Wearable Cardioverter Defibrillator

DESCRIPTION

Cardioverter defibrillators are designed to monitor an individual’s heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT) and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. Indications for cardioverter defibrillators include (1) secondary prevention in individuals who have experienced a potentially life-threatening episode of VT (near sudden death) and (2) primary prevention for use in individuals who are considered at high risk for sudden cardiac death (SCD) but who have not yet experienced life-threatening VT or VF.

A wearable cardioverter defibrillator (WCD) is an external device intended for temporary conditions when an implantable device is contraindicated. The WCD consists of a vest that is worn continuously underneath the individual’s clothing. The vest includes an electrode belt that contains the cardiac-monitoring electrodes and the therapy electrodes that deliver a counter shock. The vest is connected to a monitor with a battery pack and alarm module that is worn on the individual’s belt. The monitor contains the electronics that interpret the cardiac rhythm and determines when a counter shock is necessary. The alarm module alerts the individual to certain conditions by lights or voice messages. The Lifecor WCD® 2000 system received FDA approval in December 2001. The vest was renamed and is now called the Zoll® LifeVest.

POLICY

- Wearable cardioverter-defibrillator (WCD) for the prevention of sudden cardiac death is considered medically necessary if the medical appropriateness criteria are met. (See Medical Appropriateness below.)

- Any device utilized for this procedure must have FDA approval specific to the indication, otherwise it will be considered investigational.

MEDICAL APPROPRIATENESS

- Wearable cardioverter-defibrillator may be indicated when ANY ONE of the following are met:
  - Initial request for cardioverter-defibrillator is indicated for ALL of the following:
    - Individual is not a candidate for transvenous or subcutaneous implantable cardioverter for ANY ONE of the following reasons:
      - Individual approved for heart transplant and on wait list
      - Previously implanted ICD requires explantation due to infection with waiting period before ICD reinsertion
      - Individual with temporary infectious process that precludes initial implantation of an ICD
    - Ejection fraction 35 or less and documentation of ANY ONE of the following:
      - Individual is within 40 days of myocardial infarction
      - Revascularization (CABG or percutaneous coronary intervention [PCI]) within the last 90 days
      - Myocarditis
      - Secondary cardiomyopathy
    - Documented nonschematic dilated cardiomyopathy if ALL of the following are met:
      - New diagnosis
      - Individual has been started on guideline-directed medical therapy
    - No contraindications present as indicated by ALL of the following:
      - No condition limiting life expectancy to less than 1 year (e.g., advanced malignancy)
      - No history of significant nonadherence with medical therapy and follow-up
Request for extended use of cardioverter-defibrillator is indicated for ALL of the following:

- Reassessment prior to 90 days for consideration of an extension (e.g., to determine prognosis, to determine if individual remains a candidate for life vest or to determine if individual should receive implantable cardioverter-defibrillator based on prognosis)
- Continued high risk of sudden cardiac death as evidenced by ejection fraction 35 or less
- Documentation of compliance with use of wearable cardioverter-defibrillator

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member’s health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

There is a lack of relevant published evidence to determine the net health outcome of the wearable cardioverter defibrillator for any other indications.

SOURCES


This document has been classified as public information.


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