Cardioverter Defibrillators

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.

There are three types of cardioverter defibrillators: implantable cardioverter defibrillator (ICD), subcutaneous ICD (S-ICD®) and wearable cardioverter defibrillator (WCD).

The ICD involves placement of a generator in the subcutaneous tissue of the chest wall. Transvenous leads are attached to the generator and threaded intravenously into the endocardium. The leads sense and transmit information on cardiac rhythm to the generator which analyzes the rhythm information and produces an electrical shock when a malignant arrhythmia is recognized.

The S-ICD uses a subcutaneous electrode that is implanted adjacent to the left sternum. The electrodes sense the cardiac rhythm and deliver countershocks through the subcutaneous tissue of the chest wall.

A WCD is a temporary, 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

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

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

- 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

- Cardioverter defibrillators may be indicated for ALL of the following:
  - No contraindications present as indicated by ALL the following:
    - No condition limiting life expectancy to less than 1 year (e.g., advanced malignancy)
Policy

Medical Policy Manual  Approved: Do Not Implement Until 12/20/17

- No significant psychiatric illness that may be aggravated by device implantation or that may preclude regular follow-up
- No ongoing IV drug abuse
- No unresolved infection associated with risk for hematogenous seeding
- No history of significant nonadherence with medical therapy and follow-up

  Treatment is indicated for **ANY ONE** of the following procedures:

  - Transvenous implantable cardioverter-defibrillator (ICD) with possible electrophysiologic study is indicated by **ANY ONE** of the following:
    - Cardiac arrest due to ventricular fibrillation without known treatable precipitating cause (e.g., acute myocardial ischemia, severe electrolyte disorder)
    - Hemodynamic instability due to ventricular tachycardia without known treatable precipitating cause (e.g., acute myocardial ischemia, severe electrolyte disorder)
    - Ventricular fibrillation or polymorphic ventricular tachycardia within 48 hours of MI and **ANY ONE** of the following:
      - Left ventricular ejection fraction 35% or less
      - Revascularization of infarct vessel not feasible
      - Inducible ventricular tachycardia/ventricular fibrillation at electrophysiologic study performed 4 or more days after revascularization
  - Individual within 40 days of MI and **ANY ONE** of the following:
    - Left ventricular ejection fraction less than or equal to 40% and individual is having permanent pacemaker placed
    - Individual with episode of nonsustained (lasting less than 30 seconds) ventricular tachycardia 4 to 40 days post MI and **ANY ONE** of the following:
      - Ventricular tachycardia/ventricular fibrillation inducible at electrophysiologic study
      - Left ventricular ejection fraction less than or equal to 30%
      - Left ventricular ejection fraction less than or equal to 40% and individual was not revascularized (percutaneous coronary intervention or CABG) after MI (e.g., not feasible or amendable)
  - Individual with history of MI (more than 40 days ago) and **ANY ONE** of the following:
    - Left ventricular ejection fraction less than or equal to 35%
    - Left ventricular ejection fraction less than or equal to 40% and individual has had episode of nonsustained (lasting less than 30 seconds) ventricular tachycardia
    - Left ventricular ejection fraction less than or equal to 40% and individual is having permanent pacemaker placed
  - Spontaneous sustained (lasting 30 seconds or longer) hemodynamically stable ventricular tachycardia and **ANY ONE** of the following:
    - Left ventricular function less than or equal to 35%
    - History of MI
    - Nonischemic dilated cardiomyopathy
  - Unexplained syncope with **ANY ONE** of the following:
    - Left ventricular ejection fraction less than or equal to 35%
    - Inducible ventricular tachycardia or ventricular fibrillation on electrophysiologic study
    - History of coronary artery disease and left ventricular ejection fraction less than 50%
    - Left ventricular hypertrophy (other than hypertrophic cardiomyopathy) and left ventricular ejection fraction less than 50%
    - Hypertrophic cardiomyopathy
    - History of tetralogy of Fallot with prior corrective surgery
    - Nonischemic dilated cardiomyopathy
    - Cardiac amyloidosis
    - Left ventricular noncompaction
    - Arrhythmogenic right ventricular cardiomyopathy

This document has been classified as public information.
Medical Policy Manual  Approved: Do Not Implement Until 12/20/17

- Long QT syndrome, Brugada ECG pattern or catecholaminergic polymorphic ventricular tachycardia
- Advanced structural heart disease of unknown or untreatable cause
- Ischemic cardiomyopathy (known coronary artery disease without history of MI) and left ventricular ejection fraction less than or equal to 35%
- Nonischemic cardiomyopathy and ANY ONE of the following:
  - Left ventricular ejection fraction less than or equal to 30% with symptomatic heart failure (e.g., New York Heart Association class II-IV)
  - Left ventricular ejection fraction less than or equal to 40% and individual has been on guideline-directed medical therapy (e.g., ACE-inhibitor, beta-blocker) for at least 3 months
- History of sarcoid heart disease
- History of Chagas disease
- History of myotonic dystrophy
- History of heart failure due to amyloidosis
- History of giant cell myocarditis
- Peripartum cardiomyopathy persisting more than 3 months post-partum
- Individual has genetic condition that increases risk of sudden cardiac death as indicated by ANY ONE of the following:
  - Long QT syndrome and ANY ONE of the following:
    - History of cardiac arrest
    - Strong family history of cardiac arrest
    - Known SCN5A mutation
    - Unexplained syncope
    - Ventricular tachycardia
    - Intolerance of beta-blocker therapy
    - Corrected QT interval greater than 500 milliseconds
  - Arrhythmogenic right ventricular dysplasia or cardiomyopathy
  - Brugada syndrome and ANY ONE of the following:
    - Inducible sustained ventricular tachycardia or ventricular fibrillation on electrophysiologic study
    - History of cardiac arrest
    - History of syncope
    - Ventricular tachycardia
    - ST-segment elevation on ECG leads V1 to V3
    - Family history of cardiac arrest with inducible ventricular tachycardia or ventricular fibrillation on electrophysiologic study
  - Catecholaminergic polymorphic ventricular tachycardia and ANY ONE of the following:
    - Spontaneous sustained or nonsustained ventricular tachycardia
    - Unexplained syncope (e.g., noncardiac cause not identified)
  - Hypertrophic cardiomyopathy and ANY ONE of the following:
    - Spontaneous sustained or nonsustained ventricular tachycardia
    - Unexplained syncope (e.g., noncardiac cause not identified)
    - Left ventricle thickness of 30 mm or greater
    - Hypotensive response to exercise
    - Family history of sudden cardiac death (e.g., cardiac arrest) or ventricular tachycardia presumed to be due to hypertrophic cardiomyopathy
  - Short QT syndrome
  - Noncompaction of left ventricle
  - Other familial cardiomyopathy associated with sudden death
  - Subcutaneous implantable cardioverter-defibrillator (S-ICD®) is indicated by ALL of the following:
    - Individual meets criteria for transvenous insertion of implantable cardioverter-defibrillator
    - Pacemaker, resynchronization, anti-tachycardia pacing or remote monitoring are not required

This document has been classified as public information.
Implantable cardioverter-defibrillator not able to be placed due to **ANY ONE** of the following:
- Compromised venous access
- Increased risk of bacteremia
- Indwelling intravascular hardware at risk for endovascular infection

**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 at high risk for sudden cardiac death as evidenced by EKG, rhythm strip and/or New York Heart Association classification
  - 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
    - Individual is within 90 days of **ANY ONE** of the following:
      - Myocardial infarction
      - CABG
      - Percutaneous Coronary Intervention (PCI)
    - Documented nonischemic dilated cardiomyopathy if **ALL** of the following are met:
      - New diagnosis
      - Individual has been started on guideline-directed medical therapy
  - Ejection fraction equal to or less than 35

- 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 EKG, rhythm strip and/or New York Heart Association classification
  - 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.


This document has been classified as public information.


**EFFECTIVE DATE** 12/20/2017

ID_BT