The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

The automatic implantable cardioverter defibrillator (ICD) is a device designed to monitor a patient’s heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death.

Background

Indications for implantable cardioverter defibrillator (ICD) can be broadly subdivided into: 1) secondary prevention, i.e., their use in patients who have experienced a potentially life-threatening episode of ventricular tachyarrhythmia (VT) (near sudden cardiac death); and 2) primary prevention, i.e., their use in patients who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening VT or ventricular fibrillation (VF).

The standard ICD involves placement of a generator in the subcutaneous tissue of the chest wall. Transvenous leads are attached to the generator and threaded intravenously into the endocardium. The leads sense and transmit information on cardiac rhythm to the generator, which analyzes the rhythm information and produces an electrical shock when a malignant arrhythmia is recognized.

A totally subcutaneous ICD (S-ICD®) has also been developed. This device does not employ transvenous leads and thus avoids the need for venous access and complications associated with the venous leads. Rather, the S-ICD® uses a subcutaneous electrode that is implanted adjacent to the left sternum. The electrodes sense the cardiac rhythm and deliver countershocks through the subcutaneous tissue of the chest wall.

Several automatic ICDs are approved by the U.S. Food and Drug Administration (FDA) through the premarket application (PMA) approval process. The FDA-labeled indications generally include patients who have experienced life-threatening VT associated with cardiac arrest or VT associated with hemodynamic compromise and resistance to pharmacologic treatment. Devices manufactured by Guidant are approved by the FDA for use “in patients at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced at least one of the following: an episode of cardiac arrest (manifested by the loss of consciousness) due to a ventricular tachyarrhythmia; recurrent, poorly tolerated sustained ventricular tachycardia (VT); or a prior myocardial infarction (MI), left ventricular ejection fraction of less than or equal to 35%, and a documented episode of non-sustained VT, with an inducible ventricular tachyarrhythmia.” On July 18, 2002, the FDA expanded the approved indications for the Guidant ICD devices to include the prophylactic use of Guidant ICDs for cardiac patients who have had a previous heart attack and have an ejection fraction that is less than or equal to 30%. This expanded indication is based on the results of the second Multicenter Automatic Defibrillator Implantation
Trial (MADIT II trial), which is discussed here. Medtronic devices are approved “to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.” Other devices have approval language similar to that of Medtronic.

On September 28, 2012, the S-ICD® system by Cameron Health, Inc. was approved by the FDA “to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradyarrhythmia, continual (incessant) ventricular tachycardia, or spontaneous frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.”

NOTE: ICDs may be combined with other pacing devices, such as pacemakers for atrial fibrillation, or biventricular pacemakers designed to treat heart failure. This Protocol addresses ICDs alone, when used solely to treat patients at risk for ventricular arrhythmias.

Policy (Formerly Corporate Medical Guideline)

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 Class 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 one or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in one or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; one or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater 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.

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 (e.g., acute ischemia) have been excluded.

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

• Have had an acute myocardial infarction (i.e., less than 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 cardiac revascularization procedure in past three months (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) or are candidates for a cardiac revascularization procedure; or
• Have noncardiac disease that would be associated with life expectancy less than one year.
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;
- 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 either ventricular dysfunction or inducible ventricular arrhythmias.

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

The use of a subcutaneous ICD is considered investigational for all indications in adult and pediatric patients.

Medicare Advantage

For Medicare Advantage the following indications are medically necessary:

1. Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause.
2. Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause.
3. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy.
4. Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction (LVEF) < 0.35, and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 40 days prior to defibrillator insertion. The EP test must be performed more than four weeks after the qualifying MI.)
5. Documented prior MI and a measured LVEF < 0.30; patients must not have:
   a. New York Heart Association (NYHC) classification IV;
   b. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
   c. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past three months;
   d. Had an enzyme positive MI within past month and must not have had an acute MI in the past 40 days;
   e. Clinical symptoms or findings that would make them a candidate for coronary revascularization; 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. Patients with ischemic dilated cardiomyopathy (IDCM), documented prior MI, NYHA Class II and III heart failure, and measured LVEF < 35%;
7. Patients with non-ischemic dilated cardiomyopathy (NIDCM) > nine months, NYHA Class II and III heart failure, and measured LVEF < 35%;
8. Patients who meet all current Centers for Medicare & Medicaid Services (CMS) coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure;

All indications must meet the following criteria:

a. Patients must not have irreversible brain damage from preexisting cerebral disease;
b. MIs must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction;

Indications 3 – 8 (primary prevention of sudden cardiac death) must also meet the following criteria:

a. Patients must be able to give informed consent;

b. Patients must not have:
   1. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
   2. Had a CABG or PTCA within the past three months;
   3. Had an acute MI within the past 40 days;
   4. Clinical symptoms or findings that would make them a candidate for coronary revascularization;
   5. Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year;

c. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography;

d. The patient receiving the defibrillator implantation for primary prevention is enrolled in either a Food and Drug Administration (FDA)-approved category B investigational device exemption (IDE) clinical trial, a trial under the CMS Routine Services of a Clinical Trial Policy or a qualifying data collection system including approved clinical trials and registries. (Clinical Trials that fall under Protocol Routine Services of a Clinical Trial are covered by Original Medicare and should be billed to Original Medicare.)

e. Providers must be able to justify the medical necessity of devices other than single lead devices. This justification should be available in the patient’s medical record.

9. Patients with NIDCM > three months, NYHA Class II or III heart failure, and measured LVEF < 35%, only if the following additional criteria are also met:

a. Patients must be able to give informed consent;

b. Patients must not have:
   1. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
   2. Had a CABG or PTCA within the past three months;
   3. Had an acute MI within the past 40 days;
   4. Clinical symptoms or findings that would make them a candidate for coronary revascularization;
   5. Irreversible brain damage from preexisting cerebral disease;
   6. Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year;

c. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography;

d. MIs must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction;

e. The patient receiving the defibrillator implantation for this indication is enrolled in either an FDA-approved category B IDE clinical trial, a trial under the CMS Routine Services of a Clinical Trial Policy, or a prospective data collection system meeting the following basic criteria:
   1. Written protocol on file;
   2. Institutional Review Board review and approval;
   3. Scientific review and approval by two or more qualified individuals who are not part of the research team;
   4. Certification that investigators have not been disqualified.
CMS will determine whether specific registries or clinical trials meet these criteria. (Routine Services of a Clinical Trial are covered by Original Medicare and should be billed to Original Medicare.)

f. Providers must be able to justify the medical necessity of devices other than single lead devices. This justification should be available in the patient’s medical record.

Other Indications

All other indications for implantable automatic defibrillators not currently covered in accordance with these criteria may fall under clinical trials.

**If the indication the ICD is being implanted in the Medicare Advantage member falls under a Routine Service of a Clinical Trial category, as described above, then Original Medicare (not Medicare Advantage) is responsible for processing the claim.**

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Use of implantable cardioverter-defibrillators for prevention of sudden death in patients at high risk for ventricular arrhythmia. TEC Assessments 2002; 17(Tab 10).


32. CMS National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4), Effective Date of this Version 1/27/2005.