



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Automatic Implantable Cardioverter Defibrillator (AICD)

Policy # 00008

Original Effective Date: 05/12/2003

Current Effective Date: 12/18/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: "Biventricular Pacemakers for the Treatment of Congestive Heart Failure." is addressed in medical policy 00009.

ADULTS

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of an automatic implantable cardioverter defibrillator in adults to be **eligible for coverage**.

Primary Prevention

Patient Selection Criteria

Coverage eligibility the use of an automatic implantable cardioverter defibrillator in adults will be considered when the following criteria are met:

- Ischemic cardiomyopathy with New York Heart Association functional Class II or Class III symptoms, a history of myocardial infarction at least 40 days before automatic implantable cardioverter defibrillator treatment, and left ventricular ejection fraction of 35% or less; or
- Ischemic cardiomyopathy with New York Heart Association functional Class I symptoms, a history of myocardial infarction at least 40 days before automatic implantable cardioverter defibrillator 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 with 1 or more major risk factors for sudden cardiac death (history of premature hypertrophic cardiomyopathy-related sudden death in 1 or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 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 hypertrophic cardiomyopathy.

Note: Symptomatic heart failure is defined as the presence of dyspnea on exertion, angina, palpitations or fatigue.



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Secondary Prevention

Patient Selection Criteria

Coverage eligibility for the use of an automatic implantable cardioverter defibrillator in adults will be considered when the following criteria are met:

- As a secondary prevention for patients with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company may consider the use of an automatic implantable cardioverter defibrillator in adults for primary prevention patients in the following situations to be **investigational***:

- Have had an acute myocardial infarction (i.e., less than 40 days before automatic implantable cardioverter defibrillator treatment);
- Have New York Heart Association Class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy automatic implantable cardioverter defibrillator device);
- Have had 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.

Based on review of available data, the Company considers the use of an automatic implantable cardioverter defibrillator when patient selection criteria are not met to be **investigational**.*

PEDIATRICS

Based on review of available data, the Company may consider the use of an automatic implantable cardioverter defibrillator in children to be **eligible for coverage** who meet any of the following criteria:

- Survivors of cardiac arrest, after reversible causes have been excluded;
- Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; or
- Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of the automatic implantable cardioverter defibrillator for all other indications in pediatric patients to be **investigational**.*



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Based on review of available data, the Company considers the use of a subcutaneous ICD **investigational** for all indications in adult and pediatric patients.

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

Background/Overview

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 1) secondary prevention, i.e., their use in patients who have experienced a potentially life-threatening episode of ventricular tachyarrhythmia (VT) (near sudden cardiac death); and 2) primary prevention, i.e., their use in patients who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening VT or 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several automatic ICDs are approved by the U.S. FDA through the premarket application (PMA) approval process. The FDA-labeled indications generally include patients who have experienced life-threatening VT associated with cardiac arrest or VT associated with hemodynamic compromise and resistance to pharmacologic treatment. Devices manufactured by Guidant are approved by the FDA for use "in patients at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced at least 1 of the following: an episode of cardiac arrest (manifested by the loss of consciousness) due to a ventricular tachyarrhythmia; recurrent, poorly tolerated sustained 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, the FDA expanded the approved indications for the Guidant ICD devices to include the prophylactic use of Guidant ICDs for cardiac patients who have had a previous heart attack and have an ejection fraction that is less than or equal to 30%. This



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expanded indication is based on the results of the second Multicenter Automatic Defibrillator Implantation Trial (MADIT II trial), which is discussed here. Medtronic devices are approved "to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias." Other devices have approval language similar to that of Medtronic.

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

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

Centers for Medicare and Medicaid Services (CMS)

In January 2005, Medicare issued the following revised national coverage guideline for the use of ICDs.

The CMS determined that the evidence is adequate to conclude that an ICD is reasonable and necessary for the following:

- Patients with ischemic dilated cardiomyopathy (IDCM), documented prior MI, NYHA Class II and III heart failure, and measured LVEF of 35% or less;
- Patients with nonischemic dilated cardiomyopathy (NIDCM) >9 months, NYHA Class II and III heart failure, and measured LVEF of 35% or less;
- Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure;

For each of these groups, patients must not have:

- Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
- Had a coronary artery bypass graft (CABG) or PTCA within the past 3 months;
- Had an acute MI within the past 40 days;
- Clinical symptoms or findings that would make them a candidate for coronary revascularization;
- Irreversible brain damage from pre-existing cerebral disease;
- Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year;

In addition, CMS specifies that the beneficiary receiving the ICD implantation for primary prevention must be enrolled in either a U.S. FDA-approved category B Investigational Device Exemption clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1), or a qualifying data collection system including approved clinical trials and registries.

The Medicare policy for ischemic and nonischemic dilated cardiomyopathy is consistent with this policy.



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Rationale/Source

This policy was created in 1996 and updated periodically with literature review. The most recent update with literature review covers the period of August 2012 through August 2013.

Automatic 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 MI and a current history of a reduced ejection fraction. The key difference in the 2 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, 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 offered the following observations and conclusions:

- 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 5 randomized clinical trials (RCTs) included in the 2002 Assessment (including the Multicenter Unsustained Tachycardia Trial [MUSTT], MADIT I, MADIT II, CABG Patch Trial, and the Cardiomyopathy Trial [CAT]) and 5 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 observations.

Patients Who Have Prior MI and Reduced LVEF. The previous 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 re-analysis 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 significantly increased rates of adverse effects associated with ICD therapy; however,



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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 to 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 available evidence 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, NIDCM). 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 5 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.

Therefore, the 2004 TEC Assessment made the following conclusions:

ICD placement has been performed and investigated in multiple centers throughout the United States, and when performed by similarly experienced personnel, it is reasonable to expect that the improvements observed in the investigational setting will be attainable outside the investigational settings.

Therefore, the use of ICD devices meets the TEC criteria in the prevention of sudden death from ventricular tachyarrhythmia in patients who have:

- Symptomatic* ischemic dilated cardiomyopathy with a history of MI at least 40 days before ICD treatment and LVEF of 35% or less; or
- Symptomatic* nonischemic 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 3 months (CABG or PTCA) or are candidates for a cardiac revascularization procedure; or
- have noncardiac disease that would be associated with life expectancy less than 1 year.



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*Symptomatic heart failure is defined as the presence of dyspnea on exertion, angina, palpitations, or fatigue.

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.

Subsequent Evidence and Guidelines

Relevant evidence and most current guidelines identified through Medline published following the 2004 TEC Assessment through October 2009 include the following:

- Reports of BEST-ICD [Beta-blocker Strategy + ICD], and IRIS trials
- Implantation timing placing in NIDCM
- ICD implantation in Hypertrophic Cardiomyopathy
- ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities update of the 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death.
- ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult

BEST-ICD trial. The BEST-ICD (Beta-blocker Strategy + ICD) trial randomized 143 patients 5–30 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 1 or more non-invasive risk factors (e.g., premature ventricular contractions, heart rate variability, signal-averaged electrocardiography [SAECG]-positive) and be given maximal tolerated beta-blocker (metoprolol) therapy. The authors concluded that using electrophysiology studies to guide ICD placement within 5–30 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: 1) a heart rate 90 or more beats per minute on initial electrocardiogram (ECG), or 2) nonsustained ventricular tachycardia during Holter monitoring, or both. From 92 centers and 62,944 patients post-MI, 898 were randomized 5 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.



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High-Risk Hypertrophic Cardiomyopathy (HCM). Maron and colleagues reported appropriate ICD discharge rates (terminating either ventricular tachycardia or fibrillation) from an international registry of HCM patients enrolled at 42 referral and nonreferral 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 (standard deviation [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: 1) history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years of age; 2) left-ventricular hypertrophy greater than 30 mm; 3) one or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; and 4) 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 5-year cumulative probabilities of first appropriate discharge were 17% and 39%. If each appropriate discharge was life-saving, 5-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 NIDCM, Ellenbogen and colleagues 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 more than one 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 to non-electrophysiologists (20.8% vs. 24.8%, respectively; $p < 0.001$).

Implantation Timing in Nonischemic Dilated Cardiomyopathy. For patients with nonischemic cardiomyopathy, the optimal timing of ICD implantation remains uncertain. A substantial percent of patients diagnosed with nonischemic cardiomyopathy (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 9-month waiting period prior to ICD implantation arises from the selection criteria of the CAT trial, which restricted enrollment to patients with onset of NICM within 9



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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 NIDCM was associated with the magnitude of benefit from ICD implantation. Survival benefit was found only for those diagnosed less than 9 months prior to implantation (n=216); no benefit was apparent when NIDCM was diagnosed greater than 9 months prior (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 8 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 9 months. Neither of these pieces of evidence represents strong data to support a specific time interval prior to 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 Sudden Cardiac Death in Heart Failure Trial (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 beta 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 prior to optimal treatment and stabilization of patients with newly diagnosed NICM, since 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 National Heart, Lung and Blood Institute (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 1 month of diagnosis, with a 1-year survival for this group of 97%. Three-hundred thirty patients received an ICD between 1 and 6 months, with a 1-year survival of 98%. Seventy-three patients received an ICD at a time period longer than 6 months, with a 1-year survival. Survival at 2 and 3 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



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is not well-characterized. The most recent ACC/AHA guidelines do not specifically address the optimal waiting period prior to implantation of an ICD for patients with newly diagnosed NICM.

Adverse Events

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 2,628 (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.

Lee et al. evaluated the rate of early complications among patients enrolled in a prospective, multi-center 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 45 mm. Direct implant-related complications were associated with a major increase in early death (HR: 24.9, $p < 0.01$).

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 10-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 9 (9.9%) were acute post-surgical 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 2 days vs. 1 day) and chronic obstructive pulmonary disease (OR: 9.8, $p = 0.02$) were significant risk factors.



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Use of AICD (Automatic ICD) in the Pediatric Population

There is limited direct scientific evidence on the efficacy of ICDs in the pediatric population. The majority of 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 below.

The largest published series was a combined series of pediatric patients and patients with congenital heart disease from 4 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 hypertrophic cardiomyopathy. ICD implantation was performed for primary prevention in 52% of patients and for secondary prevention in 48%. Over a 2-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 ventricular tachycardia 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 1 year, 95% at 2 years, and 90% at 5 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 ventricular tachycardia, 40 patients (53%) with syncope, 17 patients (22%) with palpitations, 40 patients (53%) with spontaneous ventricular arrhythmias, and 36 patients (47%) with inducible ventricular tachycardia. Numerous patients had more than one indication for ICD in this study. Over a median of 2 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 6-21 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 psychological 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 pacing for bradycardia, or anti-tachycardia overdrive pacing for VT. There were no RCTs identified that compared the performance of a 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.

Kobe et al. compared the efficacy of the S-ICD and the transvenous ICD in terminating laboratory-induced VF. Sixty-nine patients from 3 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



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both groups were followed for a mean of 217 days. One patient in the S-ICD group had the device explanted at 8 weeks due to local infection, and a second patient had the S-ICD changed to a transvenous ICD because of the need for anti-tachycardia overdrive pacing due to frequent episodes of VT. There were 3 patients in the S-ICD group who received appropriate shocks for ventricular arrhythmias compared to 9 patients in the transvenous group ($p=0.05$). Inappropriate shocks occurred in 5 patients in the S-ICD group and 3 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 an S-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 S-ICD and 99% for the transvenous ICD. Specificity was 98.0% for the S-ICD device compared to 76.7% for the transvenous device ($p<0.001$).

A number of single-arm studies have been published that report on outcomes of patients treated with an S-ICD. The largest series identified was a multicenter study including 330 patients from several countries. The S-ICD was successfully implanted in 314/330 patients (95.1%). Laboratory-induced VF was successfully terminated in greater than 90% of patients, which was one 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%).

In 2010, Bardy et al. described the development and testing of the device, including empiric evidence for the optimal placement of the subcutaneous electrode. 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 53/55. All episodes were correctly detected by the subcutaneous ICD. In 52/53 patients, 2 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, 54/55 patients were alive at last follow-up. The one death was due to renal failure, and this patient requested removal of the subcutaneous ICD prior to death. An infection at the generator site occurred in 2 patients, necessitating a revision procedure. Another 3 patients had lead dislodgement requiring repositioning. There were a total of 12 episodes of ventricular tachycardia that were detected by the S-ICD; all 12 episodes were successfully terminated by countershock.

A series of 118 patients from 4 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 anti-tachycardia pacing. Over the entire follow-up period, 8 patients experienced 45 appropriate shocks, with a first-shock



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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.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

In response to requests, input was received from no physician specialty societies and 6 academic medical centers while this policy was under review in 2011. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

For most policy indications, including pediatric indications, there was agreement from those providing input. On the question of timing of ICD implantation, input was mixed, with some commenting about the potential role of early implantation in selected patients. Reviewers indicated that a waiting period of 9 months for patients with nonischemic cardiomyopathy was not supported by the available evidence or consistent with the prevailing practice patterns in academic medical centers. Specialty society input emphasized the difficulty of prescribing strict timeframes given the uncertainty of establishing the onset of cardiomyopathy and the inability to risk stratify patients based on time since onset of cardiomyopathy.

Summary

There is an extensive literature base on the use of ICDs in patients with prior arrhythmogenic events and ischemic cardiomyopathy. Earlier trials first demonstrated a benefit in overall mortality for survivors of cardiac arrest and patients with potentially lethal cardiac arrhythmias. Multiple well-done RCTs have also 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 MI do not support a benefit for immediate ICD implantation versus delayed implantation for at least 40 days.

For 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 the majority of 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 S-ICD has been developed that does not employ transvenous leads. Evidence from non-randomized 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



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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. 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.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0319T, 0320T, 0321T, 0322T, 0323T, 0324T, 0325T, 0326T, 0327T, 0328T, 33215, 33216, 33217, 333218, 22330, 33223, 33224, 33225, 33226, 33230, 33231, 33240, 33241, 33243, 33244, 33245, 33246, 33249, 33262, 33263, 33264, 93283, 93284, 93287, 93289, 93295, 93296, 93640, 93641, 93642
HCPCS	C1721, C1722, C1882, C1895, C1896, C1899
ICD-9 Diagnosis	425.11, 425.4, 427.1, 427.41, 427.9, 745.0 thru 745.9
ICD-9 Procedure	00.51, 37.94, 37.95, 37.96, 37.97, 37.98

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04/25/2003	Medical Policy Committee review
05/12/2003	Managed Care Advisory Council approval
06/01/2004	Medical Director review
06/15/2004	Medical Policy Committee review Format revision. No substance change to policy.
06/28/2004	Managed Care Advisory Council approval
04/05/2005	Medical Director review
04/18/2005	Medical Director review
04/22/2005	Medical Director review
04/27/2005	Medical Policy Committee approval. Investigational designation for specific clinical scenarios added. Clinical criteria revision.
05/23/2005	Managed Care Advisory Council approval
05/03/2006	Medical Director review Format Revisions. Government regulations, literature updated; no change in policy statement.
05/17/2006	Medical Policy Committee review
08/15/2007	Medical Policy Committee review. Policy statement not medically necessary when patient selection criteria not met changed to investigational. Removed not medically necessary policy statement for selected conditions.
12/12/2007	Medical Director review
12/19/2007	Medical Policy Committee approval. No change to coverage eligibility. CMS added. FDA updated.
12/03/2008	Medical Director review
12/17/2008	Medical Policy Committee approval. Changed format and coverage by adopting BCBSA's.
12/04/2009	Medical Policy Committee approval
12/16/2009	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2010	Medical Policy Committee approval
12/15/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/08/2011	Medical Policy Committee review
12/21/2011	Medical Policy Implementation Committee approval. Policy statements specific to AICD indications in pediatric patients added to coverage section and Rationale. Policy statement revised to clarify the indications in ischemic cardiomyopathy with separate indications for class II/III and class I patients. Policy statement with waiting time in nonischemic cardiomyopathy was revised.
12/06/2012	Medical Policy Committee review

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12/19/2012 Medical Policy Implementation Committee approval. Added new investigational statement "Based on review of available data, the Company considers the use of a subcutaneous ICD investigational for all indications in adult and pediatric patients."

02/04/2013 Coding revised

12/12/2013 Medical Policy Committee review

12/18/2013 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 12/2014

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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