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RMHP Cardioverter-Defibrillator, Wearable

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MCG Health
Ambulatory Care
27th Edition

Link to Codes

Clinical Indications for Procedure

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- For **ALL plans** , wearable cardioverter-defibrillator (K0606) may be indicated per LCD L33690 when **1 or more** of the following is present(1)(2)(3)(4)(5) :
  - 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
  - Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy
  - Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35
  - A previously implanted defibrillator now requires explantation

Alternatives to Procedure

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- Alternatives include implantable cardioverter-defibrillator.(6)(7)

Evidence Summary

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Background

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A wearable cardioverter-defibrillator consists of sensing electrodes, a continuously monitoring electrocardiogram, a microprocessor, an alarm module, and defibrillation electrodes, all incorporated into a vest worn under clothing. If ventricular fibrillation or ventricular tachycardia is detected, the alarm module warns of an impending shock, which the patient can avoid by pressing a response button. If the patient does not respond, the defibrillation electrodes release a conductive gel and deliver an electrical shock of up to 150 joules with biphasic waveforms, with a response time of 25 to 180 seconds, as programmed by the physician. The vest is meant to be worn continuously, except when bathing or showering.(8)(9)(10) **(EG 2)** In addition to its defibrillation capabilities, the device acts as a loop recorder.(11)(12) **(EG 2)** However, the device does not provide backup pacing and is contraindicated in patients with unipolar atrial or ventricular pacing due to problems with sensing arrhythmias in those contexts.(13)(14) **(EG 2)**

Criteria

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For patients at high risk for sudden cardiac death, A randomized trial of 2302 patients with acute myocardial infarction and a left ventricular ejection fraction of 35% or less found that, at 90 days' follow-up, all-cause mortality was reduced in patients randomized to receive a wearable cardioverter-defibrillator plus guideline-directed therapy compared with those who received guideline-directed therapy alone. Although there was a trend toward a lower rate of arrhythmic death (as defined as sudden death and nonsudden death due to ventricular tachyarrhythmia) in patients who received a wearable cardioverter-defibrillator, this difference did not meet statistical significance; the authors note that the trial may have been underpowered to detect a beneficial effect of the wearable cardioverter-defibrillator on the primary outcome of arrhythmic death. The authors noted challenges in classifying the cause of death for unwitnessed deaths or deaths with limited documentation; further limitations included documented device in the treatment arm. For the 20 patients in the treatment arm who were confirmed to have had a ventricular tachyarrhythmia, all 20 received an appropriate shock with successful conversion to sinus rhythm; 14 survived to 90 days.(15) **(EG 1)** A systematic review of 36 articles and abstracts from 33 studies found that the use of a wearable cardioverter-defibrillator reduced the absolute risk of sudden cardiac death due to ventricular tachycardia or ventricular fibrillation by approximately 1%, as compared with no defibrillator use, which was achieved by averting approximately 80% of all such deaths. However, the authors noted that further investigations with more robust study designs and conducted by independent researchers are needed.(16) **(EG 1)** A prospective study of 2000 patients with ischemic cardiomyopathy, nonischemic cardiomyopathy, or congenital/inherited heart disease found a high rate of sustained ventricular arrhythmias at 3 months and concluded that use of a wearable cardioverter-defibrillator is safe and effective for protecting these patients against sudden cardiac death. The authors also found that 42% of the patients received an implantable cardioverter-defibrillator at the end of wearable cardioverter-defibrillator use, with the most frequent reason for not implanting a cardioverter-defibrillator being improvement in ejection fraction.(17) **(EG 2)** A prospective study of 24 patients who were managed with a wearable cardioverter-defibrillator during a temporary waiting period post myocardial infarction found that 8.2% of patients received shock therapy from the wearable defibrillator, with first-shock success of 100% for ventricular fibrillation and no delivering of inappropriate shocks. By the end of the follow-up period, 58% of patients had received an implantable cardioverter-defibrillator.(18) **(EG 2)** In a prospective observational study of 12 consecutively admitted women with peripartum cardiomyopathy, a total of 4 ventricular fibrillation events occurred; appropriate and successful wearable cardioverter-defibrillator shocks were delivered in 3 of the 7 women who received a wearable cardioverter-defibrillator, with no inappropriate shocks. The authors recommended consideration of use of a wearable cardioverter-defibrillator in all women with early-stage peripartum cardiomyopathy and severely reduced left ventricular systolic function during the first 6 months following initiation of heart failure therapy.(19) **(EG 2)** A retrospective study of 97 patients who received a wearable cardioverter-defibrillator following implantable cardioverter-defibrillator removal due to device infection found that 4 episodes of sustained ventricular tachycardia were successfully terminated by the wearable cardioverter-defibrillator, while one patient received 2 inappropriate shocks due to signal artifact. The authors concluded that a wearable cardioverter-defibrillator can prevent sudden cardiac death until reimplantation of an implantable cardioverter-defibrillator is feasible.(20) **(EG 2)** A prospective study of 162 adult patients with congenital structural heart disease and inherited arrhythmias found that wearable cardioverter-defibrillators (pending heart transplant in the structural heart disease group and genetic testing in the inherited arrhythmias group) could be safely used in these high-risk adult patients, with successful termination of lethal arrhythmias by appropriately delivered shocks.(21) **(EG 2)** A registry analysis of 121 patients awaiting heart transplant concluded

that the wearable cardioverter-defibrillator is a reasonable bridge therapy for preventing sudden cardiac death in patients with cardiomyopathy awaiting transplant, with high adherence and efficacy and low complication rates.(22) **(EG 2)** Review articles state that wearable cardioverter-defibrillators can be used as a bridge to implantable cardioverter-defibrillator placement for patients who are at high risk of sudden cardiac death, including patients who are awaiting cardiac transplant, and during temporary waiting periods (eg, 40 days following an acute myocardial infarction, 90 days following coronary revascularization, or an initial diagnosis of nonischemic cardiomyopathy or acute myocarditis).(23)(24)(25)(26)(27) **(EG 2)** Specialty society guidelines state that a wearable cardioverter-defibrillator is reasonable for the prevention of sudden cardiac death in patients with a history of sudden cardiac arrest or sustained ventricular arrhythmia in whom removal of an existing implantable cardioverter-defibrillator is required, as in the case of an infectious process.(6)(28) **(EG 2)**

Inconclusive or Non-Supportive Evidence

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For myocardial infarction without severe left ventricular dysfunction, A study of aggregate national experience with wearable cardioverter-defibrillators (3569 patients who were tracked in the manufacturer's database) showed that none of the 104 patients with recent myocardial infarction and ejection fraction greater than 35% received an appropriate shock from the wearable cardioverter-defibrillator. However, 2.9% of patients with recent myocardial infarction and ejection fraction less than or equal to 35% received appropriate wearable cardioverter-defibrillator shocks, with 80% survival.(29) **(EG 2)**

For sudden cardiac death prevention in children, A retrospective review of 81 pediatric patients and 103 patients age 19 to 21 years at high risk of sudden cardiac death found that while the pediatric population and young adult population were similar in terms of adherence with a wearable cardioverter-defibrillator, the study was inconclusive regarding the efficacy of the wearable defibrillator in the pediatric population.(30) **(EG 2)**

Reviewer Guidance

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All RMHP plans, Medicare (both CareAdvantage and DSNP Dual Special Needs Plans), PRIME (Medicaid), CHP+, and IFP Individual and Family Plan (Commercial) follow CMS LCD L33690 and LCA A52458, which the Clinical Indications section reflects. See References.

Policy History

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Upgraded to 27th edition MCG with Medicare indications on annual review 10/24/2023.

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Codes

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