

Corporate Medical Policy

External Defibrillators

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Description of Procedure or Service

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease. When a person's heart rhythm goes into an uncoordinated electrical activity called ventricular fibrillation, the heart twitches and cannot pump blood efficiently. This condition often accompanies severe heart attacks when the patient's heart appears to have stopped beating.

Defibrillators work by giving the heart a controlled electric shock, hopefully jolting it back into a regular rhythm. The automatic implantable cardioverter defibrillator (AICD) has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, the use of AICDs has been potentially broadened by studies reporting a reduction in mortality for patients at risk for ventricular arrhythmias, such as patients with prior myocardial infarction (MI) and reduced ejection fraction. AICDs consist of implantable leads in the heart that connect to a pulse generator implanted beneath the skin of the chest or abdomen.

The wearable cardioverter-defibrillator is an external device that is intended to perform the same tasks as an AICD, without requiring any invasive procedures. It consists of a vest that is worn 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. If the device detects an abnormal heart rhythm, it sounds a series of alarms and displays a message. Since a shock is not required while conscious, the patient can press and hold two response buttons to prevent a treatment shock. If the patient does not respond to the alarms or if loss of consciousness causes involuntary release of the response buttons, the WCD automatically delivers electrical shock therapy within 60 seconds to restore the heart rhythm to normal. In the event of a life-threatening arrhythmia, the device delivers a series of up to five defibrillating shocks.

The U.S. Food and Drug Administration (FDA) approved the Lifecor WCD® 2000 system via premarket application approval in December 2001 for "adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator."

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for a wearable cardioverter defibrillator when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.

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Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

When External Defibrillators are covered

Use of wearable cardioverter defibrillators for the prevention of sudden cardiac death is considered medically necessary as an interim treatment for those who have all of the following:

- meet the criteria for an implantable cardioverter defibrillator (*see Policy Guidelines section*); **and**
- have a temporary contraindication to receiving an implantable cardioverter defibrillator, such as a systemic infection, at the current time; or is awaiting heart transplantation (defined as on a waiting list); **and**
- have been scheduled for implantable cardioverter defibrillator placement or who have had an implantable cardioverter defibrillator removed and have been rescheduled for placement of another implantable cardioverter defibrillator once the contraindication is treated.

When External Defibrillators are not covered

Use of wearable cardioverter defibrillators for the prevention of sudden cardiac death is considered investigational for all other indications including use immediately (i.e., less than 40 days) following an acute myocardial infarction.

Policy Guidelines

The use of an automatic implantable cardioverter defibrillator (AICD) may be considered medically necessary in adult patients who meet the following criteria:

Primary Prevention

- ischemic cardiomyopathy with New York Heart Association (NYHA) functional Class II or Class III symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 35% or less; or
 - ischemic cardiomyopathy with NYHA functional Class I symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 30% or less; or
 - nonischemic dilated cardiomyopathy and left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; or
 - hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with HCM.
- ### Secondary Prevention
- patients with a history of life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia.

The use of the AICD is considered investigational in primary prevention patients who:

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- have had an acute myocardial infarction (i.e., less than 40 days before AICD treatment);
- have New York Heart Association (NYHA) Class IV congestive heart failure (unless patient is eligible to receive a combination of cardiac resynchronization therapy ICD device);
- have had cardiac revascularization procedure past 3 months (CABG or PTCA) or are candidates for a cardiac revascularization procedure; or
- have noncardiac disease that would be associated with life expectancy less than 1 year.

The use of the ICD may be considered medically necessary in children who meet any of the following criteria:

- survivors of cardiac arrest, after reversible causes have been excluded;
- symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; or
- congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias.

The use of the ICD is considered investigational for all other indications in pediatric patients.

Symptomatic heart failure is defined as the presence of dyspnea on exertion, angina, palpitations, or fatigue.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 93292, 93745, K0606, K0607, K0608, K0609

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

ECRI Target Report #811. (March 2002). Wearable external cardioverter defibrillator for detection and treatment of ventricular arrhythmia. Retrieved on October 5, 2004 from http://www.target.ecri.org/summary/detail.aspx?doc_id=1722&q=wearable+external+defibrillator&anm.

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U.S. Food and Drug Administration. FDA clears over-the-counter sales of automatic external defibrillator. FDA Talk Paper. T04-39. Rockville, MD: FDA; September 16, 2004. Retrieved on September 29, 2004 from <http://www.fda.gov/bbs/topics/answers/2004/ans01314.html>.

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Feldman AM, Klein H, Tchou P, Murali S, Hall WJ, Mancini D, et al. (January 2004). Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of WEARIT/BIROAD. *Pacing Clin Electrophysiol* 2004;27(1):4-9

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Specialty Matched Consultant Advisory Panel – 3/2010

Chung MK, Szymkiewicz SJ, Shao M et al. (2010). Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. *J Am Coll Cardiol*, 56(3):194-203.

BCBSA TEC Assessment. Wearable Cardioverter-Defibrillator as a Bridge to Implantable Cardioverter-Defibrillator Treatment. November 2010.

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Food and Drug Administration (FDA). Pre-market Approval #P010030 for LifeCor WCD®2000. Retrieved on March 9, 2011 from http://www.accessdata.fda.gov/cdrh_docs/pdf/P010030a.pdf

Specialty Matched Consultant Advisory Panel review 4/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.44, 7/14/11

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.15, 10/4/11

Medical Director review 11/2011

Steinbeck G, Andresen D, Seidl K et al.; IRIS Investigators. Defibrillator implantation early after myocardial infarction. *N Engl J Med* 2009; 361(15):1427-36.

Rao M, Goldenberg I, Moss AJ et al. Wearable defibrillator in congenital structural heart disease and inherited arrhythmias. *Am J Cardiol*, Sept 13, 2011

Specialty Matched Consultant Advisory Panel review 4/2012

Policy Implementation/Update Information

- 10/28/04 New policy issued. External defibrillators are considered investigational. References added. Notification 10/28/2004. Effective 1/6/2005.
- 01/06/05 Code 93745 added. Is considered investigational.
- 11/27/06 Additional information added to Policy Guidelines section to support continued Investigational status. CPT Codes updated. References updated. Specialty Matched Consultant Advisory review 10/ 23/06. No changes to policy coverage criteria. CPT codes updated.
- 4/23/07 Policy revised to indicate BCBSNC will provide coverage for a wearable cardioverter defibrillator when it is determined to be medically necessary because the medical criteria and guidelines noted in the policy have been met. Guidelines for AICD added to Policy Guidelines section. (adn)
- 4/7/08 Description section revised, deleted information regarding Automatic External Defibrillators (AEDs). References updated. Specialty Matched Consultant Advisory Panel review 3/12/08. No change to policy statement. (adn)
- 01/05/09 CPT codes 93741 and 93742 deleted. Added code 93292.

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- 5/11/10 Specialty Matched Consultant Advisory Panel review. Added “or is awaiting heart transplantation (defined as on a waiting list)” to When External Defibrillators are covered section. Removed Medical Policy number (mco)
- 5/10/11 Specialty Matched Consultant Advisory Panel review 4/2011. References updated. Included FDA information regarding the LifeCor WCD®2000 system. (mco)
- 11/22/11 Policy Guidelines for use of AICD updated. New **adult** primary prevention guidelines are as follows: “ischemic cardiomyopathy with New York Heart Association (NYHA) functional Class II or Class III symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 35% or less; **or** ischemic cardiomyopathy with NYHA functional Class I symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 30% or less; **or** nonischemic dilated cardiomyopathy and left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; **or** hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with HCM.” New **pediatric** indications for AICDs are as follows: “The use of the ICD may be considered medically necessary in children who meet any of the following criteria: survivors of cardiac arrest, after reversible causes have been excluded; symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; or congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias. The use of the ICD is considered investigational for all other indications in pediatric patients.” References updated. Medical Director review 11/2011. Notification given 11/22/11 for effective date of 02/21/12. (mco)
- 5/15/12 Specialty Matched Consultant Advisory Panel review 4/2012. References updated. No changes to Policy Statements. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.