MASSACHUSETTS

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Medical Policy

Wearable Cardioverter Defibrillators

Table of Contents

Policy Number: 042

BCBSA Reference Number 2.02.15 (For Plan internal use only)

Related Policies

Implantable Cardioverter Defibrillators, #070

Policy[1]

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

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.

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**.

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
I47.20	Ventricular tachycardia, unspecified
I47.21	Torsades de pointes
I47.29	Other 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 (MI) and reduced ejection fraction (EF).

Implantable cardioverter defibrillators 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. Placement

of the ICD is a minor surgical procedure. Potential adverse events of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks. See 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 who 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 Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patients at High Risk for Sudden Death [WEARIT] study population);
- Bridge to implantable device or clinical improvement (ie, the Patients at High Risk for Sudden Death after a Myocardial Infarction or Bypass Surgery not receiving an ICD for up to four months [BIROAD] study population):
    - Post bypass with EF less than 30%,
    - Post bypass with ventricular arrhythmias or syncope within 48 hours of surgery,
    - Post MI with EF less than 30%,
    - Post MI 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; and
- Patients who refuse device therapy.

Summary

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

Summary of Evidence

Overview of Wearable Cardioverter Defibrillator Versus Implantable Cardioverter Defibrillator

One randomized controlled trial (RCT) has compared wearable cardioverter defibrillators (WCDs) 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 implantable cardioverter defibrillator (ICD). One small study in an electrophysiology lab demonstrated that the WCD can correctly identify and terminate most induced ventricular arrhythmias. Similarly, a study of the ASSURE WCD in patients with cardiomyopathy found the WCD to detect all events recorded by an ICD with few false-positive shock alarms in a 30-day period. 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. 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 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 an improvement in the net health outcome.

Immediate Post-Myocardial Infarction
For individuals who are in the immediate post-myocardial infarction (MI) period who receive a WCD, the evidence includes an RCT comparing WCD with guideline-based therapy, 2 cohort studies, 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 (VF) or ventricular tachycardia (VT) (82% success rate), but without a control group, interpretation is difficult. Similarly, a retrospective cohort of Medicare data found that WCD use was associated with lower 1-year mortality than no WCD use, but potential biases were noted. 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 that the technology results in an improvement in the net health outcome.

Post-Coronary Artery Bypass Graft Surgery at High Risk for Lethal Arrhythmias
For individuals who are post-coronary artery bypass graft (CABG) 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-CABG 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

Newly Diagnosed Nonischemic Cardiomyopathy
For individuals who have newly diagnosed nonischemic cardiomyopathy, the evidence includes an RCT for ICD 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
7/2023	Annual policy review. Minor editorial refinements to policy statements; intent unchanged.
10/2022	Clarified coding information.
7/2022	Annual policy review. Policy statements unchanged.
6/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
7/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2018	Clarified coding information.
10/2017	Clarified coding information.
6/2017	Annual policy review. New references added.
12/2016	New medically necessary indications described. Clarified coding information. Effective 12/1/2016.
7/2016	Annual policy review. New references added.
9/2015	Clarified coding information.
3/2015	Annual policy review. New references added.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
6/2014	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2014	Annual policy review. Description, summary, and references updated. Policy statements unchanged; 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)