Wearable Cardioverter Defibrillators
Corporate Medical Policy

Description/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.

Policy

When a service may be considered medically necessary

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

1. Are at least eight (8) years of age or older; and
2. The device will be worn at least 22 hours per day (greater than 90% wear time); and the patient meets one of the following criteria:
   a. Requires the WCD as temporary interim treatment for those who meet the criteria for an implantable cardioverter-defibrillator (see indications below) but have a documented contraindication to an ICD (e.g., systemic infection, lack of vascular access); or
   b. A previously implanted defibrillator now requires explantation and is planned to be replaced; or
   c. 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
d. As a bridge to left ventricular (LV) improvement for one of the following indications:
   i. LV ejection fraction (EF) less than or equal to 35% after cardiac events such as:
      a.) After recent acute myocardial infarction (MI) during the 40-day period under which ICD implantation is not indicated or deferred; or
      b.) Coronary revascularization procedures such as before and after coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) during the 90-day ICD waiting period; or
      c.) Recently diagnosed non-ischemic cardiomyopathy during the three (3)-month period awaiting LV improvement or ICD implantation; or
   d.) Heart transplantation.

When a service is considered investigational

Use of WCDs is considered investigational for all other indications.

Replacement of lost, stolen or destroyed Durable Medical Equipment

We will replace one lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic per Plan Year if not covered by an alternative entity (including but not limited to homeowners insurance and automobile insurance) if:
   • the Durable Medical Equipment, prosthetic or orthotic’s absence would put the member at risk of death, disability or significant negative health consequences such as a hospital admission;
   • the Durable Medical Equipment is still under warranty.

Note: In order to replace a stolen item we require you to submit documentation, such as a police report, with the request.

Exclusions
We do not cover the replacement of a lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic:
   • if the criteria above have not been met; and
   • for more than one lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic per Plan Year.

Indications for an implantable cardioverter defibrillator:

ADULTS

The use of the automatic implantable cardioverter defibrillator (ICD) may be considered medically necessary in adults who meet the following criteria.

Primary Prevention
   • Ischemic cardiomyopathy with New York Heart Association (NYHA) functional class II or 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 first-degree relatives younger than 50 years; left ventricular hypertrophy >30 mm; ≥1 runs of nonsustained ventricular tachycardia at heart rates of ≥120 beats per minute 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.

• Diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death:
  - congenital long QT syndrome; **OR**
  - Brugada syndrome; **OR**
  - short QT syndrome; **OR**
  - catecholaminergic polymorphic ventricular tachycardia.

**Secondary Prevention**

• Patients with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes (eg, acute ischemia) have been excluded.

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

• have had an acute myocardial infarction (ie, <40 days before ICD treatment);
• have NYHA class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy ICD device);
• have had a cardiac revascularization procedure in past 3 months (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) 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 for secondary prevention is considered investigational for patients who do not meet the criteria for secondary prevention.

**PEDIATRICS**

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; **OR**
• 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 ventricular dysfunction or inducible ventricular arrhythmias; OR

• HCM with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in ≥1 first-degree relatives <50 years; massive left ventricular hypertrophy based on age-specific norms; 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; OR

• diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death:
  - congenital long QT syndrome; OR
  - Brugada syndrome; OR
  - short QT syndrome; OR
  - catecholaminergic polymorphic ventricular tachycardia.

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

Reference Resources

4. Blue Cross and Blue Shield Association. Implantable Cardioverter Defibrillators, MPRM #7.01.44. Last reviewed: May 2018.


Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer’s benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member’s contract/employer benefit plan language takes precedence.
Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member’s health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.

Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

| 01/2019 | External feedback received from external providers. New policy. The following codes require prior approval: K0606, K0607, K0608, K0609, 93745, 93292. |

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).
Attachment I
Code Table & Instructions

The following codes will be considered medically necessary when applicable criteria has been met.

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Brief Description</th>
<th>Policy Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS</td>
<td>K0606</td>
<td>Automatic external defibrillator, with integrated electrocardiogram analysis, garment type</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td>HCPCS</td>
<td>K0607</td>
<td>Replacement battery for automated external defibrillator, garment type only, each</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td>HCPCS</td>
<td>K0608</td>
<td>Replacement garment for use with automated external defibrillator, each</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td>HCPCS</td>
<td>K0609</td>
<td>Replacement electrodes for use with automated external defibrillator, garment type only, each</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td>CPT ®</td>
<td>93292</td>
<td>Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td>CPT ®</td>
<td>93745</td>
<td>Initial set-up and programming by a physician or other qualified health care professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events</td>
<td>Prior Approval Required</td>
</tr>
</tbody>
</table>