Protocol

Wearable Cardioverter Defibrillators

Medical Benefit		**Effective Date**: 08/01/17	**Next Review Date**: 05/19
Preauthorization	Yes	**Review Dates**: 05/07, 05/08, 05/09, 03/10, 01/11, 01/12, 01/13, 01/14, 05/14, 05/15, 05/16, 05/17, 07/17, 05/18	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With a temporary contraindication to an implantable cardio-verter defibrillator	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • Who are in the immediate post myocardial infarction period	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • Who are post coronary artery bypass graft surgery and at high risk for lethal	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • Who are awaiting heart transplantation and are at high risk for lethal arrhythmias	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • With newly diagnosed nonischemic cardiomyopathy	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • With peripartum cardiomyopathy	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity

DESCRIPTION

A wearable cardioverter defibrillator (WCD) is a temporary, external device that is an alternative to an implantable cardioverter defibrillator (ICD). 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.

POLICY

Use of wearable cardioverter-defibrillators (WCDs) for the prevention of sudden cardiac death is considered **medically necessary** as interim treatment for those who:

- meet the criteria for an implantable cardioverter-defibrillator (ICD; refer to the Implantable Cardioverter Defibrillator Protocol) and:
  - have a temporary contraindication to receiving an ICD (i.e., systemic infection) at the current time, and;
  - 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;
- are in the ICD waiting period (i.e., less than 40 days) following an acute myocardial infarction;
- are in the ICD waiting period (i.e., less than 90 days) following coronary revascularization procedures such as coronary artery bypass graft surgery or percutaneous coronary intervention;
- are awaiting heart transplant and are considered at high risk for lethal arrhythmias.

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

- Patients with newly diagnosed nonischemic cardiomyopathy
- Women with peripartum cardiomyopathy

Use of WCDs is considered **investigational** for all other indications.

POLICY GUIDELINES

A WCD would continue to be appropriate beyond a 90 day period when the patient is compliant with use of the device and when a re-assessment has been documented including review of both the continued need for ICD implantation and the current medical regime. Compliance would be demonstrated by a wear time of 22 hours per day (≥ 90%) during the preceding 30 days.

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.

MEDICARE ADVANTAGE

A wearable defibrillator is **medically necessary** for patients at high risk for sudden cardiac death (SCD) if they meet one of the criteria (1-4), described below:

1. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction; or
2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
3. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or
4. A previously implanted defibrillator now requires explantation.

All other indications for Medicare Advantage members are considered **not medically necessary**.

BACKGROUND

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease. The ICD has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, use of ICDs 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 and reduced ejection fraction.

ICDs consist of implantable leads which are placed percutaneously in the heart that are connected to a pulse generator implanted beneath the skin of the chest or abdomen. ICD placement is a minor surgical procedure. Potential adverse effects of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks. Please see the Implantable Cardioverter Defibrillator Protocol for further information on ICDs.

The wearable cardioverter defibrillator is an external device that is intended to perform the same tasks as an ICD, without invasive procedures. It consists of a vest 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 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, during which time a conscious patient can abort or delay the shock.

REGULATORY STATUS

In December 2001, the Lifecor WCD® 2000 system was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for "adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator." The vest was renamed the Zoll® LifeVest®.

In 2015, FDA approved the LifeVest® "for certain children who are at risk for sudden cardiac arrest, but are not candidates for an implantable defibrillator due to certain medical conditions or lack of parental consent."

FDA product code: MVK.

RELATED PROTOCOL

Implantable Cardioverter Defibrillators

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data, P010030, Lifecor, Inc, WCD® 2000 System. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=P010030. Accessed May 9, 2016.
2. Beauregard LA. Personal security: Clinical applications of the wearable defibrillator. Pacing Clin Electrophysiol. Jan 2004; 27(1):1-3. PMID 14720147
3. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Wearable cardioverter-defibrillator as a bridge to implantable cardioverter-defibrillator treatment. TEC Assessments. 2010; Volume 25: Tab 2.
4. Auricchio A, Klein H, Geller CJ, et al. Clinical efficacy of the wearable cardioverter-defibrillator in acutely terminating episodes of ventricular fibrillation. Am J Cardiol. May 15, 1998; 81(10):1253-1256. PMID 9604964
5. Chung MK, Szymkiewicz SJ, Shao M, et al. Aggregate national experience with the wearable cardioverter defibrillator: event rates, compliance, and survival. J Am Coll Cardiol. Jul 13 2010; 56(3):194-203. PMID 20620738
6. Tanawuttiwat T, Garisto JD, Salow A, et al. Protection from outpatient sudden cardiac death following ICD removal using a wearable cardioverter defibrillator. Pacing Clin Electrophysiol. May 2014; 37(5):562-568. PMID 24762055
7. Feldman AM, Klein H, Tchou P, et al. Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD. Pacing Clin Electrophysiol. Jan 2004; 27(1):4-9. PMID 14720148
8. Mitrani RD, McArdle A, Slane M, et al. Wearable defibrillators in uninsured patients with newly diagnosed cardiomyopathy or recent revascularization in a community medical center. Am Heart J. Mar 2013; 165(3):386-392. PMID 23453108
9. Kao AC, Krause SW, Handa R, et al. Wearable defibrillator use in heart failure (WIF): results of a prospective registry. BMC Cardiovasc Disord. 2012; 12:123. PMID 23234574
10. Goldenberg I, Klein H, Zareba W, et al. Eighteen month results from the prospective registry and follow-up of patients using the Lifevest Wearable Defibrillator (WEARIT-II Registry) (abstract LB02-02). Heart Rhythm 2013: 34th Annual Scientific Sessions; May 10, 2013; Denver, CO.
11. Kutyifa V, Moss AJ, Klein H, et al. Use of the wearable cardioverter defibrillator in high-risk cardiac patients: data from the Prospective Registry of Patients Using the Wearable Cardioverter Defibrillator (WEARIT-II Registry). Circulation. Oct 27 2015; 132(17):1613-1619. PMID 26316618
12. Gregoratos G, Cheitlin MD, Conill A, et al. ACC/AHA guidelines for implantation of cardiac pacemakers and antiarrhythmia devices: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Pacemaker Implantation). J Am Coll Cardiol. Apr 1998; 31(5):1175-1209. PMID 9562026

13. Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias N Engl J Med. Nov 27 1997; 337(22):1576-1583. PMID 9411221
14. Wilber DJ, Zareba W, Hall WJ, et al. Time dependence of mortality risk and defibrillator benefit after myocardial infarction. Circulation. Mar 9 2004; 109(9):1082-1084. PMID 14993128
15. Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med. Dec 9 2004; 351(24):2481-2488. PMID 15590950
16. Steinbeck G, Andresen D, Seidl K, et al. Defibrillator implantation early after myocardial infarction. N Engl J Med. Oct 8 2009; 361(15):1427-1436. PMID 19812399
17. Epstein AE, Abraham WT, Bianco NR, et al. Wearable cardioverter-defibrillator use in patients perceived to be at high risk early post-myocardial infarction. J Am Coll Cardiol. Nov 19 2013; 62(21):2000-2007. PMID 23916930
18. Uyei J, Braithwaite RS. Effectiveness of wearable defibrillators: systematic review and quality of evidence. Int J Technol Assess Health Care. Apr 2014; 30(2):194-202. PMID 24893969
19. Bigger JT, Jr. Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary-artery bypass graft surgery. Coronary Artery Bypass Graft (CABG) Patch Trial Investigators. N Engl J Med. Nov 27 1997; 337(22):1569-1575. PMID 9371853
20. Zishiri ET, Williams S, Cronin EM, et al. Early risk of mortality after coronary artery revascularization in patients with left ventricular dysfunction and potential role of the wearable cardioverter defibrillator. Circ Arrhythm Electrophysiol. Feb 2013; 6(1):117-128. PMID 23275233
21. Opreanu M, Wan C, Singh V, et al. Wearable cardioverter-defibrillator as a bridge to cardiac transplantation: A national database analysis. J Heart Lung Transplant. Oct 2015; 34(10):1305-1309. PMID 26094085
22. Rao M, Goldenberg I, Moss AJ, et al. Wearable defibrillator in congenital structural heart disease and inherited arrhythmias. Am J Cardiol. Dec 1 2011; 108(11):1632-1638. PMID 21890075
23. Kadish A, Schaechter A, Subacius H, et al. Patients with recently diagnosed nonischemic cardiomyopathy benefit from implantable cardioverter-defibrillators. J Am Coll Cardiol. Jun 20 2006; 47(12):2477-2482. PMID 16781376
24. Salehi N, Nasiri M, Bianco NR, et al. The wearable cardioverter defibrillator in nonischemic cardiomyopathy: A US national database analysis. Can J Cardiol. Oct 2016; 32(10):1247 e1241-1247 e1246. PMID 26975224
25. Saltzberg MT, Szymkiewicz S, Bianco NR. Characteristics and outcomes of peripartum versus nonperipartum cardiomyopathy in women using a wearable cardiac defibrillator. J Card Fail. Jan 2012; 18(1):21-27. PMID 22196837
26. Duncker D, Haghikia A, Konig T, et als. Risk for ventricular fibrillation in peripartum cardiomyopathy with severely reduced left ventricular function-value of the wearable cardioverter/defibrillator. Eur J Heart Fail. Dec 2014; 16(12):1331-1336. PMID 25371320
27. Piccini JP, Sr., Allen LA, Kudenchuk PJ, et al. Wearable cardioverter-defibrillator therapy for the prevention of sudden cardiac death: a science advisory from the American Heart Association. Circulation. Apr 26 2016; 133(17):1715-1727. PMID 27022063
28. Kusumoto FM, Calkins H, Boehmer J, et al. HRS/ACC/AHA expert consensus statement on the use of implantable cardioverter-defibrillator therapy in patients who are not included or not well represented in clinical trials. Circulation. Jul 1 2014; 130(1):94-125. PMID 24815500
29. Amsterdam EA, Wenger NK, Brindis RG, et al. 2014 AHA/ACC guideline for the management of patients with non-ST-elevation acute coronary syndromes: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. Dec 23 2014; 130(25):e344-426. PMID 25249585
30. Gronda E, Bourge RC, Costanzo MR, et al. Heart rhythm considerations in heart transplant candidates and considerations for ventricular assist devices: International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplant candidates--2006. J Heart Lung Transplant. Sep 2006; 25(9):1043-1056. PMID 16962465.

31. Noridian Healthcare Solutions, LLC, (Jurisdiction - New York - Entire State, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania, California - Entire State, American Samoa, Guam, Hawaii, Northern Mariana Islands, Nevada) Local Coverage Determination (LCD): Automatic External Defibrillators (L33690), Revision Effective Date for services performed on or after 01/01/2017.