BlueCross BlueShield of Alabama

Name of Policy:
Cardioverter Defibrillator: Implantable

Policy #: 168
Category: Surgery

Latest Review Date: October 2014
Policy Grade: A

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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.

Indications for ICD implantation can be broadly subdivided into secondary prevention, ie, their use in patients who have experienced a potentially life-threatening episode of VT (near sudden cardiac death); and primary prevention, ie, their use in patients who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening VT or 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 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. Devices manufactured by Guidant are approved by FDA for use "in patients at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced at least 1 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 nonsustained VT, with an inducible ventricular tachyarrhythmia." On July 18, 2002, 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 30% or less. 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.

NOTE: ICDs may be combined with other pacing devices, such as pacemakers for atrial fibrillation, or biventricular pacemakers designed to treat heart failure. This policy addresses ICDs alone, when used solely to treat patients at risk for ventricular arrhythmias. Policy No.

055 addresses the use of biventricular pacemakers for the treatment of heart failure alone. Policy No. 557 addresses the use of wearable external defibrillators.

Policy:

The use of an **Implantable Cardioverter Defibrillator (ICD) meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in **adult** patients who have at least ***one*** of the following:

- ischemic cardiomyopathy with LVEF less than or equal to 35% who are at least 40 days post-myocardial infarction and who are in NYHA functional Class I, II or III; **OR**
- nonischemic dilated cardiomyopathy or heart disease with an LVEF less than or equal to 35% and who are in NYHA functional Class I, II or III; **OR**
- hypertrophic cardiomyopathy who have 1 or more major† risk factor for SCD; **OR**
- a familial cardiomyopathy associated with sudden death; **OR**
- syncope of undetermined origin with clinically relevant, hemodynamically significant sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) induced at electrophysiological study; **OR**
- syncope with significant LV dysfunction, and nonischemic dilated cardiomyopathy; **OR**
- syncope and advanced structural heart disease in whom thorough invasive and noninvasive investigations have failed to define a cause; **OR**
- are survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes; **OR**
- 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. (**effective October 2013); OR**
- nonsustained VT due to prior myocardial infarction, LVEF less than or equal to 35%, and inducible ventricular fibrillation or sustained VT at electrophysiological study; **OR**
- structural heart disease and spontaneous sustained VT whether hemodynamically stable or unstable; **OR**
- prevention of SCD in patients with arrhythmogenic right ventricular dysplasia/cardiomyopathy who have 1 or more risk factor for SCD; **OR**
- Long-QT syndrome who are experiencing syncope and/or VT while receiving beta blockers; **OR**
- Long-QT syndrome and risk factors for SCD; **OR**
- non-hospitalized patients awaiting transplantation; **OR**
- Brugada syndrome who have had syncope; **OR**
- Brugada syndrome who have documented VT that has not resulted in cardiac arrest; **OR**
- catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers; **OR**
- cardiac sarcoidosis; **OR**
- giant cell myocarditis; **OR**
- Chagas disease; **OR**
- LV noncompaction.

The use of an Implantable Cardioverter Defibrillators (ICD) does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients:

- Who do not have a reasonable expectation of survival with an acceptable functional status for at least 1 year, even if they meet ICD implantation criteria specified in the recommendations above;
- With incessant VT or VF;
- With significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up;
- With NYHA Class IV symptoms and drug-refractory congestive heart failure who are not candidates for cardiac transplantation or implantation of a CRT device that incorporates both pacing and defibrillation capabilities;
- With syncope of undetermined cause without inducible ventricular tachyarrhythmias and without structural heart disease;
- When VT or VF is amenable to surgical or catheter ablation (e.g., atrial arrhythmias associated with Wolff-Parkinson-White syndrome, right ventricular or LV outflow tract VT, idiopathic VT, or fascicular VT in the absence of structural heart disease);
- With ventricular tachyarrhythmias due to a completely reversible disorder in the absence of structural heart disease (e.g., electrolyte imbalance, drugs, or trauma).

Combination implantable cardiac defibrillators **(ICD) and biventricular pacemakers meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for patients who meet BOTH a biventricular pacemaker and an ICD. Please see policy No. 055 (Bi-Ventricular Pacemakers for the Treatment of Congestive Heart Failure) for criteria for the Bi-Ventricular Pacemaker

Pediatrics

The use of an **Implantable Cardioverter Defibrillator (ICD) meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in **pediatric** patients who have or are at least **one** of the following:

- A survivor of cardiac arrest after, after reversible causes have been excluded;
- symptomatic sustained VT in association with congenital heart disease who have undergone hemodynamic and electrophysiological evaluation;
- Recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias.

The use of a subcutaneous ICD does not meet Blue Cross and Blue Shield of Alabama's criteria for coverage and is considered **non-covered** and i**nvestigational** for the adult and pediatric patient.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best

medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy was created in 1996 and updated periodically with literature review. The most recent update with literature review covers the period through September 7, 2014.

Overview and Summary of TEC Assessments

Automatic implantable cardiac defibrillators (ICDs) were first used in survivors of near sudden cardiac death. There has been ongoing interest in using ICDs as primary preventive therapy in patients with risk factors for sudden cardiac death. The first ICD TEC Assessment, published in 2002, addressed this indication. The Assessment focused on the Multicenter Automatic Defibrillator Implantation Trials (known as MADIT I and MADIT II) that compared the use of an ICD with conventional therapy among patients with coronary artery disease with a prior history of myocardial infarction (MI) and a current history of a reduced ejection fraction. The key difference in the two trials was the patient selection criteria. In the MADIT I trial, patients were required to have a left ventricular ejection fraction (LVEF) of less than 35% but also ventricular tachyarrhythmia (VT), as evidenced on an electrophysiologic study. In the subsequent, MADIT II, trial, patients were required to have a lower ejection fraction, less than 30%, but no electrophysiologic study was required. Therefore, the patient selection criteria of the MADIT II trial potentially identify a much larger number of candidates for ICD implantation.

The 2002 TEC Assessment concluded:

- For patients who have coronary artery disease with prior MI and reduced LVEF and who are similar to those selected in MADIT I and MADIT II, the available evidence demonstrates an improvement in overall mortality associated with ICD treatment compared with conventional therapy.

In October 2004, TEC reassessed ICDs. The 2004 TEC Assessment focused on the results of the five randomized controlled trials (RCTs) included in the 2002 Assessment (including the Multicenter Unsustained Tachycardia Trial [MUSTT], MADIT I, MADIT II, Coronary Artery Bypass Graft [CABG] Patch Trial, and the Cardiomyopathy Trial [CAT]) and five additional RCTs:

1. Defibrillator in Acute Myocardial Infarction Trial (DINAMIT);
2. Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT);
3. Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION);
4. Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE); and
5. Amiodarone versus Implantable Defibrillator Randomized Trial (AMIOVIRT).

The 2004 TEC Assessment made the following conclusions about the use of ICD devices: The use of ICD devices meets the TEC criteria in the prevention of sudden death from VT in patients who have:

- Symptomatic (defined as the presence of dyspnea on exertion, angina, palpitations, or fatigue) ischemic dilated cardiomyopathy with a history of MI at least 40 days before ICD treatment and LVEF of 35% or less; or
- Symptomatic (defined as the presence of dyspnea on exertion, angina, palpitations, or fatigue) non-ischemic dilated cardiomyopathy for more than 9 months' duration and LVEF of 35% or less.

The use of ICD devices does not meet the TEC criteria in the prevention of sudden death from ventricular tachyarrhythmia in patients who:

- have had an acute MI (i.e., less than 40 days before ICD treatment);
- have New York Heart Association (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 non-cardiac disease that would be associated with life expectancy less than one year.

Further analysis of existing trial data using patient-level meta-analysis may further delineate which subgroups of patients are likely to benefit from ICD placement and those unlikely to benefit who can be spared the morbidity of ICD placement.

The 2004 TEC Assessment based its conclusions on the following indication-specific evidence:

Patients Who Have Prior MI and Reduced LVEF

The 2002 Assessment concluded that the evidence was sufficient to demonstrate that ICD therapy improves net health outcome in patients with prior MI and reduced LVEF. Both new studies (SCD-HeFT and COMPANION) and the reanalysis of MUSTT findings provide additional supportive evidence of improved outcomes in patients with prior MI. The hazard ratio (HR) for all-cause mortality in the ischemic subgroup of SCD-HeFT was 0.79 (95% confidence interval [CI], 0.60 to 1.04), which is close to that observed in MADIT II (HR=0.69, 95% CI, 0.51 to 0.93), and these findings provide additional supportive evidence that ICD therapy reduces mortality. There may be slight but not statistically significant increased rates of adverse effects associated with ICD therapy; however, serious device-related events are not common. On balance, the significant reductions in mortality associated with ICD therapy outweigh the harms associated with ICD therapy in comparison with conventional treatment. Thus, the available evidence again demonstrates that ICD therapy improves health outcomes in patients with coronary artery disease and prior MI and reduced LVEF.

Patients Who Have Acute MI and Reduced LVEF

The evidence reviewed in the 2004 TEC Assessment was insufficient to permit conclusions regarding the effect of ICD therapy on net health outcome for this indication.

Patients Who Have No Prior MI and Reduced LVEF (e.g., Nonischemic Dilated Cardiomyopathy

Results from subjects with NIDCM included in SCD-HeFT and DEFINITE suggest a mortality benefit from ICD therapy, although statistical significance that was not achieved in these studies was likely related to insufficient power. A meta-analysis of five trials including nonischemic subjects reports a statistically significant reduction in mortality associated with ICD therapy. Furthermore, when the body of evidence for ICD therapy in both ischemic and nonischemic populations is considered together, the preponderance of evidence suggests that ICD therapy improves health outcomes compared with medical management alone with a relative risk reduction in all-cause mortality between 21% and 35%. While the risk of adverse events is not well-reported in studies of patients without prior MI, it seems reasonable to expect similar low rates of device-related adverse events as seen in studies of patients with prior MI.

Device-Related Adverse Effects

Device-related adverse effects were inconsistently reported in the available trials, although serious adverse events appear to be uncommon. What is known about device-related adverse effects does not outweigh the significant mortality benefits demonstrated in various studies.

Subsequent Evidence and Guidelines for the Use of ICDs in Adults

Relevant evidence and most current guidelines identified through Medline published following the 2004 TEC Assessment through October 2014 relates to the following subjects:

- Identification of predictors of better/worse outcomes after ICD placement.
- Use of ICD after acute MI: Reports of BEST-ICD [Beta-blocker Strategy + ICD], and IRIS trials
- Use of ICD in nonischemic dilated cardiomyopathy, with focus on implantation timing
- Use of ICD in hypertrophic cardiomyopathy

Post-Myocardial Infarction

BEST-ICD Trial

The BEST-ICD (Beta-blocker Strategy + ICD) trial randomized 143 patients five to 30 days after acute MI to evaluate whether electrophysiology studies were useful to guide ICD placement and improve outcomes in patients at high risk of sudden death. Entry criteria included an LVEF less than or equal to 35% along with one or more noninvasive risk factors (e.g., premature ventricular contractions, heart rate variability, signal-averaged electrocardiography [SAECG]-positive) and be given maximal tolerated b-blockers (metoprolol) therapy. The authors concluded that using electrophysiology studies to guide ICD placement within five to 30 days after MI did not significantly improve outcomes and survival. This is consistent with the conclusions that ICD placement after early MI does not improve outcomes. The authors also noted that the study screened more than 15,000 patients but ended after randomizing only 12% of the targeted study population, largely because there were far fewer patients with LVEF less than 35% than expected based on experience reported in the literature.

IRIS trial
The Immediate Risk Stratification Improves Survival (IRIS) trial evaluated ICD implantation early after MI. Eligible patients were required to have an LVEF 40% or less and either: a heart rate 90 or more beats per minute on initial electrocardiogram, or nonsustained ventricular tachycardia during Holter monitoring, or both. From 92 centers and 62,944 patients post-MI, 898 were randomized five to 31 days following the MI to ICD implantation or medical therapy. Seventy-seven percent had experienced ST elevation MI, 72% of whom underwent PTCA. During a mean 37-month follow-up, overall mortality was similar in the two arms (ICD vs medical therapy, HR=1.04; 95% CI, 0.81 to 1.35). However, the risk of sudden cardiac death was lower following ICD (HR=0.52; 95% CI, 0.35 to 0.78), but non-sudden cardiac death risk was greater (HR=1.8; 95% CI, 1.0 to 3.2). These results are consistent with guidelines and previous trials.

High-Risk Hypertrophic Cardiomyopathy (HCM)
Maron et al reported appropriate ICD discharge rates (terminating either ventricular tachycardia or fibrillation) from an international registry of high-risk hypertrophic cardiomyopathy (HCM) patients enrolled at 42 referral and non-referral institutions. Between 1986 and 2003, ICDs were implanted in 506 patients with HCM—383 for primary prevention and 123 for secondary prevention. The mean age of patients was 42 years (SD=17), and 28% were 30 years of age or younger; 36% were female; mean follow-up was 3.7 years (SD=2.8). Criteria considered in the study placing patients at high risk and, therefore, candidates for primary prevention included: history of premature HCM-related sudden death in one or more first-degree relatives younger than 50 years of age; left ventricular hypertrophy greater than 30mm; one or more runs of nonsustained VT at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; and prior unexplained syncope inconsistent with neurocardiogenic origin. Abnormal exercise blood pressure was not reported. In the primary prevention group, appropriate discharges occurred at an annual rate of 3.6% (95% CI, 2.7% to 4.8%), in the secondary prevention group 10.6% (95% CI, 7.9% to 13.9%); respective five-year cumulative probabilities of first appropriate discharge were 17% and 39%. If each appropriate discharge was life-saving, five-year numbers needed to benefit (NNTBs) could be as low as 5.9 and 2.6 for primary and secondary prevention, respectively, when considering only the first appropriate discharge.

However, when analyzed in nonischemic dilated cardiomyopathy (NIDCM), Ellenbogen et al concluded that approximately one-half of arrhythmias terminated by appropriate ICD discharges are not life-threatening. The NNTBs calculated, therefore, represent lower bounds or greatest potential benefit, and the true benefit is likely less (only 6.3% of primary prevention patients had >1 appropriate discharge). Adverse events rates included one or more inappropriate discharges (27%); infections (3.8%); hemorrhage or thrombosis (1.6%); lead fractures, dislodgement, and oversensing (6.7%). While the number of risk factors present was not associated with cumulative probability to first appropriate discharge for primary prevention, patient selection for ICD implantation was performed by experienced clinicians. These results, obtained outside the setting of a clinical trial, apply under such conditions.

Al-Khatib and Curtis published an analysis of whether ICD implantations in the U.S. followed evidence-based guidelines using a Medicare ICD registry. There were a total of 111,707 patients

who received an ICD between January 2006 and June 2009. Of these, 25,145 (22.5%) did not meet the evidence-based criteria according to ACC/AHA/HRS guidelines. Patients who did not meet evidence-based ICD criteria had a higher mortality than patients who did meet criteria (0.57% vs 0.18%, respectively; p<0.001) and also had a higher rate of procedural complications (3.2 vs 2.4%, respectively; p<0.001). Electrophysiologists had a lower rate of non-evidence-based ICD use compared with non-electrophysiologists (20.8% vs 24.8%, respectively; p<0.001).

Nonischemic Dilated Cardiomyopathy

For patients with nonischemic cardiomyopathy (NICM), the optimal timing of ICD implantation remains uncertain. A substantial percent of patients diagnosed with NICM will improve following initial diagnosis, even when a reversible cause of NICM cannot be identified. Given the current available evidence, it is not possible to predict which patients with idiopathic NICM will improve, nor is it possible to accurately estimate the time course for improvement. The specification of a nine-month waiting period before ICD implantation arises from the selection criteria of the CAT trial, which restricted enrollment to patients with onset of NICM within nine months. While the results of this trial did not show a benefit for patients with recent onset of NICM, the trial was stopped early due to an unexpectedly low rate of events and was thus underpowered to detect a difference in mortality between groups.

Kadish and Subacius performed a post hoc analysis of the DEFINITE trial data to examine whether the time from diagnosis of nonischemic dilated cardiomyopathy (NIDCM) was associated with the magnitude of benefit from ICD implantation. Survival benefit was found only for those diagnosed less than nine months before implantation (n=216); no benefit was apparent when NIDCM was diagnosed greater than nine months before (n=242). However, there was a significant discrepancy between arms in the time from diagnosis to randomization—standard therapy patients were randomized a median of 20 months after diagnosis, while those in the ICD arm had a median of eight months. The trial was neither designed nor powered to examine a time effect, and the analyses conflict with findings of the smaller (n=104) Cardiomyopathy (CAT) trial reviewed in the 2002 TEC Assessment. Further evidence is necessary to define when in the natural history of the disease ICD implantation is appropriate.

The Definite trial enrolled NICM patients without regard to time since onset, and a post hoc analysis revealed that the benefit was found mainly in patients with onset of NICM for less than nine months. Neither of these pieces of evidence represents strong data to support a specific time interval before implanting an ICD in patients with NICM.

Zecchin et al performed a cohort study on 503 consecutive patients diagnosed with idiopathic NICM to determine the extent to which indications for an ICD evolved over the several months following an initial NICM diagnosis. At initial diagnosis, 245 met SCD-HeFT criteria for an ICD, based on an ejection fraction less than 35% and Class II-III heart failure, and 258 did not meet criteria for an ICD. At a mean follow-up of 5.4 months during which patients were treated with angiotensin-converting enzyme inhibitors and b-blockers, there were consistent improvements in ejection fraction and symptoms, such that less than one-third of evaluable patients (31%) still had indications for ICD. Of patients who initially did not have an indication

for an ICD, a total of 10% developed indications for an ICD at follow-up. This study highlights the fact that a decision for ICD implantation should not be made before optimal treatment and stabilization of patients with newly diagnosed NICM, because the indications for ICD are not stable over time and will change in a substantial numbers of patients following treatment.

A prospective registry sponsored by the NHLBI enrolled 373 patients with recent-onset NICM, and compared mortality in patients receiving an early ICD with those receiving the device at a later time. Forty-three patients received an ICD within one month of diagnosis, with a one-year survival for this group of 97%. Three hundred thirty patients received an ICD between one and six months, with a one-year survival of 98%. Seventy-three patients received an ICD at a time period longer than six months, with a one-year survival. Survival at two and three years was also similar between groups, with no significant differences.

Some experts consider patients with recently diagnosed NICM and either sustained VT or unexplained syncope to be candidates for earlier ICD implantation due to their higher risk of lethal arrhythmias. However, evidence on this specific population is lacking, and the natural history of patients in this category is not well-characterized. The most recent ACC/AHA guidelines do not specifically address the optimal waiting period before implantation of an ICD for patients with newly diagnosed NICM.

Adverse Events

Perrson et al published a systematic review and meta-analysis of adverse events following ICD implantation. The authors included data from 35 cohort studies, reported in 53 articles. In-hospital serious adverse event rates ranged from 1.2-1.4%, most frequently pneumothorax (0.4-0.5%) and cardiac arrest (0.3%). Post-hospitalization complication rates were variable: device-related complications occurred in 0.1-6.4%; lead-related complications in 0.1-3.9%; infection in 0.2-3.7%; thrombosis in 0.2-2.9%; and inappropriate shock in 3-21%.

Lead Failure

The failure of ICD leads in several specific ICD devices has lead the U.S. FDA to require St. Jude Medical to conduct three-year postmarket surveillance studies to address concerns related to premature insulation failure and to address important questions related to follow-up of affected patients.

Ricci et al evaluated the incidence of lead failure in a cohort study of 414 patients implanted with an ICD with Sprint-Fidelis leads. Patients were followed for a median of 35 months. Lead failures occurred in 9.7% (40/414) of patients, for an annual rate of 3.2% per patient-year. Most of the lead failures (87.5%) were due to lead fracture. The median time until recognition of lead failure, or until an adverse event, was 2.2 days. A total of 22 patients (5.3%) received an inappropriate shock due to lead failure.

Cheng et al examined the rate of lead dislodgements in patients enrolled in a national cardiovascular registry. Of 226,764 patients treated with an ICD between April 2006 and September 2008, lead dislodgement occurred in 2628 (1.2%). Factors associated with lead dislodgement were NYHA Class IV heart failure, atrial fibrillation/flutter, a combined ICD-CRT

device, and having the procedure performed by a non-electrophysiologist. Lead dislodgement was associated with an increased risk for other cardiac adverse events and death.

Infection

Several publications have reported on infection rates in patients receiving an ICD. Smit and Schonheyder published a retrospective, descriptive analysis of the types and distribution of infections associated with ICDs over a ten-year period in Denmark. Of 91 total infections identified, 39 (42.8%) were localized pocket infections, 26 (28.6%) were endocarditis, 17 (18.7%) were ICD-associated bacteremic infections, and nine (9.9%) were acute postsurgical infections. Nery and Nair reported the rate of ICD-associated infections among consecutive patients treated with an ICD at a tertiary referral center. There were a total of 24 infections among 2,417 patients for a rate of 1.0%. Twenty-two of 24 patients with infections (91.7%) required device replacement. Factors associated with infection were device replacement (versus de novo implantation) and use of a complex device (e.g., combined ICD-CRT or dual/triple chamber devices). Sohail et al performed a case-control study evaluating the risk factors for infection in 68 patients with an ICD infection and 136 matched controls. On multivariate analysis, the presence of epicardial leads (odds ratio [OR], 9.7; p=0.03) and postoperative complications at the insertion site (OR=27.2, p<0.001) were significant risk factors for early infection. For late-onset infections, prolonged hospitalization for >3 days (OR=33.1, p<0.001 for two days vs one day) and chronic obstructive pulmonary disease (OR=9.8, p=0.02) were significant risk factors.

Inappropriate Shocks

Ten et al conducted a systematic review to identify outcomes and adverse effects associated with ICDs that have built-in therapy reduction programming. Six randomized trials and two nonrandomized cohort studies were included, including 7,687 patients (3,598 with conventional ICDs and 4,089 therapy reduction programming). A total of 267 patients received inappropriate ICD shocks (4.9%); 99 (3.4%) in the therapy reduction and 168 (6.9%) in the conventional programming group (relative risk 50%; 95% CI 37% to 61%; P<0.001). Therapy reduction programming was associated with a significantly lower risk of death compared with conventional programming (relative risk 30%; 95% CI 16% to 41%; *P*<0.001.)

Other Complications

Lee et al evaluated the rate of early complications among patients enrolled in a prospective, multicenter population-based registry of all newly implanted ICDs in Ontario, Canada from February 2007 through May 2009. Of 3,340 patients receiving an ICD, major complications (lead dislodgement requiring intervention, myocardial perforation, tamponade, pneumothorax, infection, skin erosion, hematoma requiring intervention) within 45 days of implantation occurred in 4.1% of new implants. Major complications were more common in women, in patients who received a combined ICD-CRT (cardiac resynchronization therapy) device, and in patients with a left ventricular end-systolic size of larger than 45mm. Direct implant-related complications were associated with a major increase in early death (HR=24.9, p<0.01).

Use of Automatic ICDs in the Pediatric Population
There is limited direct scientific evidence on the efficacy of ICDs in the pediatric population. Most published studies in this area are retrospective analyses of small case series. A review of some of the representative publications of this type is summarized next.

The largest published series was a combined series of pediatric patients and patients with congenital heart disease from four clinical centers. The median age of this population was 16 years, although some adults were included up to the age of 54 years. A total of 443 patients were included. The most common diagnoses were tetralogy of Fallot and HCM. ICD implantation was performed for primary prevention in 52% of patients and for secondary prevention in 48%. Over a two-year period of follow-up, appropriate shocks occurred in 26% of patients and inappropriate shocks occurred in 21%.

Silka et al compiled a database of 125 pediatric patients treated with an ICD, through query of the manufacturers of commercially available devices. Indications for ICD placement were survivors of cardiac arrest in 95 patients (76%), drug-refractory ventricular tachycardia in 13 patients (10%), and syncope with heart disease plus inducible VT in 13 patients (10%). During a mean follow-up of 31 +/- 23 months, 73 patients (59%) received at least one appropriate shock and 25 patients (20%) received at least one inappropriate shock. The actuarial rates of sudden-death-free survival were 97% at one year, 95% at two years, and 90% at five years.

Alexander et al reported on 90 ICD procedures in 76 young patients with a mean age of 16 years (range, 1-30). Indications for placement were 27 patients (36%) with cardiac arrest or sustained VT, 40 patients (53%) with syncope, 17 patients (22%) with palpitations, 40 patients (53%) with spontaneous ventricular arrhythmias, and 36 patients (47%) with inducible VT. Numerous patients had more than one indication for ICD in this study. Over a median of two years' follow-up, 28% of patients received an appropriate shock, and 25% of patients received an inappropriate shock. Lewandowski et al reported on long-term follow-up of 63 patients between the ages of six and 21 years who were treated with an ICD device. After a 10-year follow-up, there were 13 (21%) patients with surgical infections. Fourteen patients (22%) experienced at least one appropriate shock and 17 patients (27%) had at least one inappropriate shock. Serious psychologic sequelae developed in 27 patients (43%).

Subcutaneous ICD
The subcutaneous ICD is intended for patients who do have standard indications for an ICD, but who do not require pacing for bradycardia, or antitachycardia overdrive pacing for VT. There were no RCTs identified that compared the performance of a subcutaneous ICD (S-ICD) with transvenous ICDs. Two nonrandomized, comparative studies were identified that compared the efficacy of the two different types of ICDs, and numerous single-arm studies report on outcomes of the S-ICD.

Subcutaneous ICD: Efficacy
Nonrandomized Comparative Studies
Kobe et al compared the efficacy of the S-ICD and the transvenous ICD in terminating laboratory-induced ventricular fibrillation (VF). Sixty-nine patients from three centers in

Germany treated with an S-ICD were matched for age and gender with 69 patients treated with a transvenous ICD. One patient in the transvenous ICD group developed a pericardial effusion requiring pericardiocentesis. Termination of induced VF was successful in 89.5% of the patients in the S-ICD group, compared with 90.8% of patients with a transvenous ICD (p=0.815). Patients in both groups were followed for a mean of 217 days. One patient in the S-ICD group had the device explanted at eight weeks due to local infection, and a second patient had the S-ICD changed to a transvenous ICD because of the need for antitachycardia overdrive pacing due to frequent episodes of VT. There were three patients in the S-ICD group who received appropriate shocks for ventricular arrhythmias compared with nine patients in the transvenous group (p=0.05). Inappropriate shocks occurred in five patients in the S-ICD group and three patients in the transvenous ICD group (p=0.75).

The Subcutaneous versus Transvenous Arrhythmia Recognition Testing (START) study compared the performance of a subcutaneous ICD with a transvenous ICD for detecting arrhythmias in the electrophysiology lab. The patient population included 64 patients who were scheduled for ICD implantation. All patients had a transvenous ICD placed, as well as subcutaneous electrodes attached to a subcutaneous ICD. Arrhythmias were induced and the sensitivity and specificity of detection by each device was compared. For ventricular arrhythmias, sensitivity of detection was 100% for the subcutaneous ICD and 99% for the transvenous ICD. Specificity was 98.0% for the subcutaneous ICD device compared with 76.7% for the transvenous device (p<0.001).

Noncomparative Studies

A number of single-arm studies have been published that report on outcomes of patients treated with an S-ICD. The largest such study was reported by Lambiase et al, who described patients in the EFFORTLESS-ICD registry, a multicenter European registry to report outcomes for patients treated with S-ICD. At the time of analysis, the registry included 472 patients, 241 of whom (51%) were enrolled prospectively, at a median follow up time of 498 days. Nine patients (2%) died during the reported period, none of which were known to occur in the perioperative period, although the cause of death was unknown for one patient. A total of 317 spontaneous episodes in 85 patients were recorded during the follow-up, of which 169 episodes received therapy in 59 patients. Of the 145 classified untreated episodes, 93 were adjudicated as inappropriate sensing, 37 were non-sustained VT/VF, 12 were non-sustained SVT above discrimination zone, and three were unclassified. Of the VT/VF episodes, the first shock conversion efficacy was 88%, with 100% overall successful clinical conversion after a maximum of five shocks. A total of 73 inappropriate shocks were recorded in 32 patients over an average follow-up of 18 months (360 day inappropriate shock rate of 7%).

A second largest series was a multicenter study of 330 patients from several countries, the S-ICD System Clinical Investigation (S-ICD IDE Study). The S-ICD was successfully implanted in 314/330 patients (95.1%). Laboratory-induced VF was successfully terminated in more than 90% of patients, which was one of the primary outcomes of the study. The second primary outcome, greater than 99% freedom from complications at 180 days, was also met. Patients were followed for a mean duration of 11 months. There were 38 spontaneous episodes of VT in 21 patients

(6.7%), and all were successfully terminated. Inappropriate shocks were received by 41 patients (13.1%).

Gold et al published a sub-analysis of patients in the S-ICD IDE study to evaluate a discrimination algorithm to reduce inappropriate shocks. Patients in the study could receive one of two shock detection algorithms, a single- or double-zone configuration. In the single zone configuration, shocks are delivered for detected heart rates above the programmed rate threshold. In the dual zone configuration, arrhythmia discrimination algorithms are active in a lower rate zone up to a shockable heart rate threshold. At hospital discharge, dual zone programming was used in 226 subjects (72%) and single zone programming was used in the remaining 88 subjects (28%). Inappropriate shocks occurred on 23/226 (10.2%) subjects with dual zone programming and 23/88 (26.1%; $P<0.001$) subjects with single zone programming. Freedom from appropriate shocks did not differ between the groups.

Bardy et al described the development and testing of the device, including empiric evidence for the optimal placement of the subcutaneous electrode, in 2010. A total of 55 patients were tested in the electrophysiology lab for termination of induced arrhythmias and subsequently followed for a mean of 10.1 months for successful termination of detected arrhythmias and clinical outcomes. In the electrophysiology lab study, intraoperative ventricular fibrillation was induced in 53 of 55. All episodes were correctly detected by the subcutaneous ICD. In 52 of 53 patients, two consecutive episodes of ventricular arrhythmia were successfully terminated. In the final patient, the arrhythmia was terminated on one occasion but not on the other. In the cohort portion of this study, 54 of 55 patients were alive at last follow-up. The one death was due to renal failure, and this patient requested removal of the subcutaneous ICD before death. An infection at the generator site occurred in two patients, necessitating a revision procedure. Another three patients had lead dislodgement requiring repositioning. There were a total of 12 episodes of VT that were detected by the subcutaneous ICD; all 12 episodes were successfully terminated by countershock.

A series of 118 patients from four centers in the Netherlands was published in 2013. Patients were followed for a mean of 18±7 months. Device-related complications occurred in 14% of patients, including infection (5.9%), dislodgement of the device or leads (3.3%), skin erosion (1.7%), and battery failure (1.7%). In one patient, the S-ICD was replaced with a transvenous ICD because of the need for antitachycardia pacing. Over the entire follow-up period, eight patients experienced 45 appropriate shocks, with a first-shock conversion efficacy of 98%. Fifteen patients (13%) received a total of 33 inappropriate shocks. Two patients died, one due to cancer and one to progressive heart failure.

Subcutaneous ICD Safety: Inappropriate Shocks

Although Kobe et al reported no differences between inappropriate shock rates in patients treated transvenous ICD or S-ICD, non-comparative studies have reported relatively high rates of inappropriate shocks with S-ICD. Inappropriate shocks from S-ICDs often result from T-wave oversensing. Since the sensing algorithm and the discrimination algorithm for arrhythmia detection is fixed in the S-ICD, management to reduce inappropriate shocks for an S-ICD differs from that for a transvenous ICD. Kooiman et al reported inappropriate shock rates among 69

patients treated at a single center with a S-ICD between February 2009 and July 2012 who were not enrolled in one of two other concurrent trials. Over a total follow up of 1,316 months (median per patient of 21 months), the annual incidence of inappropriate shocks was 10.8%. In eight patients, inappropriate shocks were related to T-wave oversensing. After patients underwent adjustment of the sensing vector, no further inappropriate shocks occurred in 87.5% of patients with T-wave oversensing.

Groh et al evaluated an electrocardiographic (ECG) screening test to determine patients who are potential S-ICD candidates who are at risk for T-wave oversensing. One hundred patients who had previously undergone transvenous ICD implantation and who were not receiving bradycardia pacing and did not have an indication for pacing were included. ECGs were obtained with lead placement to mimic the sensing vectors available on the S-ICD, and a patient was considered to qualify for S-ICD if the screening ECG template passed in any same lead supine and standing, at any gain, and without significant morphologic changes in QRS complexes. Of the included subjects who were potentially eligible for S-ICD, 8% were considered to fail based the ECG screening. The authors conclude that "More work is needed in S-ICD sensing algorithms to increase patient eligibility for the S-ICD.

Summary

There is an extensive literature base on the use of implantable cardioverter defibrillators (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 demonstrated a benefit in overall mortality for patients with ischemic cardiomyopathy and reduced ejection fraction. The indications for ICDs in these groups of patients parallel the inclusion criteria for the major trials and the recommendations from major specialty society guidelines. RCTs of early ICD implantation following acute myocardial infarction (MI) do not support a benefit for immediate ICD implantation versus delayed implantation for at least 40 days.

For nonischemic cardiomyopathy (NICM), there is less clinical trial evidence available, 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 not high-quality evidence available 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 reports that most patients who meet criteria for an ICD at the time of initial NICM diagnosis will no longer meet the criteria for an ICD several months after initiation of treatment.

For pediatric patients, there is no direct evidence on the benefit of ICD implantation from high-quality clinical trials. Indications for pediatric patients are based on specialty society guidelines and from specialty society clinical input, both of which extrapolate findings from adult populations to the pediatric population.

A subcutaneous ICD (S-ICD®) has been developed that does not employ transvenous leads, with the goal of reducing lead-related complications. Evidence from nonrandomized controlled

studies report success rates in terminating laboratory-induced VF that are similar to transvenous ICD. However, there is scant evidence on comparative clinical outcomes of both types of ICD over longer periods of time. Case series report high rates of detection and successful conversion of VT, and inappropriate shock rates that are in the range reported for transvenous 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 to the disorder being treated. Also, the adverse event rate is uncertain, with variable rates of adverse events reported in the available studies. At least one RCT is currently underway to compare S-ICD with transvenous ICD. Because of the uncertainties around whether the S-ICD is as effective as transvenous ICD and uncertainties around the adverse event rates, the use of the S-ICD is considered investigational.

Practice Guidelines and Position Statements

ACC/AHA Heart Failure Management Guidelines

In 2013, the American College of Cardiology (ACC) and American Heart Association issued practice guidelines on the management of heart failure which made the following recommendations about the use of implantable cardioverter defibrillator (ICD) devices as primary prevention:

- For patients with stage B heart failure, an ICD is reasonable in patients with asymptomatic ischemic cardiomyopathy who are at least 40 d post-MI, have an LVEF ≤30%, and on guideline-directed medical therapy (GDMT). (Class of recommendation: IIa; level of evidence: B).
- For patients with stage C heart failure:
    - ICD therapy is recommended for primary prevention of sudden cardiac death (SCD) in selected patients with heart failure with reduced ejection fraction (HFrEF) at least 40 d post-myocardial infarction (MI) with left ventricular ejection fraction (LVEF) ≤35% and NYHA Class II or III symptoms on chronic GDMT, who are expected to live at least one year. (Class of recommendation: I; level of evidence: A).
    - ICD therapy is recommended for primary prevention of SCD in selected patients with HFrEF at least 40 d post-MI with LVEF ≤330% and NYHA Class I symptoms while receiving GDMT, who are expected to live at least one year. (Class of recommendation: I; level of evidence: B).
    - An ICD is of uncertain benefit to prolong meaningful survival in patients with a high risk of non-sudden death such as frequent hospitalizations, frailty, or severe comorbidities. (Class of recommendation: IIb; level of evidence: B).

ACC/AHA Device-Based Therapy for Cardiac Rhythm Abnormalities Guidelines

In 2012, the ACC and AHA, together with the Heart Rhythm Society (HRS), the American Association of Thoracic Surgeons, and the Society of Thoracic Surgeons, issued a focused update to 2008 guidelines for device-based therapy of cardiac rhythm abnormalities. The guidelines make the following recommendations related to ICD therapy in adults, all of which are based on the expectation that patients are receiving optimal medical therapy and have a reasonable expectation of survival with a good functional status for more than a year:

- Class I recommendations:
    - ICD therapy is indicated in patients who are survivors of cardiac arrest due to ventricular fibrillation (VF) or hemodynamically unstable sustained ventricular tachycardia (VT) after evaluation to define the cause of the event and to exclude any completely reversible causes. (Level of Evidence: A).
    - ICD therapy is indicated in patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable. (Level of Evidence: B)
    - ICD therapy is indicated in patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study. (Level of Evidence: B)
    - ICD therapy is indicated in patients with LVEF less than or equal to 35% due to prior MI who are at least 40 days post-MI and are in NYHA functional Class II or III. (Level of Evidence: A)
    - ICD therapy is indicated in patients with nonischemic dilated cardiomyopathy (DCM) who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III. (Level of Evidence: B)
    - ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 30%, and are in NYHA functional Class I. (Level of Evidence: A)
    - ICD therapy is indicated in patients with nonsustained VT due to prior MI, LVEF less than or equal to 40%, and inducible VF or sustained VT at electrophysiological study. (Level of Evidence: B)
- Class IIa recommendations:
    - ICD implantation is reasonable for patients with unexplained syncope, significant LV dysfunction, and nonischemic DCM. (Level of Evidence: C)
    - ICD implantation is reasonable for patients with sustained VT and normal or near-normal ventricular function. (Level of Evidence: C)
    - ICD implantation is reasonable for patients with HCM who have one or more major† risk factors for sudden cardiac death (SCD). (Level of Evidence: C)
    - ICD implantation is reasonable for the prevention of SCD in patients with arrhythmogenic right ventricular dysplasia/cardiomyopathy who have one or more risk factors for SCD. (Level of Evidence: C)
    - ICD implantation is reasonable to reduce SCD in patients with long-QT syndrome who are experiencing syncope and/or VT while receiving beta blockers. (Level of Evidence: B)
    - ICD implantation is reasonable for nonhospitalized patients awaiting transplantation. (Level of Evidence: C)
    - ICD implantation is reasonable for patients with Brugada syndrome who have had syncope. (Level of Evidence: C)
    - ICD implantation is reasonable for patients with Brugada syndrome who have documented VT that has not resulted in cardiac arrest. (Level of Evidence: C)
    - ICD implantation is reasonable for patients with catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers. (Level of Evidence: C)

    - ICD implantation is reasonable for patients with cardiac sarcoidosis, giant cell myocarditis, or Chagas disease. (Level of Evidence: C)
- Class IIb recommendations:
    - ICD therapy may be considered in patients with nonischemic heart disease who have an LVEF of less than or equal to 35% and who are in NYHA functional Class I. (Level of Evidence: C)
    - ICD therapy may be considered for patients with long-QT syndrome and risk factors for SCD. (Level of Evidence: B)
    - ICD therapy may be considered in patients with syncope and advanced structural heart disease in which thorough invasive and noninvasive investigations have failed to define a cause. (Level of Evidence: C)
    - ICD therapy may be considered in patients with a familial cardiomyopathy associated with sudden death. (Level of Evidence: C)
    - ICD therapy may be considered in patients with LV non-compaction. (Level of Evidence: C)
- Class III recommendations (not recommended):
    - ICD therapy is not indicated for patients who do not have a reasonable expectation of survival with an acceptable functional status for at least one year, even if they meet ICD implantation criteria specified in the Class I, IIa, and IIb recommendations above. (Level of Evidence: C)
    - ICD therapy is not indicated for patients with incessant VT or VF. (Level of Evidence: C)
    - ICD therapy is not indicated in patients with significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up. (Level of Evidence: C)
    - ICD therapy is not indicated for NYHA Class IV patients with drug-refractory congestive heart failure who are not candidates for cardiac transplantation or cardiac resynchronization/defibrillator. (Level of Evidence: C)
    - ICD therapy is not indicated for syncope of undetermined cause in a patient without inducible ventricular tachyarrhythmias and without structural heart disease. (Level of Evidence: C)
    - ICD therapy is not indicated when VF or VT is amenable to surgical or catheter ablation (e.g., atrial arrhythmias associated with the Wolff-Parkinson-White syndrome, RV or LV outflow tract VT, idiopathic VT, or fascicular VT in the absence of structural heart disease). (Level of Evidence: C)
    - ICD therapy is not indicated for patients with ventricular tachyarrhythmias due to a completely reversible disorder in the absence of structural heart disease (e.g., electrolyte imbalance, drugs, or trauma). (Level of Evidence: B)

The 2012 guidelines make the following recommendations related to ICD therapy in children:

- Class I recommendations:
    - ICD implantation is indicated in the survivor of cardiac arrest after evaluation to define the cause of the event and to exclude any reversible causes. (Level of Evidence: B)

    - ICD implantation is indicated for patients with symptomatic sustained VT in association with congenital heart disease who have undergone hemodynamic and electrophysiological evaluation. Catheter ablation or surgical repair may offer possible alternatives in carefully selected patients. (Level of Evidence: C)
- Class IIa recommendations: ICD implantation is reasonable for patients with congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study. (Level of Evidence: B)
- Class IIb recommendations: ICD implantation may be considered for patients with recurrent syncope associated with complex congenital heart disease and advanced systemic ventricular dysfunction when thorough invasive and noninvasive investigations have failed to define a cause. (Level of Evidence: C)
- Class III recommendations: All Class III recommendations found in Section 3, "Indications for Implantable Cardioverter-Defibrillator Therapy," apply to pediatric patients and patients with congenital heart disease, and ICD implantation is not indicated in these patient populations. (Level of Evidence: C)

ACC/AHA Expert Consensus Statement on ICD Therapy in Patients Not Well Represented in Clinical Trials

In 2014, HRS, ACC, and AHA published an expert consensus statement on the use of ICD therapy in patients who were not included or poorly represented in ICD clinical trials, which made a number of consensus-based guidelines on the use of ICDs in selected patient populations.

ACC/AHA Guidelines for Hypertrophic Cardiomyopathy

In 2011, ACCF/AHA guidelines were published on the management of patients with hypertrophic cardiomyopathy. These guidelines contained the following statements about the use of ICD in patients with HCM:

- Class I recommendations
    - The decision to place an ICD in patients with HCM should include application of individual clinical judgment, as well as a thorough discussion of the strength of evidence, benefits, and risks to allow the informed patient's active participation in decision making. (Level of Evidence: C)
    - ICD placement is recommended for patients with HCM with prior documented cardiac arrest, ventricular fibrillation, or hemodynamically significant VT. (Level of Evidence: B)
- Class IIa recommendations
    - It is reasonable to recommend an ICD for patients with HCM with:
        - Sudden death presumably caused by HCM in one or more first-degree relatives. (Level of Evidence: C)
        - A maximum LV wall thickness greater than or equal to 30 mm. (Level of Evidence: C)
        - One or more recent, unexplained syncopal episodes. (Level of Evidence: C)

- An ICD can be useful in select patients with NSVT [nonsustained VT] (particularly those <30 years of age) in the presence of other SCD risk factors or modifiers. (Level of Evidence: C)
- An ICD can be useful in select patients with HCM with an abnormal blood pressure response with exercise in the presence of other SCD risk factors or modifiers. (Level of Evidence: C)

It is reasonable to recommend an ICD for high-risk children with HCM, based on unexplained syncope, massive LV hypertrophy, or family history of SCD, after taking into account the relatively high complication rate of long-term ICD implantation. (Level of Evidence: C).

- Class IIb recommendations
  - The usefulness of an ICD is uncertain in patients with HCM with isolated bursts of NSVT when in the absence of any other SCD risk factors or modifiers. (Level of Evidence: C)
  - The usefulness of an ICD is uncertain in patients with HCM with an abnormal blood pressure response with exercise when in the absence of any other SCD risk factors or modifiers, particularly in the presence of significant outflow obstruction. (Level of Evidence: C)
- Class III recommendations: Harm
  - ICD placement as a routine strategy in patients with HCM without an indication of increased risk is potentially harmful. (Level of Evidence: C)
  - ICD placement as a strategy to permit patients with HCM to participate in competitive athletics is potentially harmful. (Level of Evidence: C)
  - ICD placement in patients who have an identified HCM genotype in the absence of clinical manifestations of HCM is potentially harmful. (Level of Evidence: C)

U.S. Preventive Services Task Force Recommendations
Use of implantable cardioverter defibrillators is not a preventive service.

Key Words:
Ventricular fibrillation (VF), ventricular tachycardia (VT), defibrillator, automatic implantable cardioverter defibrillator (AICD), Subcutaneous ICD, S-ICD® system

Approved by Governing Bodies:
The U.S. Food and Drug Administration (FDA) has approved a large number of implantable cardioverter defibrillators (ICDs) 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, and nine combined systems) through new PMA applications. Many originally-approved ICDs have undergone multiple supplemental applications. A summary of some currently-available ICDs is provided in Table 1 (not an exhaustive list):

Table 1: ICDs with FDA Approval

Device	Manufacturer	Original PMA Approval Date	Type
Ellipse/ Fortify Assura Family (originally: Cadence Tiered Therapy Defibrillation System)	St. Jude Medical, Inc. (St. Paul, MN)	July 1993	Transvenous
Current Plus ICD (originally: Cadence Tiered Therapy Defibrillation System)	St. Jude Medical, Inc. (St. Paul, MN)	July 1993	Transvenous
Dynagen, Inogen, Origen, and Teligen Family (originally: Ventak, Vitality, Cofient family)	Boston Scientific, Inc. (Marlborough, MA)	January 1998	Transvenous
Evera Family (originally: Virtuosos/ Entrust/Maximo/ Intrisic/ Marquis family)	Medtronic, Inc. (Minneapolis, MN)	December 1998	Transvenous
Subcutaneous Implantable Defibrillator System	Cameron Health, Inc. (San Clemente, CA); acquired by Boston Scientific, Inc.	November 2012	Subcutaneous

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:

33215	Repositioning of previously implanted transvenous pacemaker or pacing cardioverter-defibrillator (right atrial or right ventricular) electrode
33216	Insertion of a single transvenous electrode, permanent pacemaker or cardioverter-defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or cardioverter-defibrillator
33218	Repair of single transvenous electrode, permanent pacemaker or pacing cardioverter-defibrillator
33220	Repair of two transvenous electrodes for permanent pacemaker or pacing cardioverter-defibrillator
33223	Revision of skin pocket for cardioverter-defibrillator
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal, insertion and/or replacement of existing generator)
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system and pocket revision) (list separately in addition to code for primary procedure)
33230	Insertion of pacing cardioverter-defibrillator pulse generator only; with existing dual leads
33231	Insertion of pacing cardioverter-defibrillator pulse generator only; with existing multiple leads
33240	Insertion of pacing cardioverter-defibrillator pulse generator only; with existing single lead
33241	Removal of pacing cardioverter-defibrillator pulse generator only
33243	Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by thoracotomy
33244	; by transvenous extraction
33249	Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber
33262	Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; single lead system
33263	; dual lead system
33264	; multiple lead system
93287	Peri-procedural device evaluation(in person) and programming of device system parameters before or after a surgery, procedure, or test with physician analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable cardioverter-defibrillator system

93289	Interrogation device evaluation (in person) with physician analysis, review and report, by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead implantable cardioverter-defibrillator system, including analysis of heart rhythm derived data elements
0319T	Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode (For removal and replacement of subcutaneous defibrillator system [pulse generator and electrode], report 0319T in conjunction with 0322T and 0324T)
0320T	Insertion of subcutaneous defibrillator electrode (Do not report 0320T in conjunction with 0319T)
0321T	Insertion of subcutaneous implantable defibrillator pulse generator only with existing subcutaneous electrode (Do not report 0321T in conjunction with 0322T, 0323T for removal and replacement of the subcutaneous defibrillator pulse generator) (For removal of pulse generator with insertion of a new subcutaneous implantable defibrillator pulse generator without any replacement or insertion of a lead, use 0323T)
0322T	Removal of subcutaneous implantable defibrillator pulse generator only (Do not report 0322T in conjunction with 0321T, 0323T for removal and replacement of the subcutaneous defibrillator pulse generator) (For removal and replacement of subcutaneous defibrillator system [pulse generator and electrode], report 0322T in conjunction with 0319T and 0324T)
0323T	Removal of subcutaneous implantable defibrillator pulse generator with replacement of subcutaneous implantable defibrillator pulse generator only (Do not report 0323T in conjunction with 0322T) (For removal of electrode[s] in conjunction with pulse generator removal or replacement, use 0324T in conjunction with 0322T or 0323T)
0324T	Removal of subcutaneous defibrillator electrode (For removal and replacement of subcutaneous defibrillator system [pulse generator and electrode], report 0324T in conjunction with 0319T and 0322T)
0325T	Repositioning of subcutaneous implantable defibrillator electrode and/or pulse generator (Do not report 0325T in conjunction with 0319T-0324T)
0326T	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters) (Report 0326T separately during device insertion, replacement or for follow-up device testing, when performed)
0327T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system (Do not report 0327T in conjunction with pulse generator and lead insertion or repositioning codes 0319T-0325T, 0326T, 0328T) (For peri-

		procedural device evaluation and programming for evaluating of the implantable defibrillator to adjust device to settings appropriate for the patient prior to or after a surgery, procedure, or test, see 0327T, 0328T)
	0328T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis; implantable subcutaneous lead defibrillator system (Do not report 0328T in conjunction with pulse generator and lead insertion or repositioning codes 0319T-0327T)
HCPCS		
	G0300	Insertion or repositioning of electrode lead(s) for dual chamber pacing cardioverter defibrillator and insertion of pulse generator
	G0448	Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

References:

1. Adams KF, Lindenfeld J, Arnold JM, Baker DW, et al. Heart Failure Society of America. Electrophysiologic testing and the use of devices in heart failure. J Card Fail 2006; 12(1): e70-75.
2. Al-Khatib SM, et al. Non-Evidence-Based ICO implantations in the United States. JAMA Jan 2011; 305(1): 43-49.
3. Alexander ME CF, Walsh EP et al. Implications of implantable cardioverter-defibrillator therapy in congenital heart disease and pediatrics. J Cardiovasc Electrophysiol 2004; 15(1):72-6.
4. Bansch D AM, Boczor S et al. Primary prevention of sudden cardiac death in idiopathic dilated cardiomyopathy: the Cardiomyopathy Trial (CAT). Circulation 2002; 105(12):1453-8.
5. Bardy GH, Smith WM, Hood MA et al. An entirely subcutaneous implantable cardioverter-defibrillator. N. Engl. J. Med. 2010; 363(1):36-44.
6. Berul CI VHG, Kertesz NJ et al. Results of a multicenter retrospective implantable cardioverter-defibrillator registry of pediatric and congenital heart disease patients. J Am Coll Cardiol 2008; 51(17):1685-91.
7. 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).
8. 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 2004; 19(Tab 19).
9. Cheng A WY, Curtis JP et al. Acute lead dislodgement and in-hospital mortality in patients enrolled in the national cardiovascular data registry implantable cardioverter-defibrillator registry. J Am Coll Cardiol 2010; 56(20):1651-6.

10. Desai AS FJ, Maisel WH et al. Implantable defibrillators for the prevention of mortality in patients with nonischemic cardiomyopathy—a meta-analysis of randomized controlled trials. JAMA 2004; 292(23):2874-9.
11. Ellenbogen KA, Levine JH, Berger RD et al. Are implantable cardioverter defibrillator shocks a surrogate for sudden cardiac death in patients with nonischemic cardiomyopathy? Circulation 2006; 113(6):776-82.
12. Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): Developed in Collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. Circulation 2008; 117: e350-e408.
13. Ermis C, Zhu AX, Vanheel L, et al. Comparison of ventricular arrhythmia frequency in patients with ischemic cardiomyopathy versus nonischemic cardiomyopathy treated with implantable cardioverter defibrillators. American Journal of Cardiology, July 2005, Vol. 96, No. 2.
14. Gersh BJ, Maron BJ, Bonow RO et al. 2011 ACCF/AHA guideline for the diagnosis and treatment of hypertrophic cardiomyopathy: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation 2011; 124(24):e783-831.
15. Gold MR, Theuns DA, Knight BP et al. Head-to-head comparison of arrhythmia discrimination performance of subcutaneous and transvenous ICD arrhythmia detection algorithms: the START study. J. Cardiovasc. Electrophysiol. 2012; 23(4):359-66.
16. Gold MR, Weiss R, Theuns DA, et al. Use of a discrimination algorithm to reduce inappropriate shocks with a subcutaneous implantable cardioverter-defibrillator. Heart Rhythm. Aug 2014; 11(8):1352-1358.
17. Gregoratos G, Abrams J, Epstein AE, et al. ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee on Pacemaker Implantation). 2002. www.acc.org/clinical/guidelines/pacemaker/pacemaker.pdf.
18. Groh CA, Sharma S, Pelchovitz DJ, et al. Use of an electrocardiographic screening tool to determine candidacy for a subcutaneous implantable cardioverter-defibrillator. Heart Rhythm. Aug 2014;11(8):1361-1366.
19. Gruberg Luis. DEFINITE: Defibrillators in non-ischemic cardiomyopathy treatment evaluation. American Heart Association Scientific Session 2003. www.medscape.com/viewarticle/464653?src=search.
20. Heidenreich PA, Keeffee B, McDonald KM and Hlatky MA. Overview of randomized trials of antiarrhythmic drugs and devices for the prevention of sudden cardiac death. Am Heart J 2002; 144(3): 422-430.
21. Jessup M AW, Casey DE et al. 2009 focused update: ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the International Society for Heart and Lung Transplantation.

Circulation 2009; 119(14):1977-2016. Available online at: content.onlinejacc.org/cgi/reprintsidebar/53/15/1343. Last accessed November 2009.
22. Kadish A and Goldberger J. Selecting patients for ICD implantation – are clinicians choosing appropriately? JAMA Jan 2011; 305(1): 43-49.
23. Kadish A, Schaechter A, Subacius H, et al. Patients with recently diagnosed nonischemic cardiomyopathy benefit from implantable cardioverter-defibrillators. J Am Coll Cardiol. 2006; 47(12):2477-2482.
24. Kobe J, Reinke F, Meyer C et al. Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators: a multicenter case-control study. Heart Rhythm 2013; 10(1):29-36.
25. Kooiman KM, Knops RE, Olde Nordkamp L, et al. Inappropriate subcutaneous implantable cardioverter-defibrillator shocks due to T-wave oversensing can be prevented: Implications for management. Heart Rhythm. 2014; 11(3):426-434.
26. Kusumoto FM, Calkins H, Boehmer J, et al. HRS/ACC/AHA Expert Consensus Statement on the Use of Implantable Cardioverter-Defibrillator Therapy in Patients Who Are Not Included or Not Well Represented in Clinical Trials. J Am Coll Cardiol. 2014; 64(11):1143-1177.
27. Lambiase PD, Barr C, Theuns DA, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. Eur Heart J. Jul 1 2014; 35(25):1657-1665.
28. Lee DS KA, Healey JS et al. Evaluation of early complications related to De Novo cardioverter-defibrillator implantation insights from the Ontario ICD database. J Am Coll Cardiol 2010; 55(8):774-82.
29. Lewandowski M SM, Maciag A et al. Long-term follow-up of children and young adults treated with implantable cardioverter-defibrillator: the authors' own experience with optimal implantable cardioverter-defibrillator programming. Europace 2010; 12(9):1245-50.
30. Maron BJ SP, Shen WK et al. Implantable cardioverter-defibrillators and prevention of sudden cardiac death in hypertrophic cardiomyopathy. JAMA 2007; 298(4):405-12.
31. Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. NEJM 19996; 335: 1933-1940.
32. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. NEJM 2002; 346: 877-883.
33. Multicenter Automatic Defibrillator Implantation Trial (MADIT): Design and clinical protocol. PACE 1991; 14: 920-927.
34. Nazarian S, Maisel WH, Miles S, et al. Impact of implantable cardioverter defibrillators on survival and recurrent hospitalization in advanced heart failure. Am Heart J 2005; 150(5): 955-960.
35. Nery PB FR, Nair GM et al. Device-related infection among patients with pacemakers and implantable defibrillators: incidence, risk factors, and consequences. J Cardiovasc Electrophysiol 2010; 21(7):786-90.
36. Olde Nordkamp LR, Dabiri Abkenari L, Boersma LV et al. The entirely subcutaneous implantable cardioverter-defibrillator: initial clinical experience in a large Dutch cohort. J Am Coll Cardiol 2012; 60(19):1933-9.

37. Persson R, Earley A, Garlitski AC, et al. Adverse events following implantable cardioverter defibrillator implantation: a systematic review. J Interv Card Electrophysiol. Aug 2014; 40(2):191-205.
38. Phang RS, Kang D, et al. High risk of ventricular arrhythmias in patients with nonischemic dilated cardiomyopathy presenting with syncope. American Journal of Cardiology, February 2006, Vol. 97, No. 3.
39. Raviele A BM, Brignole M et al. Early EPS/ICD strategy in survivors of acute myocardial infarction with severe left ventricular dysfunction on optimal beta-blocker treatment. The Beta-blocker Strategy plus ICD trial. Europace 2005; 7(4):327-37.
40. Ricci RP, Pignalberi C, Magris B et al. Can we predict and prevent adverse events related to high-voltage implantable cardioverter defibrillator lead failure? J Interv Card Electrophysiol 2012; 33(1):113-21.
41. Rome BN, Kramer DB, Kesselheim AS. FDA approval of cardiac implantable electronic devices via original and supplement premarket approval pathways, 1979-2012. *JAMA.* Jan 22-29 2014; 311(4):385-391.
42. Sheppard R, Mather PJ, Alexis JD et al. Implantable cardiac defibrillators and sudden death in recent onset nonischemic cardiomyopathy: results from IMAC2. J Card Fail 2012; 18(9):675-81.
43. Silka M KJ, Dunnigan A et al. Sudden cardiac death and the use of implantable cardioverter-defibrillators in pediatric patients. Circulation 1993; 87(3):800-7.
44. Sohail MR, Hussain S, Le KY et al. Risk factors associated with early- versus late-onset implantable cardioverter-defibrillator infections. J Interv Card Electrophysiol 2011; 31(2):171-83.
45. Steinbeck G, Andersen D, et al. Defibrillator implantation early after myocardial infarction. NEJM, October 2009, Vol. 361, No. 15, pp. 1427-1436.
46. Smit J KE, Schonheyder HC. Infections associated with permanent pacemakers and implanted cardioverter-defibrillator devices. A 10-year regional study in Denmark. Scand J Infect Dis 2010; 42(9):658-64.
47. Tan VH, Wilton SB, Kuriachan V, et al. Impact of programming strategies aimed at reducing nonessential implantable cardioverter defibrillator therapies on mortality: a systematic review and meta-analysis. Circ Arrhythm Electrophysiol. Feb 2014; 7(1):164-170.
48. Theuns D, Klootwijk A, Peter J, et al. Clinical variables predicting inappropriate use of implantable cardioverter-defibrillator in patients with coronary heart disease or nonischemic dilated cardiomyopathy. American Journal of Cardiology, January 2005, Vol. 95, No. 2.
49. Tracy CM, Epstein AE, Darbar D, et al. 2012 ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm AbnormalitiesA Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2013; 61(3):e6-e75.
50. U.S. Food and Drug Administration. Premature Insulation Failure in Recalled Riata Implantable Cardioverter Defibrillator (ICD) Leads Manufactured by St. Jude Medical, Inc.: FDA Safety Communication. 2014;

www.fda.gov/medicaldevices/safety/alertsandnotices/ucm314930.htm. Accessed September, 2014.
51. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data, P01012b, Contak CD CRT-D. www.fda.gov/cdrh/pdf/P010012b.pdf.
52. U. S. Food and Drug Administration. Summary of Safety and Effectiveness Data, P010031b, InSync® ICD. www.fda.gov/cdrh/pdf/P010031b.doc.
53. van Rees JB, et al. Inappropriate implantable cardioverter-defibrillator shocks. Journal of the American College of Cardiology 2011; 57:556-562.
54. Weiss R, Knight BP, Gold MR et al. Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator. Circulation 2013; 128(9):944-53.
55. Wilber DJ, Zareba W, Hall WJ, et al. Time dependence of mortality risk and defibrillator benefit after myocardial infarction. Circulation 2004; 109: 1082-1084.
56. Yancy CW, Jessup M, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. AHA Journal 2013(June 2013).
57. Zecchin M, Merlo M, Pivetta A et al. How can optimization of medical treatment avoid unnecessary implantable cardioverter-defibrillator implantations in patients with idiopathic dilated cardiomyopathy presenting with "SCD-HeFT criteria?". Am. J. Cardiol. 2012; 109(5):729-35.

Policy History:

Medical Policy Group, June 2004 **(4)**
Medical Policy Administration Committee, July 2004
Available for comment July 12-August 25, 2004
Medical Policy Group, February 2006 **(1)**
Medical Policy Administration Committee, February 2006
Available for comment March 4-April 17, 2006
Medical Policy Group, May 2006 **(4)**
Medical Policy Administration Committee, June 2006
Available for comment June 3-July 17, 2006
Medical Policy Group, September 2006 **(2)**
Medical Policy Administration Committee, September 2006
Available for comment September 22-November 5, 2006
Medical Policy Group, August 2008 **(1)**
Medical Policy Administration Committee, August 2008
Available for comment August 13-September 26, 2008
Medical Policy Group, October 2008 **(1)**
Medical Policy Administration Committee, October 2008
Available for comment October 22-December 6, 2008
Medical Policy Group, October 2009 **(1)**
Medical Policy Group, October 2010 **(1):** No literature updates available, no change in policy statement for wearable cardioverter-defibrillator
Medical Policy Group, April 2011; Updated Key Points (2011) and References

Medical Policy Group October 2011 **(1):** Update to Key Points and References; no change in policy statement
Medical Policy Group, December 2011 **(1):** 2012 Code revisions **(3)** and additions **(1)**
Medical Policy Group, April 2012: **(3):** Policy change for wearable defibrillators, Reference
Medical Policy Administration Committee April 2012
Available for comment April 12 through May 28, 2012
Medical Policy Group, December 2012 **(3):** 2013Coding updates: Added range of codes **0319T** through **0328T**; Verbiage update to Codes **93287**, **93289**, **93292**, and **93745**.
Medical Policy Group, December 2012 (**4**)**:** Added sub q defibrillator to Policy, updated Description, Key Points, Approved Governing Bodies, Key Words and References.
Medical Policy Administration Committee February 2013
Available for comment February 21 through April 7, 2013
Medical Policy Group, July 2014 **(4):** Removed portions of policy #168 relating to wearable/external cardioverter defibrillators which are now located on policy #557. Added an indication to policy statement excluding reversible causes, such as acute ischemia, prior to implanting the defibrillator. Also updated Description, Key Points and References.
Medical Policy Administration Committee, August 2014
Available for comment July 24 through September 6, 2014
Medical Policy Panel, October 2014
Medical Policy Group, October 2014 **(3):** 2014 Updates to Description, Key Points, Governing Bodies & References; no change in policy statement

---