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| Developed By: Medical Criteria Committee |                                |

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**Description:**

A **wearable cardiac defibrillator** (WCD) is an external vest-like device that is intended to perform the same functions as an implanted cardiac defibrillator (ICD) without requiring an invasive procedure. This device is used to monitor and treat abnormal heart rhythms in people at risk of dying from sudden cardiac arrest. A WCD consists of a vest that is worn under the clothing 24 hours a day except when the patient is bathing or showering. The vest includes an electrode belt that contains the cardiac monitoring electrodes and the therapy electrodes that deliver an electrical shock if a life-threatening ventricular arrhythmia is detected. The WCD is programmable and communicates with the patient through voice and display messages, tones, or alarms and vibration against the skin. When an arrhythmia is detected, the device instructs the patient to stop the impending shock by pressing a response button to avoid receiving a shock while conscious. The WCD is designed to deliver an electric shock within 60 seconds of the onset of ventricular tachycardia or ventricular fibrillation unless a conscious patient presses the response button. The patient can also connect the WCD to an external modem and send the data it has collected over the phone to a physician's computer for review. The Lifecor Wearable Cardioverter Defibrillator 2000 System received FDA approval on December 18, 2001. This system is intended for adult patients who are at risk for sudden cardiac arrest and who are not candidates for or refuse an implanted cardiac defibrillator.

An **automatic external defibrillator** (AED) is a compact, portable device that is used to deliver an electrical shock to a victim of sudden cardiac arrest. The use of AEDs has become an important component of emergency medical systems and advances in technology have allowed the expansion AED use to trained first responders and laypersons who witness an arrest. There is little published medical literature regarding the efficacy of AED use in the home.

**Criteria:**

- I. ODS will cover an FDA approved wearable cardiac defibrillator (WCD) up to plan limitations when **all** of the following criteria are met:
- A. The patient is an adult, 18 years of age or older; and
  - B. The patient has completed electrophysiologic studies to determine the type of arrhythmia present and confirm that an automatic cardiac defibrillator is the best course of treatment; and
  - C. The patient is at high risk for sudden cardiac death

**AND**

**One** of the following criteria is met:

- D. The WCD is being used temporarily until the patient receives a heart transplant; or
- E. The patient suffered complications or removal of an implanted cardiac defibrillator (ICD); or
- F. The patient is not a suitable candidate for an ICD; or
- G. The WCD is being used post myocardial infarction as a bridge during the 40 days post event while awaiting an automatic implantable
- H. The patient refuses ICD placement

\*Wearable cardiac defibrillators (i.e. Lifecor LifeVest) are intended for short-term use. If approved, the WCD will be rented on a monthly basis.

- II. Automatic external defibrillators (AED) will be reviewed for medical necessity on a case-by-case basis by the ODS Medical Director for pediatric patients age 1 through 17. A pediatric AED is specifically designed to be worn by a child typically between the ages of 1 and 8 years of age or who weighs less than 55 pounds. If a child is over the age of 8 or weighs more than 55 pounds, an adult AED might be appropriate.

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III. Automatic external defibrillators (AED) for adults (age 18 and older) are considered investigational for home use. There are few peer-reviewed published studies that report on clinical outcomes of AEDs used in the home setting for adult patients by lay persons, and no studies that evaluate the efficacy of AEDs in reducing mortality compared to alternatives, i.e. ICD or emergency treatment by first responders.

**Information to be Submitted with Pre-Authorization Request:**

1. History and physical from treating physician
2. Results from electrophysiology studies
3. Patient contraindication to ICD
4. Anticipated length of time that WCD will be used

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