Preauthorization is not required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

<table>
<thead>
<tr>
<th>Populations</th>
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<td>Relevant outcomes include: • Overall survival • Morbid events • Quality of life • Treatment-related morbidity • Treatment-related mortality</td>
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<td>Interventions of interest are: • Transvenous implantable cardioverter defibrillator placement</td>
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<td>Individuals: • With high risk of sudden cardiac death due to an inherited cardiac ion channelopathy</td>
<td>Interventions of interest are: • Transvenous implantable cardioverter defibrillator placement</td>
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<td>Interventions of interest are: • Subcutaneous implantable cardioverter defibrillator placement</td>
<td>Comparators of interest are: • Transvenous implantable cardioverter defibrillator placement</td>
<td>Relevant outcomes include: • Overall survival • Morbid events • Quality of life • Treatment-related morbidity • Treatment-related mortality</td>
</tr>
</tbody>
</table>
Description
The automatic implantable cardioverter defibrillator (ICD) is a device designed to monitor a patient’s heart rate, recognize ventricular fibrillation or ventricular tachycardia, and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. A subcutaneous ICD (S-ICD) has been developed that does not employ transvenous leads, with the goal of reducing lead-related complications.

Summary of Evidence
For individuals who have a high risk of sudden cardiac death (SCD) due to ischemic or to nonischemic cardiomyopathy (NICM) in adulthood who receive transvenous ICD (TV-ICD) placement, the evidence includes multiple well-designed, well-conducted randomized controlled trials (RCTs) and systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related morbidity and mortality. There is an extensive literature on the use of ICDs in patients with prior arrhythmogenic events and ischemic cardiomyopathy. Earlier trials first demonstrated a benefit in overall mortality for survivors of cardiac arrest and patients with potentially lethal cardiac arrhythmias. Multiple, well-done, RCTs have also shown a benefit in overall mortality for patients with ischemic cardiomyopathy and reduced ejection fraction. RCTs of early ICD implantation following acute myocardial infarction (MI) did not support a benefit for immediate versus delayed implantation for at least 40 days. For NICM, there is less clinical trial data, but the available evidence from a limited number of RCTs enrolling patients with NICM and from subgroup analysis of RCTs with mixed populations supports a survival benefit for this group. There is no high-quality evidence to determine whether early versus delayed implantation improves outcomes for patients with NICM and it is not possible to determine the optimal waiting period for ICD implantation following onset of NICM. At least one cohort study has reported that most patients who meet criteria for an ICD at the time of initial NICM diagnosis will no longer meet the criteria several months after initiation of treatment. The evidence is sufficient to determine qualitatively that the technology results in a large improvement in the net health outcome.

For individuals who have a high risk of SCD due to hypertrophic cardiomyopathy (HCM) in adulthood who receive TV-ICD placement, the evidence includes several large registry studies. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related morbidity and mortality. In these studies, the annual rate of appropriate ICD discharge ranged from 3.6% to 5.3%. Given the long-term high risk of patients with HCM for SCD risk, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence for the use of ICDs in patients with HCM. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a high risk of SCD due to an inherited cardiac ion channelopathy who receive TV-ICD placement, the evidence includes small cohort studies of patients with these conditions treated with ICDs. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related morbidity and mortality. The limited evidence for patients with long QT syndrome (LQTS), catecholaminergic polymorphic ventricular tachycardia (CPVT), and Brugada syndrome (BrS) has reported high rates of appropriate shocks. No studies were identified on the use of ICDs for patients with short QT syndrome (SQTS). Studies comparing outcomes between patients treated and untreated with ICDs are not available. However, given the relatively small patient populations and the high risk of cardiac arrhythmias, clinical trials are unlikely. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have need for a cardioverter defibrillator but no indications for antibradycardia pacing and no antitachycardia pacing–responsive arrhythmias who receive subcutaneous ICD (S-ICD) placement, the evidence includes nonrandomized studies and case series. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related morbidity and mortality. Nonrandomized controlled studies have reported success rates in terminating laboratory-induced ventricular fibrillation that are similar to TV-ICD.
However, there is scant evidence on comparative clinical outcomes of both types of ICD over longer periods. Case series have reported high rates of detection and successful conversion of ventricular tachycardia, and inappropriate shock rates in the range reported for TV-ICD. This evidence is not sufficient to determine whether there are small differences in efficacy between the two types of devices, which may be clinically important due to the nature of the disorder being treated. Also, adverse event rate is uncertain, with variable rates reported. At least one RCT is currently underway comparing S-ICD with TV-ICD. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

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.
- Diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death (see Policy Guidelines):
  - 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 (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.

• 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; 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.

• diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death (see Policy Guidelines):
  - 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.

**Subcutaneous ICD**

The use of a subcutaneous ICD may be considered **medically necessary** for adults or children who have an indication for ICD implantation for primary or secondary prevention for any of the above reasons and meet all of the following criteria:

• Have a contraindication to a transvenous ICD due to one or more of the following: (1) lack of adequate vascular access; (2) compelling reason to preserve existing vascular access (i.e., need for chronic dialysis; younger patient with anticipated long-term need for ICD therapy); or (3) history of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy.

• Have no indication for anti-bradycardia pacing; AND

• Do not have ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing.

The use of a subcutaneous ICD is considered **investigational** for individuals who do not meet the criteria outlined above.

**Policy Guidelines**

This Protocol addresses the use of ICD devices as stand-alone interventions, not as combination devices to treat
heart failure (i.e., cardiac resynchronization devices) or in combination with pacemakers. Unless specified, the policy statements are referring to transvenous ICDs.

Indications for pediatric ICD use are based on American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS) guidelines published in 2008, which acknowledged the lack of primary research on pediatric patients in this field. These indications are derived from nonrandomized studies, extrapolation from adult clinical trials, and expert consensus.

**Criteria for ICD Implantation in Patients with Cardiac Ion Channelopathies**

Individuals with cardiac ion channelopathies may have a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes, in which case they should be considered for ICD implantation for secondary prevention, even if they do not meet criteria for primary prevention.

Criteria for ICD implantation in patients with cardiac ion channelopathies are derived from results of clinical input, a 2013 consensus statement from the HRS, European Heart Rhythm Association (EHRA), and the Asia-Pacific Heart Rhythm Society on the diagnosis and management of patients with inherited primary arrhythmia syndromes (Priori et al, 2013), 2013 guidelines from the ACC, AHA, HRS, the American Association of Thoracic Surgeons, and the Society of Thoracic Surgeons on device-based therapy of cardiac rhythm abnormalities (Tracy et al, 2013), and a report from the HRS/EHRA’s Second Consensus Conference on Brugada syndrome (Antzelevitch et al, 2005).

Indications for consideration for ICD implantation for each cardiac ion channelopathy are as follows:

- **Long QT syndrome:**
  - Patients with a diagnosis of LQTS who are survivors of cardiac arrest.
  - Patients with a diagnosis of LQTS who experience recurrent syncopal events while on beta-blocker therapy.

- **Brugada syndrome:**
  - Patients with a diagnosis of BrS who are survivors of cardiac arrest.
  - Patients with a diagnosis of BrS who have documented spontaneous sustained ventricular tachycardia (VT) with or without syncope.
  - Patients with a spontaneous diagnostic type 1 ECG who have a history of syncope, seizure, or nocturnal agonal respiration judged to be likely caused by ventricular arrhythmias (after noncardiac causes have been ruled out).
  - Patients with a diagnosis of BrS who develop ventricular fibrillation (VF) during programmed electrical stimulation.

- **Catecholaminergic polymorphic ventricular tachycardia:**
  - Patients with a diagnosis of CPVT who are survivors of cardiac arrest.
  - Patients with a diagnosis of CPVT who experience recurrent syncope or polymorphic/bidirectional VT despite optimal medical management, and/or left cardiac sympathetic denervation.

- **Short QT syndrome:**
  - Patients with a diagnosis of SQTS who are survivors of cardiac arrest.
  - Patients with a diagnosis of SQTS who are symptomatic and have documented spontaneous VT with or without syncope.
Patients with a diagnosis of SQTS or are asymptomatic or symptomatic and have a family history of sudden cardiac death.

**NOTE:** For congenital LQTS, patients may have one or more clinical or historical findings other than those outlined above that may, alone or in combination, put them at higher risk for sudden cardiac death. These may include patients with a family history of sudden cardiac death due to LQTS, infants with a diagnosis of LQTS with functional 2:1 atrioventricular block, patients with a diagnosis of LQTS in conjunction with a diagnosis of Jervell and Lange-Nielsen syndrome or Timothy syndrome, and patients with a diagnosis of LQTS with profound QT prolongation (greater than 550 msec). These factors should be evaluated on an individualized basis by a clinician with expertise in LQTS in considering the need for an ICD implantation.

**Medicare Advantage**

For Medicare Advantage an implantable automatic defibrillator is **medically necessary** when the following indications are met:

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) less than 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 less than 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 less than 35%;
7. Patients with non-ischemic dilated cardiomyopathy (NIDCM) greater than nine months, NYHA Class II and III heart failure, and measured LVEF less than 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:

c. Patients must be able to give informed consent;

d. 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;

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

f. 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 Clinical Trial Policy or a qualifying data collection system including approved clinical trials and registries.

g. 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 greater than three months, NYHA Class II or III heart failure, and measured LVEF less than 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.
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 meeting these criteria may fall under clinical trials.

Background
Automatic ICDs monitor a patient’s heart rate, recognize VF or ventricular tachycardia VT, and deliver an electric shock to terminate these arrhythmias to reduce the risk of SCD. Indications for ICD implantation can be broadly subdivided into (1) secondary prevention, i.e., use in patients who have experienced a potentially life-threatening episode of VT (near SCD); and (2) primary prevention, i.e., use in patients who are considered at high risk for SCD but who have not yet experienced life-threatening VT or VF.

The standard ICD implantation 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 subcutaneous ICD (S-ICD®) has 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 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 approval process. 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. In addition, devices typically have approval in the secondary prevention setting in patients with a previous myocardial infarction and reduced injection fraction.

Regulatory Status
Transvenous Implantable Cardioverter Defibrillators
A large number of ICDs have been approved by the FDA through the premarket approval (PMA) process (FDA product code: LWS). A 2014 review of FDA approvals of cardiac implantable devices reported that, between 1979 and 2012, FDA approved 19 ICDs (seven pulse generators, three leads, nine combined systems) through new PMA applications.¹ Many originally approved ICDs have undergone multiple supplemental applications. A summary of some currently available ICDs is provided in Table 1 (list not exhaustive).
Table 1: Implantable Cardioverter Defibrillators With FDA Approval

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Original PMA Approval Date</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ellipse/Fortify Assura Family (originally: Cadence Tiered Therapy Defibrillation System)</td>
<td>St. Jude Medical (St. Paul, MN)</td>
<td>Jul 1993</td>
<td>Transvenous</td>
</tr>
<tr>
<td>Dynagen, Inogen, Origen, and Teligen Family (originally: Ventak, Vitality, Cofient family)</td>
<td>Boston Scientific (Marlborough, MA)</td>
<td>Jan 1998</td>
<td>Transvenous</td>
</tr>
<tr>
<td>Evera Family (originally: Virtuosos/Entrust/Maximo/Intrisic/Marquis family)</td>
<td>Medtronic (Minneapolis, MN)</td>
<td>Dec 1998</td>
<td>Transvenous</td>
</tr>
<tr>
<td>Subcutaneous Implantable Defibrillator System</td>
<td>Cameron Health (San Clemente, CA); acquired by Boston Scientific</td>
<td>Sep 2012</td>
<td>Subcutaneous</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration; PMA: premarket application.

Subcutaneous ICDs

In September 2012, the Subcutaneous Implantable Defibrillator (S-ICD®) System (Cameron Health, San Clemente, CA; acquired by Boston Scientific. Marlborough, MA) was approved by FDA through the PMA process for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with antitachycardia pacing.

In March 2015, the Emblem S-ICD™ (Boston Scientific), which is smaller and longer-lasting than the original S-ICD, was approved by FDA through the PMA supplement process.

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.

Related Protocol

Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure

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.


86. Khairy P, Van Hare GF, Balaji S, et al. PACES/HRS expert consensus statement on the recognition and management of arrhythmias in adult congenital heart disease: developed in partnership between the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS). Endorsed by the governing bodies of PACES, HRS, the American College of Cardiology (ACC), the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), the Canadian Heart Rhythm Society (CHRS), and the International Society for Adult Congenital Heart Disease (ISACHD). Can J Cardiol. Oct 2014; 30(10):e1-e63. PMID 25262867