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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Wearable and Non-wearable Cardioverter Defibrillator Policy

Indication/Usage:

Automatic defibrillators are devices that are capable of monitoring cardiac rhythms, detecting dysrhythmias, and delivering a defibrillation shock to the heart when appropriate without any user decision-making. Automatic external defibrillators for patients at high risk for sudden cardiac death (SCD) as outlined in the policy below.

Medical Indications for Authorization Commercial Members

SummaCare considers wearable cardioverter-defibrillator and non-wearable cardioverterdefibrillator medically necessary for patients who are high risk for sudden cardiac death if they meet one of the criteria 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.

2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy.

3. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 35%.

4. A previously implanted defibrillator now requires explanation. It is expected the ordering physician be experienced in the management of patients at risk for SCD.

5. Implantable cardioverter-defibrillator not able to be placed due to infectious process or other temporary condition (eg, waiting period before or following a cardiac event, peripartum cardiomyopathy, recently diagnosed nonischemic cardiomyopathy, patient awaiting cardiac transplant, Terminal disease with life expectancy of less than 1 year).

CPT 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
E0617: Non-wearable, automatic external defibrillators with integrated electrocardiogram capability are coded using HCPCS code

Medicare Members

CGS CMS LCD L33690 Automatic External Defibrillators

Automatic external defibrillators are covered for beneficiaries at high risk for sudden cardiac death (SCD) due to one of the conditions described under I or II. It is expected the treating practitioner be experienced in the management of beneficiaries at risk for SCD.

A wearable defibrillator (K0606) is covered for beneficiaries if they meet one of the criteria (14), described below:

- 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**

- Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; **or**

- Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 35% **or**

- A previously implanted defibrillator now requires explanation

A nonwearable automatic defibrillator (E0617) is covered for beneficiaries in two circumstances. They meet either (1) both criteria A and B or (2) criteria C, described below:

A. **The beneficiary has one of the following conditions (1-8)**

1. A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause
2. A sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, either spontaneous or induced during an electrophysiologic (EP) study, not associated with acute myocardial infarction, and not due to a transient or reversible cause
3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrythmias such as long QT syndrome or hypertrophic cardiomyopathy
4. Coronary artery disease with a documented prior myocardial infarction with a measured left ventricular ejection fraction less than or equal to 35%, and inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) during an EP study. To meet this criterion;
    a. The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription; and,
    b. The EP test must have been performed more than 4 weeks after the qualifying myocardial infarction.
5. Documented prior myocardial infarction and a measured left ventricular ejection fraction less than or equal to 30%.

    Beneficiaries must not have:

    a. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or,

b. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months; or,
c. Had an enzyme-positive MI within past month; or,
d. Clinical symptoms or findings that would make them a candidate for coronary revascularization; or,
e. Irreversible brain damage from preexisting cerebral disease; or,
f. Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year.

6. Beneficiaries with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%.
7. Beneficiaries with nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%
8. Beneficiaries who meet one of the previous criteria (1-7) and have NYHA Class IV heart failure

Limitations

Use of wearable cardioverter-defibrillators is considered investigational for all other indications.

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

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