MASSACHUSETTS

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Medical Policy

Wearable Cardioverter Defibrillators

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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[SM] and Medicare PPO Blue[SM] 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.

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

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 medical necessity criteria 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 MP 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 sudden cardiac arrest (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

Temporary Contraindications
For individuals who have a temporary contraindication to an ICD who receive a WCD, the evidence includes prospective cohort studies. Relevant outcomes are overall survival, 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 RCTs and a technology assessment that assess ICD devices, given the absence of evidence on WCD devices. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. Two RCTs have reported that overall survival did not improve after treatment with a permanent ICD. While both trials reported a decrease in sudden cardiac death, there was a corresponding increase in non-sudden cardiac death events, resulting in no net survival benefit. Analysis of data from a retrospective postmarket registry with WCD reported a success rate of 82% but interpretation of registry data is limited in absence of a control group. Given the lack of

evidence that a permanent ICD improves outcomes in the immediate post myocardial infarction period, a WCD would not be expected to improve outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Other High-Risk Conditions
For individuals who are post coronary artery bypass graft surgery and are at high risk for lethal arrhythmias, awaiting heart transplantation and at high risk for lethal arrhythmias, have newly diagnosed nonischemic cardiomyopathy, or have peripartum cardiomyopathy who receive a WCD, the evidence includes an RCT evaluating early ICD placement after coronary artery bypass graft, and case series and registry data for other indications that assess ICD devices, given the absence of evidence on WCD devices. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. For high-risk post coronary artery bypass graft patients, an RCT reported no difference in overall survival associated with early ICD placement. For other indications, there are no RCTs that demonstrate benefit of an ICD placement. Because of absence of any benefit of ICD and lack of any RCTs to demonstrate benefit of a WCD, the evidence does not currently permit conclusions that a WCD will improve patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
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

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Endnotes

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