Protocol

Implantable Cardioverter Defibrillators

(70144)

Medical Benefit		**Effective Date**: 04/01/19	**Next Review Date**: 11/19
Preauthorization	No	**Review Dates**: 02/07, 02/08, 03/09, 01/10, 01/11, 09/11, 09/12, 01/13, 01/14, 05/14, 01/15, 11/15, 11/16, 11/17, 11/18, 01/19	

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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With a high risk of sudden cardiac death due to ischemic cardiomyopathy in adulthood	Interventions of interest are: • Transvenous implantable cardioverter defibrillator placement	Comparators of interest are: • Medical management without implantable cardioverter defibrillator placement	Relevant outcomes include: • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity
Individuals: • With a high risk of sudden cardiac death due to nonischemic cardiomyopathy in adulthood	Interventions of interest are: • Transvenous implantable cardioverter defibrillator placement	Comparators of interest are: • Medical management without implantable cardioverter defibrillator placement	Relevant outcomes include: • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity
Individuals: • With a high risk of sudden cardiac death due to hypertrophic cardiomyopathy in adulthood	Interventions of interest are: • Transvenous implantable cardioverter defibrillator placement	Comparators of interest are: • Medical management without implantable cardioverter defibrillator placement	Relevant outcomes include: • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity
Individuals: • With a high risk of sudden cardiac death due to an inherited cardiac ion channel-opathy	Interventions of interest are: • Transvenous implantable cardioverter defibrillator placement	Comparators of interest are: • Medical management without implantable cardioverter defibrillator placement	Relevant outcomes include: • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity
Individuals: • With life-threatening ventricular tachyarrhyth-mia or fibrillation or who have been resuscitated from sudden cardiac arrest	Interventions of interest are: • Transvenous implantable cardioverter defibrillator placement	Comparators of interest are: • Medical management without implantable cardioverter defibrillator placement	Relevant outcomes include: • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • Who need an implantable cardioverter defibrillator and have a contraindication to transvenous ICD	Interventions of interest are: • Subcutaneous implantable cardioverter defibrillator placement	Comparators of interest are: • Medical management without implantable cardioverter defibrillator placement	Relevant outcomes include: • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity
Individuals: • Who need an implantable cardioverter defibrillator and have no contraindication to transvenous ICD	Interventions of interest are: • Subcutaneous implantable cardioverter defibrillator placement	Comparators of interest are: • Transvenous implantable cardioverter defibrillator placement	Relevant outcomes include: • Overall survival • Morbid events • Quality of life • Treatment-related mortality • Treatment-related morbidity

DESCRIPTION

An 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), which lacks transvenous leads, is intended to reduce lead-related complications.

SUMMARY OF EVIDENCE

TRANSVENOUS ICDS

For individuals who have a high risk of sudden cardiac death (SCD) due to ischemic or to nonischemic cardiomyopathy in adulthood who receive transvenous ICD (TV-ICD) placement for primary prevention, the evidence includes multiple well designed and well-conducted randomized controlled trials (RCTs) as well as systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Multiple, well done RCTs have shown a benefit in overall mortality for patients with ischemic cardiomyopathy and reduced ejection fraction. RCTs assessing early ICD use following recent myocardial infarction did not support a benefit for immediate vs. delayed implantation for at least 40 days. For nonischemic cardiomyopathy, there is less clinical trial data, but pooled estimates of available evidence from RCTs enrolling patients with nonischemic cardiomyopathy and from subgroup analyses of RCTs with mixed populations have supported a survival benefit for this group. The evidence is sufficient to determine that the technology results in a meaningful 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 for primary prevention, the evidence includes several large registry studies. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. In these studies, the annual rate of appropriate ICD discharge ranged from 3.6% to 5.3%. Given the long-term high risk of SCD in patients with HCM, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence to support the use of ICDs in patients with HCM. The evidence is sufficient to determine 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 for primary prevention, 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 mortality and morbidity. The limited evidence for patients with long QT syndrome, catecholaminergic polymorphic ventricular tachycardia, and Brugada syndrome has reported high rates of appropriate shocks. No studies

were identified on the use of ICDs for patients with short QT syndrome. Studies comparing outcomes between patients treated and untreated with ICDs are not available. However, given the relatively small patient populations with these channelopathies and the high risk of cardiac arrhythmias, clinical trials are unlikely. Given the long-term high risk of SCD in patients with inherited cardiac ion channelopathy, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence to support the use of TV-ICDs in patients with inherited cardiac ion channelopathy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have had symptomatic life-threatening sustained ventricular tachycardia or ventricular fibrillation (VF) or who have been resuscitated from sudden cardiac arrest (secondary prevention) who receive TV-ICD placement, the evidence includes multiple well-designed and well-conducted RCTs as well as systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs have demonstrated a 25% reduction in mortality for ICD compared with medical therapy. Analysis of data from a large administrative database has confirmed that this mortality benefit is generalizable to the clinical setting. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

SUBCUTANEOUS ICDS

For individuals who need an ICD and have a contraindication to a TV-ICD but no indications for antibradycardia pacing and no antitachycardia pacing-responsive arrhythmias who receive S-ICD placement, the evidence includes nonrandomized studies and case series. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Nonrandomized controlled studies have reported success rates in terminating laboratory-induced VF that are similar to TV-ICD. Case series have reported high rates of detection and successful conversion of VF, and inappropriate shock rates in the range reported for TV-ICD. Given the need for ICD placement in this population at risk for SCD, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence to support the use of S-ICDs in patients with contraindication to TV-ICD. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have need for an ICD and have no contraindication to TV-ICD but no indications for antibradycardia pacing and no antitachycardia pacing-responsive arrhythmias who receive S-ICD placement, the evidence includes nonrandomized studies and case series. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Nonrandomized controlled studies have reported success rates in terminating laboratory-induced VF 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 does not support conclusions on whether there are small differences in efficacy between the two types of devices, which may be clinically important due to the nature to the disorder being treated. Also, adverse event rates are 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.

Clinical input was obtained in 2011 and 2015 on the use of ICDs in pediatric populations and for primary prevention in patients with cardiac ion channelopathies, and on the use of the S-ICD. For the use of ICDs in children with HCM or with a history of congenital heart disease, the evidence includes case series. These conditions have a low prevalence and heterogeneous patient populations, creating barriers to trials. There was a consensus that the use of ICDs in certain pediatric populations, consistent with specialty society guidelines, is medically necessary. Indications for the use of ICDs to prevent SCD in HCM in pediatric patients parallel those in adults. There was also consensus that the use of an ICD should be considered medically necessary for primary prevention of ventricular arrhythmias in adults and children with a diagnosis of QTS, Brugada syndrome, short, QT syndrome,

or catecholaminergic polymorphic ventricular tachycardia. Criteria for determining patients at high risk of SCD for the cardiac ion channelopathies was derived from clinical input and specialty society guidelines. There was a consensus that the use of an S-ICD should be considered medically necessary, particularly for patients with indications for an ICD but who have difficult vascular access (e.g., children or patients undergoing chronic dialysis) or have had TV-ICD lead explantation due to complications.

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 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 a cardiac revascularization procedure in past three months (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) or are candidates for a cardiac revascularization procedure; or
- have noncardiac disease that would be associated with life expectancy less than one year.

The use of the ICD for secondary prevention is considered **investigational** for patients who do not meet the criteria for secondary prevention.

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 ventricular dysfunction or inducible ventricular arrhythmias.
- 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 antibradycardia pacing; AND
- Do not have ventricular arrhythmias 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 and rationale refer to transvenous ICDs.

Indications for pediatric ICD use are based on American College of Cardiology (ACC), American Heart Association (AHA) and Heart Rhythm Society (HRS) guidelines published in 2008 (updated in 2012), which acknowledged the lack of primary research on pediatric patients in this field. These indications derive 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 placement in patients with cardiac ion channelopathies derive 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]), 2017 guidelines from ACC, AHA, and HRS on the management of heart failure (Al-Khatib et al [2017]), and a report from the HRS and EHRA's Second Consensus Conference on Brugada syndrome.

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

- Long QT syndrome (LQTS):
  - 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 β-blocker therapy.
- Brugada syndrome(BrS):
  - 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 electrocardiogram (ECG) who have a history of syncope, seizure, or nocturnal agonal respiration judged to be likely caused by ventricular arrhythmias (after non-cardiac causes have been ruled out)
  - Patients with a diagnosis of BrS who develop ventricular fibrillation during programmed electrical stimulation.
- Catecholaminergic polymorphic ventricular tachycardia (CPVT):
  - 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 (SQTS):
  - 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 could, alone or in combination, put them at higher risk for sudden cardiac death. They can 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 ms). These factors should be evaluated on an individualized basis by a clinician with expertise in LQTS when considering the need for an ICD placement.

MEDICARE ADVANTAGE

For Medicare Advantage the use of ICDs (also referred to as defibrillators) may be considered **medically necessary** under the following conditions:

1. Patients with a personal history of sustained Ventricular Tachyarrhythmia (VT) or cardiac arrest due to Ventricular Fibrillation (VF). Patients must have demonstrated:
   - An episode of sustained 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; or
   - An episode of cardiac arrest due to VF, not due to a transient or reversible cause.

*2. Patients with a prior MI and a measured Left Ventricular Ejection Fraction (LVEF) <0.30. Patients must not have (see exceptions in the policy guidelines):
   - New York Heart Association (NYHA) classification IV heart failure; or,
   - Had a Coronary Artery Bypass Graft (CABG), or Percutaneous Coronary Intervention (PCI) with angioplasty and/or stenting, within the past three (3) months; or,
   - Had an MI within the past 40 days; or,
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

*3. Patients who have severe, ischemic, dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have NYHA Class II or III heart failure, LVEF <35%. Additionally, patients must **not** have (see exceptions in the policy guidelines):
   - Had a CABG, or PCI with angioplasty and/or stenting, within the past three (3) months; or,
   - Had an MI within the past 40 days; or,
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

*4. Patients who have severe, non-ischemic, dilated cardiomyopathy but no personal history of cardiac arrest or sustained VT, NYHA Class II or III heart failure, LVEF <35%, been on optimal medical therapy for at least three (3) months. Additionally, patients must **not** have (see exceptions in the policy guidelines):
   - Had a CABG or PCI with angioplasty and/or stenting, within the past three (3) months; or,
   - Had an MI within the past 40 days; or,
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

5. Patients with documented, familial or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained VT or VF, to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy).

6. Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, Elective Replacement Indicator (ERI), or device/lead malfunction.

For each of the six (6) **medically necessary** indications above, the following additional criteria must also be met:

1. Patients must be clinically stable (e.g., not in shock, from any etiology);
2. LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac Magnetic Resonance Imaging (MRI), or catheter angiography;
3. Patients must **not** have:
    - Significant, irreversible brain damage; or,
    - Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than one (1) year; or,
    - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

MEDICARE ADVANTAGE POLICY GUIDELINES

For all circumstances identified under the first medically necessary policy statement above with the EXCEPTION of #1 and #6, a formal shared decision making encounter must occur between the patient and a physician (or qualified non-physician practitioner; meaning a physician assistant, nurse practitioner, or clinical nurse specialist) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

*EXCEPTIONS to waiting periods for patients that have had a CABG, or PCI with angioplasty and/or stenting, within the past three (3) months, or had an MI within the past 40 days:

- Cardiac Pacemakers: Patients who meet all medically necessary criteria for cardiac pacemakers, and who meet the criteria for an ICD, may receive the combined devices in one procedure, at the time the pacemaker is clinically indicated;
- Replacement of ICDs: Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, ERI, or device/lead malfunction.

BACKGROUND

VENTRICULAR ARRHYTHMIA AND SUDDEN CARDIAC DEATH

The risk of ventricular arrhythmia and SCD may be significantly increased in various cardiac conditions such as ischemic cardiomyopathy, particularly when associated with reduced left ventricular ejection fraction and prior myocardial infarction; nonischemic dilated cardiomyopathy with reduced left ventricular ejection fraction; hypertrophic cardiomyopathy and additional risk factors; congenital heart disease, particularly with recurrent syncope; and cardiac ion channelopathies.

Treatment

ICDs 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 SCD. Indications for ICD placement 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 placement surgery 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 ventricular fibrillation shock when a malignant arrhythmia is recognized.

A subcutaneous ICD (S-ICD) has been developed. It does not use transvenous leads and thus avoids the need for venous access and complications associated with the insertion of 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 have been 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. Also, devices typically have approval in the secondary prevention setting for patients with previous myocardial infarction and reduced ejection 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, the FDA approved 19 ICDs (seven pulse generators, three leads, nine combined systems) through new PMA applications.[1] Many originally approved ICDs have received multiple supplemental applications. A selective summary of some currently available ICDs is provided in Table 1.

Subcutaneous ICDs

In 2012, the Subcutaneous Implantable Defibrillator (S-ICD™) System was approved by the FDA through the PMA process for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant VT, or spontaneous, frequently recurring VT that is reliably terminated with antitachycardia pacing (see Table 1).

In 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.

Table 1. Implantable Cardioverter Defibrillators With FDA Approval

Device	Manufacturer	Original PMA Approval Date
Transvenous		
Ellipse™/Fortify Assura™ Family (originally: Cadence Tiered Therapy Defibrillation System)	St. Jude Medical	Jul 1993
Current® Plus ICD (originally: Cadence Tiered Therapy Defibrillation System)	St. Jude Medical	Jul 1993
Dynagen™, Inogen™, Origen™, and Teligen® Family (originally: Ventak, Vitality, Cofient family)	Boston Scientific	Jan 1998
Evera™ Family (originally: Virtuosos/Entrust/Maximo/Intrisic/Marquis family)	Medtronic	Dec 1998
Subcutaneous		
Subcutaneous Implantable Defibrillator System (S-ICD™)	Cameron Health; acquired by Boston	Sep 2012

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

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

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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.

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