Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS’s Coverage Issues Manual can be found on the CMS website.

SERVICE: Wearable Cardioverter Defibrillator (WCD)

PRIOR AUTHORIZATION: Required

POLICY: SWHP covers wearable cardioverter defibrillators for situations in which the member is at high risk for sudden cardiac death. WCD’s are covered under Durable Medical Equipment benefit; DME benefit limits do apply.)

SWHP may consider a wearable cardioverter defibrillator medically necessary when ANY of the following criteria are met AND the requesting provider is a cardiologist:

- Patients with cardiomyopathy (ischemic or non-ischemic) with an indication for ICD placement but are ineligible for implantable cardioverter defibrillator (ICD) placement due to systemic infection or other medically appropriate contraindications for which ICD cannot be placed
- Congenital cardiac conditions with high risk of ventricular tachydysrhythmias (Long QT, Tetralogy of Fallot, Brugada Syndrome, etc.),
- Left ventricular dysfunction with ejection fraction (EF) ≤ 35% before and after coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) (Coverage during the required 90 day ICD waiting period),
- Hypertrophic cardiomyopathy (also referred to as idiopathic hypertrophic subaortic stenosis (IHSS)) with at least one risk factor for sudden cardiac death (documented ventricular tachyarrhythmia, drop or blunted systolic blood pressure during exercise, left ventricular wall thickness > 3 cm, syncope, family history of sudden cardiac death),
- Documented active myocarditis,
- Patients listed for cardiac transplantation; LifeVest used as an alternative to ICD implant.
- Patients who have had an ICD removed and have been waiting for the placement of another ICD as a bridge therapy.

If it is determined that this device is medically necessary, the initial approval will be for up to 3 months duration. Extension of this authorization will be month-by-month and will be based on a review of clinical documentation supporting the medical necessity of additional usage.

OVERVIEW: The wearable cardioverter defibrillator monitors electrocardiogram (ECG) changes through a programmable microprocessor-based device and an electrode belt containing non-adhesive electrodes that is integrated into the vest. If a life-threatening arrhythmia is detected, the non-adhesive therapeutic electrodes release a conductive gel to the skin and deliver a shock to the heart.

Wearable Cardioverter Defibrillator
Page 1 of 4
MANDATES: There are no mandated benefits or regulatory requirements.

SUPPORTING DATA:

Technical Assessment:
A WCD used on an outpatient basis and is designed to perform the same functions as an automatic ICD, but is worn outside the body and therefore is noninvasive. An example is LifeVest™. It is a combination of two different devices. As a cardioverter, it uses low-energy electrical shocks to return a heart undergoing ventricular tachycardia (abnormally rapid heartbeat) to a normal rhythm. As a defibrillator, it uses high-energy shocks to a heart in a state of ventricular fibrillation to return it to a normal rhythm. If a life-threatening arrhythmia is detected, the non-adhesive therapeutic electrodes release a conductive gel and deliver a shock. Alarms sound prior to shock delivery, and if the patient is conscious the device may be disarmed. The potential patient population consists of adults who are at high risk for Sudden Cardiac Arrest (SCA) and Sudden Cardiac Death (SCD), but who are not suitable candidates for or who refuse an ICD.

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

<table>
<thead>
<tr>
<th>CPT Codes:</th>
<th>93292 Interrogation device evaluation (in person) with physician analysis</th>
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<tbody>
<tr>
<td></td>
<td>93745 Initial setup and programming by a physician</td>
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<tr>
<td>HCPCS Codes:</td>
<td>K0606 Automatic external defibrillator, with integrated electrocardiogram analysis, garment type</td>
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<td>K0607 Replacement battery for automated external defibrillator, garment type only, each,</td>
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<tr>
<td></td>
<td>K0608 Replacement garment for use with automated external defibrillator, each</td>
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<tr>
<td></td>
<td>K0609 Replacement electrodes for use with automated external defibrillator, garment type only, each</td>
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<td>ICD10 Codes:</td>
<td>I25.5 – Ischemic cardiomyopathy</td>
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<td>I42.0 - I43 Cardiomyopathy</td>
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<td></td>
<td>I44.1x - I45.9 Conduction disorders</td>
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<td></td>
<td>I46.2 - I46.9 Cardiac arrest</td>
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<td></td>
<td>I47.0 - I47.9 Paroxysmal tachycardia</td>
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<td></td>
<td>I49.01 - I49.9 Ventricular fib and flutter, SSS, arrhythmia</td>
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CMS: LCD L33690 CGS Administrators

POLICY HISTORY:

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<td>11/14/2013</td>
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<td>Reviewed</td>
<td>08/21/2014</td>
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<td>Reviewed</td>
<td>09/24/2015</td>
<td>Minor corrections.</td>
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REFERENCES:
The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.


20. 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. 2014;130:94-125


