blue of california

Medical Policy

Wearable Cardioverter-Defibrillators	
Type: Medical Necessity and Investigational / Experimental	**Policy Specific Section:** Durable Medical Equipment
Original Policy Date: December 7, 2006	**Effective Date:** July 14, 2014

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

A wearable cardioverter-defibrillator (WCD) is a temporary, external device that is an alternative to an implantable cardioverter-defibrillator (ICD) and is intended to perform the same tasks as an ICD without requiring invasive procedures. It is primarily intended for temporary conditions for which an implantable device is contraindicated, or for a period of time during which the need for

a permanent implantable device is uncertain. It consists of a vest that is worn continuously underneath the patient's clothing. Part of this vest is the 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 patient'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 patient to certain conditions by lights or voice messages.

Policy

Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death may be considered **medically necessary** as interim treatment for those who have **all** of the following:

- Meet the criteria for an implantable cardioverter-defibrillator (ICD) (see Blue Shield of California Medical Policy: Implantable Cardioverter Defibrillator)
- Have a temporary contraindication to receiving an ICD (e.g., a systemic infection at the current time)
- Have been scheduled for an ICD placement or who had an ICD removed and have been rescheduled for placement of another ICD once the contraindication is treated

Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered **investigational** for **all** of the following indications when they are the sole indication for a wearable cardioverter-defibrillator:

- Patients in the immediate period (i.e., less than 40 days) following an acute myocardial infarction
- Patients post coronary artery bypass graft (CABG) surgery
- Patients with newly diagnosed nonischemic cardiomyopathy
- Women with peripartum cardiomyopathy
- High-risk patients awaiting heart transplant

Use of wearable cardioverter-defibrillators is considered **investigational** for all other indications.

Policy Guideline

It is uncommon for patients to have a temporary contraindication to ICD placement. The most common reason will be a systemic infection that requires treatment before the ICD can be implanted. The wearable cardioverter-defibrillator should only be used short-term while the temporary contraindication (e.g., systemic infection) is being clinically managed. Once treatment is completed, the permanent ICD should be implanted.

Coding

There are specific CPT and HCPCS codes that are associated with the wearable cardioverter-defibrillator:

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- **93745**: Initial set-up and programming by a physician of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events*
- **93292**: Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; wearable defibrillator system*

***93745** and **93292** cannot be billed together

A wearable cardioverter-defibrillator (K0606) is a rental DME (durable medical equipment) device only. The rental allowance includes all necessary equipment, delivery, set-up, maintenance, and repair costs.

- **K0606**: Automatic external defibrillator, with integrated electrocardiogram analysis, garment type

The following codes represent replacement supplies and accessories for use with K0606; however, these supplies are inclusive in the rental of the wearable cardioverter defibrillator (K0606):

- **K0607**: Replacement battery for automated external defibrillator, garment type only, each
- **K0608**: Replacement garment for use with automated external defibrillator, each
- **K0609**: Replacement electrodes for use with automated external defibrillator, garment type only, each

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review

• History and physical and/or cardiology consultation report including:
  o Clinical justification for a Wearable Cardioverter Defibrillator
  o Documentation specifying temporary contraindication to receiving an ICD (e.g., systemic infection)
  o Past cardiac surgical history (e.g., ICD placement or explantation, revascularization procedures) and dates associated (if applicable)
  o Specific documentation required to meet ICD criteria (when applicable):
  ▪ Date ICD procedure is planned and type of ICD requested (automatic or subcutaneous)
  ▪ Clinical justification for ICD placement

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- Myocardial infarction history including date
- Past medical treatment and response(s)
- Family history of sudden cardiac death (including generation)
- Cardiac monitoring result(s) (e.g., EKG, Holter, hemodynamic or EP studies, echocardiogram)
- Left ventricular ejection fraction and date obtained
- NYHA Functional Classification
- Major risk factors for sudden cardiac death
- Estimated life expectancy based on medical history (non-cardiac)

- Echocardiogram report within the past six months

Post Service

- Operative procedure report(s) relating to an ICD (if applicable)

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available

Click here to view the appendix for this policy

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