider Manual, at www.emedny.org/ProviderManuals/DME/index.html. Specifically:

1. The procedure code for a WAED is *K0606 Automatic external defibrillator, with integrated electrocardiogram analysis, garment type*.
2. WAED's are subject to prior approval and if approved, will be approved as a rental at a reimbursement rate that will maximize at 10 months.
3. The monthly rental payment includes all necessary equipment, delivery, maintenance and repair costs, parts, supplies and services for equipment set-up, maintenance and replacement of worn essential accessories or parts.
4. After the initial 120 days of treatment, a new fiscal order must be written for the remaining 180 days. The prior approval request must include documentation of compliance with the treatment plan inclusive of, but not limited to, the read out downloaded from the defibrillator and continued coverage as stated in II, Criteria for Coverage.
5. All services must be supported by the original, signed written order specific to the item being requested from a qualified licensed prescriber. (DME Manual, Policy Section).
6. All providers are responsible for assuring that adequate and less costly alternatives for services have been explored and, where appropriate and cost effective, are provided. (18NYCRR 513).
7. It is an unacceptable practice to order or furnish inappropriate, improper, unnecessary or excessive services. Providers engaging in unacceptable practices are subject to liability for overpayments or penalties and administrative action that could affect their continued participation in the Medicaid Program (18 NYCRR 515.2)
8. The financial liability of the ordering practitioner as well as the provider of any durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances or devices or orthopedic footwear determined on audit not to be medically necessary is set forth in 18NYCRR 518.