MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Wearable Cardioverter Defibrillators

Table of Contents

Policy Number: 042

BCBSA Reference Number 2.02.15
NCD/LCD: Local Coverage Determination (LCD): Automatic External Defibrillators (L33690)

Related Policies

Implantable Cardioverter Defibrillator (ICD), #070

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Automatic external defibrillators are considered **MEDICALLY NECESSARY** for patients who meet the criteria in Policy 070, Implantable Cardioverter Defibrillator) or for patients at high risk for sudden cardiac death (SCD) due to one of the following conditions:

A wearable defibrillator (K0606) is covered for patients 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.

It is expected the ordering physician be experienced in the management of patients at risk for SCD.

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

Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link(s) below.

Local Coverage Determinations (LCDs) for National Government Services, Inc.

Local Coverage Determination (LCD): Automatic External Defibrillators (L33690)

Note: To review the specific LCD, please remember to click "accept" on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at https://www.cms.gov for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement battery for automated external defibrillator, each
K0608	Replacement garment for use with automated external defibrillator, each
K0609	Replacement electrodes for use with automated external defibrillator, each

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if <u>medical necessity criteria</u> are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
A18.84	Tuberculosis of heart
I21.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery
I21.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery
I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery
I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery
I21.29	ST elevation (STEMI) myocardial infarction involving other sites
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I21.9	Acute myocardial infarction, unspecified
I21.A1	Myocardial infarction type 2
I21.A9	Other myocardial infarction type
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
I22.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site
I25.2	Old myocardial infarction
I42.0	Dilated cardiomyopathy
I42.1	Obstructive hypertrophic cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.3	Endomyocardial (eosinophilic) disease
I42.4	Endocardial fibroelastosis
I42.5	Other restrictive cardiomyopathy
I42.6	Alcoholic cardiomyopathy
I42.7	Cardiomyopathy due to drug and external agent
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified
I43	Cardiomyopathy in diseases classified elsewhere
I45.81	Long QT syndrome
I46.2	Cardiac arrest due to underlying cardiac condition
I46.8	Cardiac arrest due to other underlying condition
I46.9	Cardiac arrest, cause unspecified
I47.0	Re-entry ventricular arrhythmia
I47.2	Ventricular tachycardia
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
T82.110A	Breakdown (mechanical) of cardiac electrode, initial encounter
T82.111A	Breakdown (mechanical) of cardiac pulse generator (battery), initial encounter
T82.118A	Breakdown (mechanical) of other cardiac electronic device, initial encounter

T82.119A	Breakdown (mechanical) of unspecified cardiac electronic device, initial encounter
T82.120A	Displacement of cardiac electrode, initial encounter
T82.121A	Displacement of cardiac pulse generator (battery), initial encounter
T82.128A	Displacement of other cardiac electronic device, initial encounter
T82.129A	Displacement of unspecified cardiac electronic device, initial encounter
T82.190A	Other mechanical complication of cardiac electrode, initial encounter
T82.191A	Other mechanical complication of cardiac pulse generator (battery), initial encounter
T82.198A	Other mechanical complication of other cardiac electronic device, initial encounter
T82.199A	Other mechanical complication of unspecified cardiac device, initial encounter
T82.6XXA	Infection and inflammatory reaction due to cardiac valve prosthesis, initial encounter
T82.7XXA	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter

Description

Sudden Cardiac Arrest

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease.

Treatment

The implantable cardioverter defibrillator (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 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 placed beneath the skin of the chest or abdomen. ICD placement is a minor surgical procedure. Potential adverse events of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks. See medical policy #070 for further information on ICDs.

The wearable cardioverter defibrillator (WCD) is an external device 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.

U.S. Food and Drug Administration (FDA) labeled indications for the WCD are adults at risk for SCA and either are not candidates for or refuse an implantable ICD.[1] Some experts have suggested that the indications for a WCD should be broadened to include other populations at high-risk for SCA.[2] The potential indications include:

- Bridge to transplantation (ie, the WEARIT study population)
- Bridge to implantable device or clinical improvement (ie, the BIROAD study population)
    - Post bypass with ejection fraction less than 30%
    - Post bypass with ventricular arrhythmias or syncope within 48 hours of surgery
    - Post myocardial infarction with ejection fraction less than 30%
    - Post myocardial infarction with ventricular arrhythmias within 48 hours
- Drug-related arrhythmias (during drug washout or after, during evaluation of long-term risk)
- Patients awaiting revascularization
- Patients too ill to undergo device implantation
- Patients who refuse device therapy.

Summary

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 the period during which the need for a permanent implantable device is uncertain.

Overview of Wearable Cardioverter Defibrillator Versus Implantable Cardioverter Defibrillator
One RCT has compared WCD with usual guideline-based care and found no significant benefit to WCD over usual care. No studies have directly compared the performance of a WCD with a permanent ICD. One small study in an electrophysiology lab demonstrated that the WCD can correctly identify and terminate most induced ventricular arrhythmias. A cohort study of WCD use estimated that the percentage of successful resuscitations was approximately 70%. Multiple studies have demonstrated suboptimal adherence. Device failures were largely attributed to incorrect device use and/or nonadherence. A more recent registry study has reported a high compliance rate, although these results may be biased by self-selection. Collectively, this evidence indicates that the WCD can successfully detect and terminate arrhythmias in at least some patients but that overall performance in clinical practice might be inferior to a permanent ICD.

Temporary Contraindications
For individuals who have a temporary contraindication to an ICD who receive a WCD, the evidence includes prospective cohort studies and a technology assessment that assessed ICD devices, given the absence of evidence on WCD devices. The relevant outcomes are overall survival (OS), morbid events, functional outcomes, and treatment-related morbidity. A small number of patients meet established criteria for an ICD but have a transient contraindication for an implantable device, most commonly an infectious process. The available data have established that the WCD device can detect lethal arrhythmias and can successfully deliver a countershock in most cases. In patients scheduled for ICD placement, the WCD will improve outcomes as an interim treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Immediate Post Myocardial Infarction
For individuals who are in the immediate post myocardial infarction period who receive a WCD, the evidence includes a randomized controlled trial (RCT) comparing WCD with guideline-based therapy, a cohort study, and a systematic review. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The RCT reported no benefit of WCD over guideline-based therapy. The cohort study of 8453 patients showed that 252 shocks successfully terminated ventricular fibrillation or ventricular tachycardia (82% success rate), but without a control group, interpretation is difficult. Evidence from the systematic review was deemed of low to very low quality, and the reviewers had weak confidence in the reported estimates. The evidence is insufficient to determine the effects of the technology on health outcomes.

Post–Coronary Artery Bypass Graft Surgery at High Risk for Lethal Arrhythmias
For individuals who are post–coronary artery bypass graft surgery and are at high risk for lethal arrhythmias, the evidence includes an RCT for ICD and a registry study. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. For high-risk post coronary artery bypass graft patients, an RCT reported no difference in OS associated with early ICD placement. The registry study found survival benefits with WCD but had limited interpretation of data. The evidence is insufficient to determine the effects of the technology on health outcomes.

Awaiting Heart Transplantation at High Risk for Lethal Arrhythmias
For individuals who are awaiting heart transplantation and are at high risk for lethal arrhythmias, the evidence includes analyses of subsets of patients from the manufacturer registry, a subset from a prospective cohort study, and a case series. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. These studies do not provide sufficient evidence to determine whether a WCD is of benefit compared with usual care. The evidence is insufficient to determine the effects of the technology on health outcomes.

Newly Diagnosed Nonischemic Cardiomyopathy
For individuals who have newly diagnosed nonischemic cardiomyopathy, the evidence includes an RCT for IDC and several retrospective analyses of WCD registry data. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The RCT found that prophylactic ICD placement for nonischemic cardiomyopathy did not improve mortality compared with usual care. Evidence from the retrospective analysis was not sufficient to determine whether WCD improves outcomes compared with usual care. Given the lack of evidence that ICD improves outcomes, WCD is not expected to improve outcomes under the conditions studied in these trials. The evidence is insufficient to determine the effects of the technology on health outcomes.

Peripartum Cardiomyopathy
For individuals who have peripartum cardiomyopathy, the evidence includes a retrospective registry data analysis and a small cohort study. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The registry study revealed that no shocks were delivered during use over an average of 124 days. The cohort study identified 4 episodes of appropriate electric shock over 133 days. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
7/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
6/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
6/2018	New references added from BCBSA National medical policy. Background and summary clarified.
1/2018	Clarified coding information.
10/2017	Clarified coding information.
6/2017	New references added from BCBSA National medical policy.
12/2016	New medically necessary indications described. Clarified coding information. Effective 12/1/2016.
7/2016	New references added from BCBSA National medical policy.
9/2015	Clarified coding information.
3/2015	New references added from BCBSA National medical policy.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
6/2014	BCBSA National medical policy review. New investigational indications described. Effective 6/1/2014.
3/2014	BCBSA National medical policy review. Coding information clarified. New investigational indications described; title changed. Effective 3/1/2014.
6/2013	New medically necessary indications for Medicare described. Effective immediately, 6/17/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group – Cardiology and Pulmonology. No changes to policy statements.
4/2010	Reviewed - Medical Policy Group - Cardiology. No changes to policy statements.
4/2009	Reviewed - Medical Policy Group - Cardiology. No changes to policy statements.
4/2008	Reviewed - Medical Policy Group - Cardiology. No changes to policy statements.
3/1/2008	Medical Policy 042 effective 3/1/2008, describing covered and non-covered indications.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

1. Food and Drug Administration. Summary of Safety and Effectiveness Data, P010030, Lifecor, Inc. WCD 2000 System. 2001; https://www.accessdata.fda.gov/cdrh_docs/pdf/p010030b.pdf. Accessed March 19, 2020.
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): 1253-6. 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): 562-8. PMID 24762055
7. 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): 386-92. PMID 23453108
8. Kao AC, Krause SW, Handa R, et al. Wearable defibrillator use in heart failure (WIF): results of a prospective registry. BMC Cardiovasc Disord. Dec 12 2012; 12: 123. PMID 23234574
9. 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
10. 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): 1613-9. PMID 26316618
11. 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): 1175-209. PMID 9562026
12. Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med. Dec 09 2004; 351(24): 2481-8. PMID 15590950
13. Steinbeck G, Andresen D, Seidl K, et al. Defibrillator implantation early after myocardial infarction. N Engl J Med. Oct 08 2009; 361(15): 1427-36. PMID 19812399
14. Olgin JE, Pletcher MJ, Vittinghoff E, et al. Wearable Cardioverter-Defibrillator after Myocardial Infarction. N Engl J Med. Sep 27 2018; 379(13): 1205-1215. PMID 30280654
15. 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
16. 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
17. Bigger JT. 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): 1569-75. PMID 9371853

18. 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): 117-28. PMID 23275233
19. 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): 1305-9. PMID 26094085
20. Wassnig NK, Gunther M, Quick S, et al. Experience With the Wearable Cardioverter-Defibrillator in Patients at High Risk for Sudden Cardiac Death. Circulation. Aug 30 2016; 134(9): 635-43. PMID 27458236
21. Rao M, Goldenberg I, Moss AJ, et al. Wearable defibrillator in congenital structural heart disease and inherited arrhythmias. Am J Cardiol. Dec 01 2011; 108(11): 1632-8. PMID 21890075
22. 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): 2477-82. PMID 16781376
23. 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.e1-1247.e6. PMID 26975224
24. Duncker D, Konig T, Hohmann S, et al. Ventricular arrhythmias in patients with newly diagnosed nonischemic cardiomyopathy: Insights from the PROLONG study. Clin Cardiol. Aug 2017; 40(8): 586-590. PMID 28333373
25. Duncker D, Konig T, Hohmann S, et al. Avoiding Untimely Implantable Cardioverter/Defibrillator Implantation by Intensified Heart Failure Therapy Optimization Supported by the Wearable Cardioverter/Defibrillator-The PROLONG Study. J Am Heart Assoc. Jan 17 2017; 6(1). PMID 28096098
26. 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): 21-7. PMID 22196837
27. Duncker D, Haghikia A, Konig T, et al. 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): 1331-6. PMID 25371320
28. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. Sep 25 2018; 138(13): e272-e391. PMID 29084731
29. Piccini JP, 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): 1715-27. PMID 27022063
30. Klein HU, Meltendorf U, Reek S, et al. Bridging a temporary high risk of sudden arrhythmic death. Experience with the wearable cardioverter defibrillator (WCD). Pacing Clin Electrophysiol. Mar 2010; 33(3): 353-67. PMID 19889186
31. 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): 1043-56. PMID 16962465

Endnotes

[1] Based on Local Coverage Determination (LCD): Automatic External Defibrillators (L33690)