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FOCUSED REPORT: Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy (CRT)

Implications for Driving a Commercial Motor Vehicle (CMV)

The use of pacemakers and implantable cardiac defibrillators (ICDs) in the treatment of heart failure and cardiac arrhythmias has advanced substantially over the last decade. Reimbursable indications have expanded to include prophylactic treatment or primary prevention of various cardiovascular diseases (CVDs). Similarly, the use of pacemakers combined with an ICD (cardiac resynchronization therapy-CRT) for the treatment of various stages of heart failure has become a growing option. The Federal Motor Carrier Safety Administration (FMCSA) has commissioned this focused report to inform its position on the use of ICDs—in particular dual-functioning ICD-pacemaker devices—in interstate CMV drivers.

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About this Document

This document was produced by request from and under contract with the U.S. Department of Transportation's (DOT's) Federal Motor Carrier Safety Administration (FMCSA). This document is intended to provide a focused assessment of current indications for and use of implantable cardioverter defibrillators (ICDs) combined with pacemakers in the general population, and implications for CMV drivers relative to FMCSA's medical qualifications for driving.

Table of Contents

List of Tables

Section 1: Background

Introduction

The Federal Motor Carrier Safety Administration (FMCSA) has defined and codified in regulation specified in 49 CFR Part 391 of the Federal Motor Carrier Safety Regulations (FMCSRs) medical fitness for duty requirements intended to ensure that truck and bus drivers are capable of safely carrying out the activities of their job.

Among the medical conditions that FMCSA has established medical fitness standards for is cardiovascular disease (CVD). CVD encompasses a broad range of disorders that affect the heart or blood vessels, including cardiac arrhythmias, cardiomyopathy, coronary artery disease (CAD), heart failure (HF), hypertension, myocardial infarction (MI), and stroke.

Conditions captured under the broad umbrella of CVDs have the highest prevalence rates of all diseases in the United States. For instance, in 2005, an estimated 80.7 million American adults (one in three) had one or more types of CVD. In addition, in 2005 (most recent data available) CVD was the leading cause of death in the United States accounting for more than a third (~862,000) of the ~2.4 million deaths (Kung, et al., 2008).

Because CVDs can cause sudden incapacitation or death, they are diseases of concern to FMCSA in regulating physical health requirements for interstate CMV drivers. FMCSA's current physical qualification standards for individuals with CVD, including hypertension, are presented in Table 1.

Table 1: FMCSA's Current Cardiovascular Regulations

49 CFR 391.41(b)(4) & (6) A person is physically qualified to drive a commercial motor vehicle if that person:
(4) Has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive cardiac failure; (6) Has no current clinical diagnosis of high blood pressure likely to interfere with his/her ability to operate a commercial motor vehicle safely;

In addition to the rules stated above, medical guidance has been developed by an advisory panel of medical experts to assist medical examiners when evaluating drivers. Under the current guidance, available at http://www.fmcsa.dot.gov/rules-regulations/administration/medical.htm, FMCSA has identified a number of criteria that disqualify drivers from receiving the necessary medical certification to drive a CMV or trigger additional testing of the driver by a cardiovascular specialist. One disqualifying condition that is the subject of this report is the use of an implantable cardioverter defibrillator (ICD) in drivers, because of their association with syncope, sudden incapacitation, and death, all of which could be catastrophic for a driver behind the wheel of a CMV or passenger-carrying bus.

Current FMCSA CVD Advisory Panel guidelines on the use of pacemakers and implantable defibrillators are summarized in Table 2. Under the current guidance, individuals with an ICD are barred from driving a CMV. Individuals with a pacemaker are permitted to drive beginning one to three months following the implantation of the device if they are symptom free.

Table 2: FMCSA CVD Advisory Panel Guidelines on Pacemakers and Implantable Defibrillators

Diagnosis	Physiology/ Functional	Recertification	Re-certification
Pacemakers			
Sinus Node Dysfunction	Variable long-term prognosis depending on underlying disease, but cerebral hypoperfusion corrected by support of heart rate by pacemaker.	No	
		Yes if: • 1 month after pacemaker implantation; documented correct function by pacemaker center; • Underlying disease is not disqualifying.	Annual Documented pacemaker checks.
Atrioventricular (AV) Block	Variable long-term prognosis depending on underlying disease, but cerebral hypoperfusion corrected by support of heart rate by pacemaker.	No	
		Yes if: • 1 month after pacemaker implantation and documented correct function by pacemaker center; • Underlying disease is not disqualifying.	Annual Documented pacemaker checks.
Neurocardiogenic Syncope	Excellent long-term survival prognosis but there is risk for syncope that may be caused by cardioinhibitory (slowing heart rate) or vasodepressor (drop in blood pressure) components, or both. Pacemaker will affect only cardioinhibitory component, but will lessen effect of vasodepressor component.	No, with symptoms.	
		Yes if: • 3 months after pacemaker implantation; • Documented correct function by pacemaker center; • Absence of symptom recurrence.	Annual Documented pacemaker checks; Absence of symptom recurrence.
Hypersensitive Carotid Sinus with Syncope	Excellent long-term survival prognosis but risk for syncope that may be caused by cardioinhibitory (slowing heart rate) or vasodepressor (drop in blood pressure) components, or both. Pacemaker will affect only cardioinhibitory component, but will lessen effect of vasodepressor component.	No, with symptoms.	
		Yes if: • 3 months after pacemaker implantation; • Documented correct function by pacemaker center; • Absence of symptom recurrence.	Annual Documented regular pacemaker checks; and absence of symptom recurrence.
Implantable Cardiac Defibrillators			
Primary Prevention	Patient has high risk of death or sudden incapacitation.	No	
Secondary Prevention	Patient demonstrated to have high risk of death or sudden incapacitation.	No	

Topic of the Current Report

The use of pacemakers and ICDs in the treatment of heart failure and cardiac arrhythmias has advanced substantially over the last decade. For example, during an episode of ventricular arrhythmia, early ICD devices often took up to 15 seconds or more to recognize an arrhythmic problem, charge, and defibrillate. As a result, such patients were likely to experience a syncopal or near-syncopal episode as the device attempted to respond to the arrhythmic event, presenting a significant concern about an individual's ability to safely operate a motor vehicle following implantation of such a device. Other factors also contributed to the ongoing concerns about driving safety in individuals with an implanted ICD, including the fact that ICDs, while effective, do not completely eliminate the risk for sudden cardiac death (SCD). In addition,

ICD discharges, appropriate or not, can startle or temporarily incapacitate a patient and thereby disrupt safe motor vehicle operation. As a result, a number of professional bodies and government organizations continue to recommend driving restrictions on individuals following implantation of an ICD.

In recent years, however, the function of these devices has improved dramatically, significantly reducing the likelihood of incapacitating events with device discharge. In addition, the indications for the use of the devices have expanded greatly to include prophylactic treatment or primary prevention of various CVDs. Similarly, the use of pacemakers combined with an ICD for the treatment of various stages of heart failure has become a growing option, thus necessitating re-examination of the current rule and guidance regarding use of these devices and driving qualifications.

The current report was commissioned by the FMCSA to inform its position on the use of ICDs—in particular dual-functioning ICD-pacemaker devices—in interstate CMV drivers.

Document Scope

The purpose of this focused report is to address several key questions posed by the FMCSA on the use of dual-functioning implantable cardioverter defibrillators (ICDs) and pacemaker devices.

Specifically, this document summarizes:

- Current indications for the use of ICDs, specifically, dual-functioning ICD-pacemaker devices
- National standards and guidelines for the use of these devices, as well as existing recommendations on driving
- Medicare coverage policies (i.e., for whom and under what circumstances)
- FDA-approved devices and current indications
- Implications for commercial drivers given current physical requirements defined and codified in regulation §391.41 of the Federal Motor Carrier Safety Regulations (FMCSRs)

Document Layout

The format of this report is:

- **Section 1** identifies the scope of this report
- **Section 2** presents a brief background about the technology
- **Section 3** presents the current discussion of indications for the use of ICD-pacing devices, including discussion of:
    - clinical trials that have evaluated the use of ICD-pacing devices,
    - other systematic reviews on the use of these devices,
    - current evidence-based guidelines on the recommended use of these devices,
    - Medicare and Medicaid coverage policies for the use of ICDs, AND
    - indications by the U.S. Food and Drug Administration (FDA) for currently approved devices
- **Section 4** provides a brief summary of the implications for CMV drivers

Section 2: Cardiac Medical Devices

The human body has an internal electrical system that controls the synchronized pumping action of the four heart chambers (two upper atria and two lower ventricles). The normal heartbeat originates in a section of the right atrium known as the sinoatrial (SA) node, which is considered the internal pacemaker of the heart. The electrical signal from the SA node spreads through both atria causing them to contract and move blood into the ventricles. The electrical signal then passes through an electrical bridge known as the atrioventricular (AV) node. After a split-second delay, the signal continues to the ventricles by way of a specialized network known as the left and right bundle branches. The bundle branches separate into the left and right ventricles, which enables the electrical signal to stimulate both ventricles simultaneously. The ventricles then contract and send blood to the rest of the body. The combined contraction of the atria and ventricles constitutes a heartbeat. This coordinated contraction, or squeezing, of the ventricles is necessary for optimal pumping of blood to the body (from the left ventricle) and lungs (from the right ventricle).

A delay or problem in any component of this system can result in an arrhythmia. During an arrhythmia, the heart can beat too fast, too slow, or with an irregular rhythm. Such conditions are treated with a variety of methods including pharmacological therapy or cardiac stimulation devices, such as pacemakers, ICDs, or dual-functioning ICD-pacemakers. Other cardiovascular conditions, such as a previous heart attack, hypertension, coronary artery disease, etc., can significantly weaken or stress the heart, leading to heart failure. Chronic heart failure can also result in life-threatening arrhythmias that can be treated with pacemakers, ICDs, or dual-functioning ICD-pacemakers, the subject of this report.

In this section we briefly describe these devices and how they are differ one from another (in terms of functionality and the conditions they treat). While ICD technology is the focus of this short report, some background on pacemakers is necessary given advances in device technology that have combined the use of defibrillators and pacing (e.g., dual-functioning ICD-pacemakers) to treat a variety of conditions.

Pacemakers and ICDs

Pacemakers

A pacemaker is a small, battery-powered device implanted permanently into the body to monitor the electrical impulses in the heart. It continuously monitors the heart rate and when necessary, delivers small electrical signals that keep the heart beating at the correct pace. Originally, indications for pacemaker therapy included the treatment of bradycardias—slowing of heart rate or atrial fibrillation. With recent advances in pacemaker technology, indications have expanded to include some tachyarrhythmias (fast heart rates), certain types of syncope, and advanced heart failure.

The pacemaker is connected to the heart using one to three insulated wires (leads) that are attached directly to the heart's chambers. Several basic types exist to serve different purposes (see Table 3). These range from simple single-chamber, fixed-rate pacemakers (e.g., original devices) to multi-chamber, rate-responsive units capable of pacing, cardioversion, and defibrillation (more recent devices and relevant to the topic of this report).

Arrhythmias that result from sinus node dysfunction or atrial ventricular block are typically treated with pacemakers. The dual-chamber pacemaker, composed of two leads (one to the right atrium and one to the right ventricle), has the ability to synchronize the contraction of the atrium and ventricle to more closely resemble the natural action of the heart. These are often preferred by physicians and used more often over single-chamber devices (lead to the right atrium). Single-chamber pacemakers, although used less frequently, are still indicated for the treatment of sinus node dysfunction when the flow of electrical impulses between the upper and lower chambers of the patient's heart is normal.

In addition to the two leads (right atrium and right ventricle) used by dual-chamber pacemakers, biventricular pacing devices have a third lead positioned in a vein on the surface of the left ventricle. With heart failure, often the right and left ventricles do not pump together, diminishing the ability of the heart to pump blood to the body. Biventricular pacing (also called cardiac resynchronization therapy or CRT) is used to help synchronize the right and left ventricles. Additional discussion of biventricular pacing devices is provided in the section, Pacemakers and ICDs in Heart Failure.

Table 3: Types of Pacemakers

Type (number of chambers innervated)	**Description**	**Fixed Rate vs. Rate Responsive**
Single-Chambered Pacemakers	These pacemakers use only one lead placed into the right upper chamber of the heart (right atrium typically to treat sinus node dysfunction) or the right lower chamber (right ventricle to treat atrial fibrillation).	Rate-responsive pacemakers may be programmed to increase or decrease heart rate to match the patient's activities (i.e., resting or walking). **NOTE**: In the year 2000, roughly 97% of pacemakers implanted in the United States had rate-responsive pacemakers
Dual-Chambered Pacemakers	These pacemakers have two leads. One is placed in the right atrium and the other in the right ventricle (used more frequently than single-chamber models to treat sinus node dysfunction or atrial ventricular block).	
Biventricular Pacemakers **Cardiac Resynchronization Therapy*	These pacemakers have three leads. One is in the right atrium, one is in the right ventricle, and one is placed through the heart's veins to the left ventricle. These types of pacing devices are referred to as **CRT-P** devices. These pacemakers can also include cardiac defibrillator capabilities (referred to as **CRT-D**).	

ICDs

An ICD is a device designed to quickly detect a life-threatening, rapid or asynchronous heartbeat coming from the bottom chambers (ventricles) of the heart. It tries to convert an abnormal rhythm back to normal by delivering an electrical shock to the heart. ICDs have traditionally been used as secondary prevention for individuals who have suffered ventricular tachycardia or ventricular fibrillation (the most severe arrhythmias). The most common causes of ventricular arrhythmias are a previous heart attack, which weakens or scars the myocardium, or ischemic heart disease. More recently, however, ICDs are being used for primary prevention in patients who are at risk of ventricular arrhythmias because of previous cardiac arrest, heart failure, or ineffective drug therapy for abnormal heart rhythms.

Current indications for an ICD include (*refer to **Appendix A** for current complete listing of indications as provided by the American College of Cardiology Foundation and the American Heart Association*):

- **A prior cardiac arrest** (myocardial infarction)
- **Ventricular tachycardia** (VT): an episode of rapid heartbeat originating from the lower chambers of the heart
- **Ventricular fibrillation** (VF): is similar to VT but characterized by a heartbeat that is too rapid and is irregular or chaotic
- **Ejection fractions of less than 30% to 40%** (depending on the associated condition): the proportion, or fraction, of blood pumped by the heart with each beat. A normal heart pumps out a

little more than half the heart's volume of blood with each beat, making a normal EF 55% or higher
- Patients at high risk for sudden cardiac death (SCD) because of an inherited heart abnormality

Similar to pacemakers, ICDs are small devices, about the size of a pager, that are placed below the collarbone to continuously monitor the heart's rhythm. The ICD has two component parts: the lead(s) and a pulse generator. The lead(s) monitor the heart rhythm and deliver energy used for pacing and defibrillation. The generator houses the battery and a tiny computer. Energy is stored in the battery until it is needed. The computer receives information from the leads to determine what rhythm is occurring.

As with pacemakers, there are different types of ICDs.

- **Single-chamber ICD**: A lead is attached in the right ventricle
- **Dual-chamber ICD**: Leads are attached in the right atrium and the right ventricle
- ***Biventricular ICD**: Leads are attached in the right atrium, the right ventricle, and the left ventricle. *This technique is specifically used for patients with heart failure to resynchronize the contractions of the ventricles (**CRT**), as described above with biventricular pacing; however, these devices also have defibrillator capabilities (**CRT-D**).*

Hospital Discharge Statistics for Pacemakers, ICDs, and CRT

Pacemakers: According to the Agency for Healthcare Research and Quality's (AHRQ's) Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS), about 77,000 patients were discharged from hospitals following initial implantation or re-implantation of a single or double-chamber pacemaker, or a biventricular pacemaker (CRT-P) in 2006. More than 77% of implants were dual-chamber pacemakers. Fewer than 15% were single-chamber pacemakers. In both instances, the majority (>85%) were placed in patients older than 65. Approximately 6,200 patients were discharged following implantation of a biventricular pacing device (CRT-P), accounting for only 8% of pacing devices.

ICDs: According to the AHRQ's HCUP NIS, in 2002 approximately 68,000 patients were discharged from hospitals following initial implantation of an ICD. Nearly all of these (97%) were patients discharged following a standard (single- or dual-chamber) ICD device with approximately 3% having received a CRT-D device.

In 2006, the number of patients discharged following implantation of an ICD had doubled (~137,000) with close to 40% (~50,000) receiving a CRT-D device. The majority (~55%–68% for CRT-D and standard ICDs, respectively) were aged 65 or older. However, a reasonably significant percentage of individuals (28% to 37% for CRT-D and standard ICDs, respectively) were aged 45 to 64.

This increase is explained in large part by changes in Medicare reimbursement occurring in both 2003 and 2005 that expanded coverage to include conditions that lead to sudden cardiac death (primary prevention) and the use of CRT (approved in 2005 for certain indications).

Pacemakers and ICDs in Heart Failure

As mortality from myocardial infarction has decreased because of improved treatment, the number of persons living with congestive heart failure (CHF) has increased. Heart failure is the only major cardiovascular disorder that is increasing in incidence and prevalence; roughly 5 million people in the United States have this disorder (American Heart Association, 2006). More than half of the deaths caused by heart failure are from SCD. The remainder are caused by progressive heart failure.

CRT to Treat Heart Failure

While ICDs provide effective therapy for arrhythmic episodes of VT or VF, they do not address the underlying pathophysiologic processes in the heart that lead to an increased risk of SCD. Heart failure is

a progressive disease, and the mechanisms used to compensate for inefficient cardiac pumping can, over time, change the architecture of the left ventricle—a process known as ventricular remodeling. One of the principal changes that occur with LV dysfunction is that healthy cardiac muscle cells are replaced by fibrotic tissue. Electrical conduction through fibrotic tissue is much slower than through normal cardiac cells, and this delay can lead to conduction system abnormalities, which cause the heart to contract in an uncoordinated manner, causing reduced systolic function and increased systolic volume.

CRT emerged as a therapy to manage symptoms in patients with heart failure and intraventricular conduction delays as well as potentially reduce the deterioration in cardiac function caused by this ventricular dyssynchrony.

CRT specifically targets the adverse effects of ventricular dyssynchrony. In patients with primary or secondary dilated cardiomyopathies characterized by intraventricular conduction delays, a CRT device uses two ventricular leads that simultaneously stimulate the left and right ventricles, leading to coordinated lateral and septal wall contraction and improved ventricular systolic function. This process, referred to as CRT, aims to relieve symptoms of CHF by improving the coordination of the heart's contractions. CRT builds on the technology used in pacemakers and ICDs. CRT devices can also protect the patient from slow and fast heart rhythms.

The ideal candidate for a CRT device is someone with:

- Moderate to severe CHF symptoms, despite lifestyle changes and medication
- A weakened and enlarged heart muscle
- A significant electrical delay in the lower pumping chambers (bundle branch block)

CRT-D Device

As described above for CRT pacemakers, some CRT candidates also have a high risk of SCD. For these patients, defibrillation with an ICD may be necessary. The CRT-D device (biventricular ICD) incorporates a standard ICD with a CRT pacemaker, creating a dual-functioning ICD-pacemaker.

Section 3: Current Indications for CRT-P and CRT-D – *Clinical Trials, Current Guidelines, Medicare Coverage, and Food and Drug Administration (FDA)-Approved Devices*

This section addresses results of clinical trials on the use of CRT, including discussion of patients included in these trials. This is relevant to the current discussion in order to critically evaluate the characteristics of individuals for whom this treatment option is being used. We also describe current indications of currently approved FDA CRT-D devices to assess the characteristics of individuals for whom this treatment option has been approved. Last, we present recommendations of the most current evidence-based guidelines from professional associations, such as the American College of Cardiology Foundation and the American Heart Association, on the use of these devices.

The goal of this section is to characterize the group of patients who are most likely to receive CRT-D as a treatment option, and the potential implications for drivers and current FMCSA CMV driver qualifications.

Clinical Trials of CRT and CRT-D

ICDs have traditionally been approved and recommended for use in the secondary treatment of patients with SCA. Over the past decade, however, a number of trials have evaluated the use of ICD therapy for primary prevention. These trials have focused specifically on reducing total cardiac mortality rates by reducing the risk of sudden cardiac arrest in post-MI patients with impaired LV function. The results of these primary prevention trials are summarized in Table 4. Generally speaking, these trials affirmed that prophylactic ICDs for the prevention of SCD are effective. However, under FMCSA's current guidance, individuals treated with an ICD for primary prevention are not qualified to drive a CMV. This is largely because these individuals have left ventricular ejection fractions (LVEFs) of ≤35%, along with other symptoms such as inducible ventricular arrhythmias that continue to place them at significant risk of SCA or sudden incapacitation from an arrhythmic event.

Table 4: ICD Trials for the Primary Prevention of Sudden Cardiac Death

Trial (Year)	Patients (N)	Primary Outcome
MADIT I (1996)	NYHA I, II, or III; prior MI; LVEF ≤ 35%, nonsustained VT; inducible nonsuppressible ventricular arrhythmia on EPS (N = 196)	ICD resulted in a 56% reduction in total mortality (*P* = .009)
CABG Patch (1997)	LVEF ≤ 35%, abnormal SAECG, undergoing elective CABG (N = 900)	ICD had a neutral effect on total mortality
MUSTT (1999)	Coronary artery disease, LVEF ≤ 40%, nonsustained VT, inducible sustained VT on EPS (N = 704)	ICD resulted in a 76% RR reduction in the primary end point (cardiac arrest or death from arrhythmia) (*P* = .001)
MADIT II (2002)	Prior MI, LVEF ≤ 30% (N = 1232)	ICD resulted in a 31% RR reduction in total mortality (*P* = .016)
DEFINITE (2004)	Nonischemic cardiomyopathy, LVEF < 36%, PVCs or nonsustained VT (N = 458)	ICD resulted in a 35% RR reduction in total mortality (*P* = .08)
SCD-HeFT (2004)	NYHA class II and III, LVEF ≤ 35% (N = 2521)	ICD resulted in a 23% RR reduction in total mortality (*P* = .007)
DINAMIT (2004)	Within 4-40 days of MI, LVEF ≤ 35% and either depressed heart rate variability or an elevated average heart rate (N = 674)	ICD had a neutral effect on total mortality

CABG = coronary artery bypass graft surgery; DEFINITE = Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation; DINAMIT = Defibrillator in Acute Myocardial Infarction Trial; EPS = electrophysiologic study; ICD = implantable cardioverter defibrillator; LVEF = left ventricular ejection fraction; MADIT = Multicenter Automatic Defibrillator Implantation Trial; MI = myocardial infarction; MUSTT = Multicenter Unsustained Tachycardia Trial; NYHA = New York Heart Association Class; PVC = premature ventricular complex; RR = relative risk; SAECG = signal averaged electrocardiogram; SCD-HeFT = Sudden Cardiac Death in Heart Failure Trial; VT = ventricular tachycardia

More recently, two multicenter prospective clinical trials (detailed in Table 5) have examined the effectiveness of CRT-D devices in decreasing mortality in patients with heart failure without ventricular arrhythmias.

- Multicenter InSync Randomized Clinical Evaluation (**MIRACLE**) ICD Study (Abraham, et al., 2002)
- Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure or **COMPANION** (Bristow, et al., 2004)

One of the first trials to evaluate the effectiveness of CRT-D therapy on mortality was the **MIRACLE** ICD Study. This study was performed following the MIRACLE CRT study that examined the effectiveness of CRT (without ICD) for patients with heart failure.

The MIRACLE ICD study enrolled 369 patients implanted with a combined CRT/ICD device (InSync ICD; Medtronic Inc; Minneapolis, MN). Patients were randomized to either CRT off (control, n = 182) or CRT on (n = 187) for 6 months. ICD function was activated in all patients. In the CRT group, the device was programmed to pace both ventricles simultaneously following atrial-sensed events at rates of $\leq$130 beats per min (bpm). Atrial pacing occurred only for sinus rates of $\leq$35 bpm. In the control group, the device was programmed to inhibit atrial or ventricular pacing unless the intrinsic rate was <35 bpm.

Primary endpoints of the trial were changes in NYHA Functional Class[1], quality-of-life score, and distance covered in the six-minute walking test at baseline and six months. Among other secondary endpoints also evaluated were changes in peak $V0_2$, treadmill exercise duration, LVEF, LV end-systolic and end-diastolic volumes, LV end-diastolic dimension, severity of mitral regurgitation, QRS duration, and a clinical composite response that assigned patients a rating of worsened, improved, or unchanged.

CRT-D patients were observed to have significant improvement in quality-of-life score, compared with ICD-only controls (P = .02), as well as significantly greater median decrease in NYHA functional class (P = .007). However, there was no significant difference between the two groups in median distance covered during six-minute walking at baseline and at six months.

In addition, there was no significant difference between the two groups in terms of ICD detection times for ventricular fibrillation episodes or in the number of patients receiving either appropriate or inappropriate ICD shocks during the six-month evaluation period. This suggests that the group receiving CRT incurred no added benefit from the additional resynchronization therapy they received. Both groups had similar cumulative survival rates at six-month follow-up; a total of 15 patients in the control group and 14 patients in the CRT group died during the study, and three deaths in each group were attributed to SCD.

The authors attribute these findings to the fact that compared with patients in the previous MIRACLE CRT trial (Abraham, et al., 2002), the MIRACLE ICD patients tended be more ill with an indication for an ICD, and thus, may have had less chance for any morphometric remodeling benefits associated with CRT. The authors further noted that the study was not designed nor powered to detect differences in survival, adding that the six-month follow-up period may have been too short to detect differences in hospitalization rates.

A subsequent trial, referred to as the **COMPANION** trial, was the first sufficiently powered to evaluate the effects of CRT-D on the incidence of death and hospitalization. The study was a parallel, randomized,

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[1] **New York Heart Association (NYHA) Classification**: A functional and therapeutic classification for prescription of physical activity for cardiac patients.

Class I: patients with no limitation of activities— suffer no symptoms from ordinary activities.
Class II: patients with slight, mild limitation of activity—comfortable with rest or with mild exertion.
Class III: patients with marked limitation of activity—comfortable only at rest.
Class IV: patients who should be at complete rest, confined to bed or chair—any physical activity brings on discomfort and symptoms occur at rest.

open-label, three-arm trial enrolling 1,520 patients with advanced HF (NYHA functional class III/IV), LVEF≤35%, and a QRS interval of >120 milliseconds (ms) (*Note: the QRS complex is a structure on the electrocardiogram (ECG) that corresponds to the depolarization of the ventricles. The QRS duration is the period of time from the initial deflection of the QRS complex from the isoelectric line to the end of the QRS complex. In normal sinus rhythm, each P wave is followed by a QRS complex. The QRS complex represents the time it takes for depolarization of the ventricles. Activation of the anterioseptal region of the ventricular myocardium corresponds to the negative Q wave. The Q wave is not always present. Activation of the rest of the ventricular muscle from the endocardial surface corresponds to the rest of the QRS wave. The R wave is the point when half of the ventricular myocardium has been depolarized. Activation of the posteriobasal portion of the ventricles give the RS line. The normal QRS duration range is from 0.04 sec to 0.12 sec measured from the initial deflection of the QRS from the isoelectric line to the end of the QRS complex.*). Patients were also required to have no clinical indication for a pacemaker or defibrillator and had to have been hospitalized within the previous year for treatment of HF. All patients were treated with medical therapy, a regimen that consisted of beta-blockers, diuretics as needed, angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs), and spironolactone.

Patients were randomized in a nonblinded fashion to receive either medical therapy alone (n = 308), medical therapy + CRT pacing alone (CRT-P) (n = 617), or medical therapy + CRT-D (n = 595). Most patients (mean age, 67 years) were male, were in NYHA class III HF, had significantly impaired LV function (LVEF <23%), and had widened QRS intervals at an average of 160 ms.

The trial's primary end point was the composite of death from any cause or hospitalization from any cause at 12 months. Secondary end points included all-cause death as well as the composite of death from HF or hospitalization for HF; other outcome variables, including NYHA class, six-minute hall walk distance, and quality of life, were also assessed at three and six months.

Trial investigators found that the risk of death or hospitalization from any cause was significantly reduced by either CRT-P or CRT-D therapy. Overall, CRT-P and CRT-D similarly reduced the risk for this primary end point by approximately 20% compared with medical therapy alone. However, the survival benefits were more pronounced in the CRT-D group than in the CRT-P group.

The results from the **COMPANION** trial show that for HF patients with conduction system disease, both CRT-P and CRT-D reduce HF hospitalizations and improve HF symptoms. The therapies also reduce the risk of sudden death, as well as all-cause mortality. In addition, the results in the CRT-D arm of the study suggest that defibrillators can still work in a population of patients with advanced HF.

CRT alone and CRT plus an implantable cardioverter defibrillator were more effective than optimal medical treatment in reducing morbidity and all-cause mortality in patients with moderate to severe heart failure.

The COMPANION and CARE-HF trials suggest that, in selected patients, CRT pacing alone or CRT-D can improve the clinical course of patients with chronic HF and markers of LV dyssynchrony.

Patient Characteristics for CRT-D

To summarize, patients included in these trials had advanced HF. In both studies, patients had NYHA classification III or IV, with LVEF $\leq$35% and a QRS interval of $\geq$120 ms.

Device Complications

Data from the clinical trials described above show that the complication rate of device implantation increases as the complexity of devices increases. After device insertion, complications can be associated with the leads or with the device generator. Lead complications include lead dislodgement, loose setscrew, lead fracture, lead insulation defect, and fluid within the ICD connector (Alter, et al., 2005;

Gradaus, et al., 2003; Niu, et al., 2006). Complications or problems related to the device generator include malfunction during testing, premature battery depletion, erosion of pulse generator, and manufacturer recall (Alter, et al., 2005). The most common complications or problems are lead-related complications and inappropriate shocks, each of which occurs in 12% of recipients; procedure-related complications, which occur in 10%; generator-related complications, which occur in 6%; and manufacturer recall, which occurs in 4% (Alter, et al., 2005).

Table 5: Clinical Trial Comparison

TRIAL INFO	MIRACLE ICD-2002	COMPANION-2004
Primary sponsor	InSync ICD; Medtronic, Inc	Guidant Corporation (now part of Boston Scientific Corp, Natick, MA)
Purpose	To examine the efficacy and safety of combined CRT-D and ICD therapy in patients with New York Heart Association (NYHA) class III or IV congestive CHF despite appropriate medical management.	To test the hypotheses that prophylactic CRT with or without an ICD reduces mortality and morbidity of patients with moderate to severe heart failure (NYHA class III and class IV) and prolonged QRS duration.
Device(s) used	ICD –vs– CRT-D	Medical Therapy –vs– Medical therapy + CRT-P –vs– Medical therapy + CRT-D
Design of trial	Randomized, double-blind, parallel-controlled trial conducted from October 1, 1999, to August 31, 2001, of 369 patients with: • **LVEF ≤35%**, • **QRS duration of 130 ms or greater,** • **at high risk of life-threatening ventricular arrhythmias, and** • **NYHA class III (n = 328) or IV (n = 41) despite optimized medical treatment.** Of 369 randomized patients who received devices with combined CRT and ICD capabilities, 182 were controls (ICD activated, CRT off) and 187 were in the CRT group (ICD activated, CRT on).	From January 2000 to December 2002, a total of 1.520 patients with heart failure were randomized to 3 treatment arms: OPT only (n = 308), CRT-D (n = 595), and CRT only (n = 617). • **LVEF ≤35%,** • **QRS interval of ≥120 ms;** • **Advanced HF (NYHA functional class III/IV),** Patients were also required to have no clinical indication for a pacemaker or defibrillator and had to have been hospitalized within the previous year for treatment of HF
Follow-up	The primary double-blind study end points were changes between baseline and 6 months in quality of life, functional class, and distance covered during a 6-minute walk. Additional outcome measures included changes in exercise capacity, plasma neurohormones, left ventricular function, and overall HF status. Survival, incidence of ventricular arrhythmias, and rates of hospitalization were also compared	The primary end point was a composite of all-cause mortality and hospitalization for any cause. The secondary end point was all-cause mortality. All analyses were conducted according to the intention-to-treat principle. The median duration of follow-up for the primary end point was shorter in the OPT-only group (11.9 months) than in the CRT-D (15.7 months) and CRT-only (16.2 months) groups.
Results	At 6 months, patients assigned to CRT had a greater improvement in median quality of life score (–17.5 [–21 to –14] vs –11.0 [–16 to –7], *P* = .02) and functional class than controls but were no different in change in distance walked in 6 minutes (55 m [44-79] vs 53 m [43-75], *P* = .36). Peak oxygen consumption increased by 1.1 mL/kg per min. (0.7-1.6) in the CRT group vs 0.1 mL/kg per min. (–0.1 to 0.8) in controls (*P* = .04), although treadmill exercise duration increased by 56 secs (30-79) in the CRT group and decreased by 11 secs (–55 to 12) in controls (*P*<.001). No significant differences were observed in changes in left ventricular size or function, overall HF status, survival, and rates of hospitalization. No proarrhythmia was observed and arrhythmia termination capabilities were not impaired. The study concluded that CRT improved quality of life, functional status, and exercise capacity in patients with moderate to severe HF, a wide QRS interval, and life-threatening arrhythmias. These occurred in the context of underlying appropriate medical management without proarrhythmia or compromised ICD function.	• CRT-D significantly reduced all-cause mortality by 36% compared with medical therapy. • CRT alone insignificantly reduced all-cause mortality by 24%. Because all-cause mortality alone was the secondary endpoint and the number of deaths was small, the apparent lack of effectiveness of CRT alone is not conclusive. • The primary endpoint in COMPANION, a composite of all-cause mortality and hospitalization for heart failure, was reduced significantly by 19% in the CRT-only group; 20% in the CRT-D group compared with the medical therapy-only group. • In patients with NYHA class III heart failure, CRT-D resulted in a significant 46% reduction in all-cause mortality compared with medical therapy. • In patients with NYHA class IV heart failure, no reductions in all-cause mortality were found with CRT-D, but the results were inconclusive because of the small sample size. • CRT-D was significantly more effective than medical therapy for men and patients younger than 65 with an LVEF < 20%, a QRS interval >147 millisecs, or nonischemic cardiomyopathy.

Systematic Review of Evidence

AHRQ Evidence Report on CRT and ICDs

To further evaluate the effectiveness of CRT and ICDs, AHRQ commissioned a systematic evidence review (McAlister et al., 2007). This evaluation looked specifically at the efficacy, effectiveness, and safety of CRT or implantable cardioverter defibrillators in patients with left ventricular systolic dysfunction (LVSD).

All patients in the CRT studies evaluated in this review had LVSD (mean LVEF from 21% to 30%) and prolonged QRS duration (mean from 155 to 209 ms), and 91% had New York Heart Association (NYHA) class III or IV symptoms.

In patients with LVSD and heart failure symptoms, CRT improved ejection fraction, quality of life, and function. The proportion of patients hospitalized for HF was reduced by 37% and all-cause mortality was reduced by 22%. While this evaluation did not specifically distinguish between the effectiveness of CRT-P and CRT-D, subgroup analyses were attempted to discern any significant differences. None was observed. The authors noted, however, that subgroup analyses and meta-regression using the aggregated trial data were post-hoc analyses and were underpowered to detect such effects.

The authors concluded that both ICD and CRT reduce all-cause mortality in patients with LVSD meeting RCT entry criteria.

Current Evidence-Based Recommendations

American College of Cardiology/American Heart Association/Heart Rhythm Society 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities

The following guidelines are updates to previous guidelines published in 1984, 1991, 1998, and 2002. Recommendations for ICD implantation have been updated to reflect the numerous new developments in this field and the voluminous literature related to the efficacy of these devices in the treatment and prophylaxis of SCD and malignant ventricular arrhythmias. According to the ACC/AHA/HRS, indications for ICDs, CRT devices, and combined ICDs and CRT devices are continuously changing and can be expected to change further as new trials are reported. It is inevitable that the indications for device therapy will be refined with respect to both expanded use and the identification of patients expected to benefit the most from these therapies. Furthermore, it is emphasized that when a patient has an indication for both a pacemaker (whether it be single-chamber, dual-chamber, or biventricular) and an ICD, a combined device with appropriate programming is indicated.

The schema for classification of recommendations and level of evidence is summarized in Table 6, at the end of this section.

CRT and CRT-D Indications

CRT in Patients with Severe Systolic Heart Failure

Class I

- **For patients who have LVEF ≤35%, a QRS duration ≥0.12 seconds, and sinus rhythm, CRT with or without an ICD is indicated for the treatment of NYHA functional Class III or ambulatory Class IV heart failure symptoms with optimal recommended medical therapy. (Level of Evidence: A)**

Class IIa

- **For patients who have LVEF ≤35%, a QRS duration ≥0.12 seconds, and AF, CRT with or without an ICD is reasonable for the treatment of NYHA functional Class III or ambulatory Class IV heart failure symptoms on optimal recommended medical therapy. (Level of Evidence: B)**

- **For patients with LVEF ≤35% with NYHA functional Class III or ambulatory Class IV symptoms who are receiving optimal recommended medical therapy and who have frequent dependence on ventricular pacing, CRT is reasonable. (Level of Evidence: C)**

Class IIb

- **For patients with LVEF ≤35% with NYHA functional Class I or II symptoms who are receiving optimal recommended medical therapy and who are undergoing implantation of a permanent pacemaker or ICD with anticipated frequent ventricular pacing, CRT may be considered. (Level of Evidence: C)**

Class III

- CRT is not indicated for asymptomatic patients with reduced LVEF in the absence of other indications for pacing. (Level of Evidence: B)

- CRT is not indicated for patients whose functional status and life expectancy are limited predominantly by chronic noncardiac conditions. (Level of Evidence: C)

Table 6: ACC/AHA Evidence Classification Scheme

	Size of treatment effect			
	Class I *Benefit >>> Risk* Procedure/Treatment SHOULD BE Performed/Administered	Class IIa *Benefit >> Risk* *Additional studies with focused objectives needed* IT IS REASONABLE to perform procedure; administer treatment	Class IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment MAY BE CONSIDERED	Class III *Risk ≥ Benefit* Procedure/treatment SHOULD NOT BE performed/administered SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL
Level A Multiple populations evaluated* Data derived from multiple randomized clinical trials	• Recommendation that treatment or procedure is useful/effective • Sufficient evidence from multiple randomized trials or meta-analyses	• Recommendation in favor of treatment or procedure being useful/effective • Some conflicting evidence from multiple randomized trials or meta-analyses	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from multiple randomized trials or meta-analyses	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Sufficient evidence from multiple randomized trials or meta-analyses
Level B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	• Recommendation that treatment or procedure is useful/effective • Evidence from single randomized trial or nonrandomized studies	• Recommendation in favor of treatment or procedure being useful/effective • Some conflicting evidence from single randomized trial or nonrandomized studies	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from single randomized trial or nonrandomized studies	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Evidence from single randomized trial or nonrandomized studies
Level C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	• Recommendation that treatment or procedure is useful/effective • Only expert opinion, case studies, or standard of care	• Recommendation in favor of treatment or procedure being useful/effective • Only diverging expert opinion, case studies, or standard of care	• Recommendation's usefulness/efficacy less well established • Only diverging expert opinion, case studies, or standard of care	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Only expert opinion, case studies, or standard of care

American Heart Association and Heart Rhythm Society, Addendum 2007

In 1996, AHA and HRS jointly released recommendations on personal and public safety issues related to arrhythmias that may affect consciousness. The AHA and HRS focused specifically on driving safety. Subsequent to these recommendations, numerous trials as defined in Table 4 established the role of ICDs for the primary prevention of sudden cardiac death in patients at risk for life-threatening ventricular arrhythmias.

In February 2007, the AHA and HRS jointly released an addendum to these guidelines to update previous recommendations on safe driving practices for patients with implantable ICDs. The new guidelines focus specifically on the primary prevention patient population, which now represents the majority of patients implanted with ICDs in the United States.

The revised statement's recommendations are entirely focused on private, non-commercial driving restrictions. Under the revised guidelines, AHA and the HRS recommend that:

(1) Patients receiving ICDs for primary prevention should be restricted from driving a private automobile for at least 1 week to allow for recovery from implantation of the defibrillator. Thereafter, these driving privileges should not be restricted in the absence of symptoms potentially related to an arrhythmia.

(2) Patients who have received an ICD for primary prevention who subsequently received an appropriate therapy for ventricular tachycardia or ventricular fibrillation, especially with symptoms of cerebral hypoperfusion, should then be considered to be subject to the driving guidelines previously published for patients who received an ICD for secondary prevention, which suggests a period of six months symptom free before resuming driving.

(3) Patients with ICDs for primary prevention must be instructed that impairment of consciousness is a possible future event.

(4) These recommendations do not apply to the licensing of commercial drivers.

Medicare Indications and Limitations of Coverage for ICDs and Pacemakers

Medicare has national coverage determinations (NCDs) for both pacemakers and ICDs. These are in Appendix A. As of December 2008, no NCDs for CRT-P or CRT-D are available. However, as of January 25, 2005 (refer to Appendix A), Medicare expanded its indications in its NCD to include the following.

> "Patients who meet all current Centers for Medicare & Medicaid Services (CMS) coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure. "

The Medicare Coverage Policy Statement available for CRT and CRT-D therapy is described below.

The policy statement was prepared by Highmark Medicare Services Pennsylvania Carrier in 2004. It states that CRT is considered medically reasonable and necessary in the treatment of patients who meet all the following criteria:

- **Moderate to severe chronic heart failure (NYHA Functional Class III or IV);**
- **Symptomatic despite stable, optimal heart failure drug therapy;**
- **Left ventricular ejection fraction ≤35%; and**
- **QRS duration ≥120ms.**

Furthermore, if the patient is at high risk for sudden cardiac death, a cardiac resynchronization therapy defibrillator (CRT-D) should be considered. CRT-D is considered reasonable and necessary in the treatment of patients who meet all the above criteria and the following:

Secondary prevention

- **Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) caused by a ventricular tachyarrhythmia, *or***

Primary prevention

- **Recurrent, poorly tolerated sustained ventricular tachycardia, *or***
- **Prior myocardial infarction and a documented episode of non-sustained VT, with an inducible ventricular tachyarrhythmia, *or***
- **Prior myocardial infarction and a left ventricular ejection fraction of ≤30%.**

Medical record documentation must be available to administrators on request and must support the indications outlined above. In addition, the documentation must include: a functional classification of the patient's heart failure, including appropriate diagnostic studies performed; an operative note, indicating the rationale for the procedure; and the type of equipment implanted, with a statement confirming the equipment's approval by the U.S. Food and Drug Administration.

Thus, while no NCD for CRT (also referred to as CRT-P) or CRT-D exists, coverage is approved under certain circumstances using FDA-approved devices.

FDA-Approved Devices and Indications

This subsection examines devices approved by the FDA as of December 2008, and the list of their current indications.

Since 2000, the FDA has approved three devices specifically indicated for biventricular pacing or cardiac resynchronization therapy with a pacemaker (CRT-P). These are presented in Table 7 below.

More relevant to the current discussion, FDA has approved an additional five devices since 2002 for CRT-D therapy. These are listed in Table 8. All these devices are dual-chamber ICD systems that are multi-programmable, and combine defibrillation capabilities with biventricular pacing for cardiac resynchronization therapy.

In each case, the devices are intended to treat life-threatening arrhythmias, such as ventricular tachycardia and ventricular fibrillation. They are also intended to reduce heart failure symptoms in individuals with advanced heart failure (NYHA Functional Class of III and IV). In most cases, patients should be receiving optimized heart failure drug therapy. In some cases, these devices are also indicated for atrial tachyarrhythmia or individuals at risk of developing atrial tachyarrhythmia.

Common FDA-approved indications for the use of these devices include:

- **NYHA Functional Class III and IV patients with left ventricular ejection fraction of 35% or less**
- **Receiving optimized and stable CHF drug therapy**
- **Intraventricular conduction delays (QRS duration >120 ms or more)**

Table 7: FDA Approved CRT-P or Biventricular Pacing Devices and Associated Indications

Device Name, Company, and Date Approved	Device Description	Indications
Stratos LV and Stratos LV T CRT Ps and Corox OTW BP and Corox OTW S BP Left Ventricular Pacing Leads Biotronik Inc. May 12, 2008	The Medtronic ® Attain StarFix™ Model 4195 Lead is a surgically implanted insulated wire designed to be used as part of a biventricular pacemaker system. The 4195 lead is designed to be implanted in a branch of the coronary vein that goes over the surface of the heart's left ventricle. The tip of the lead has lobes that open to help keep it in place. A small amount of steroid (beclomethasone dipropionate) at the tip is intended to reduce inflammation of the surrounding tissue. The other end of the lead connects to an implanted biventricular pacemaker or ICD, so signals and electrical impulses can be sent between that device and the left ventricle.	The CRT-P pacemakers are for use in patients who have moderate to severe heart failure (NYHA Class III/IV). They are indicated for use in patients who: • exhibit symptoms related to heart failure (left ventricular dysfunction (EF≤ 35%) and QRS ≥ 120 ms) • remain symptomatic despite stable, optimal heart failure drug therapy The Corox OTW(-S) BP left ventricular pacing leads are bipolar steroid‑eluting leads, intended for permanent implantation in the left ventricle via the coronary veins to provide pacing and/or sensing when used in conjunction with a compatible IS-1 pulse generator.
CONTAK® RENEWAL™ TR Models H120 and H125 - P030005 Guidant Corporation January 26, 2004	The CONTAK® RENEWAL™ TR system is an implantable pulse generator (IPG) that delivers cardiac resynchronization therapy (CRT). The CRT portion of this device uses small electrical pulses to coordinate the heartbeat and improve blood-pumping ability in certain patients with moderate to severe heart failure.	The RENEWAL TR pulse generator is indicated for patients who have moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF < 35%) and QRS duration > 120 ms and remain symptomatic despite stable, optimal heart failure drug therapy (as defined in the clinical trials section). The device provides atrial–ventricular tracking modes to help preserve AV synchrony, and adaptive-rate pacing for patients who would benefit from adjusted pacing rates concurrent with physical activity.
Medtronic® InSync® Biventricular Cardiac Pacing System includes the InSync® Model 8040 Pulse Generator and leads (Attain™LV Model 2187 and CS Model 2188). Medtronic, Inc. August 28, 2001	The InSync®System is used to help treat congestive heart failure, a condition where the heart cannot adequately pump blood around the body. It does this by providing specially timed electrical impulses to simultaneously stimulate the heart's lower chambers (right and left ventricles). The system consists of a pulse generator (containing a battery and electronic circuitry) connected to three leads (insulated wires) that deliver electrical impulses to stimulate the heart. One lead is placed in an upper heart chamber (right atrium) and the other two leads are placed in each of the ventricles.	It should only be used in patients who: • have moderate to severe symptoms of congestive heart failure; • have an electrical disturbance in the heart that causes the ventricles not to contract at the same time; and • are not likely to improve with additional drug therapy.

Table 8: FDA Approved CRT-D Devices and Associated Indications

Device Name, Company, and Date Approved	Device Description	Indications
OVATIO CRT SYSTEM ELA MEDICAL, INC. May 15, 2008	Ovatio CRT-D is a rate- responsive ICD with biventricular pacing for cardiac resynchronization therapy.	Ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening arrhythmias. For reduction of heart failure symptoms in medically optimized NYHA Functional Class III and IV patients with left ventricular ejection fraction of *35%* or less, and a QRS duration of 150 mns or longer.
TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD; BIOTRONIK, INC. Aug. 10, 2006	The Tupos LV/ATx and Kronos LV-T System ICDs designed to provide cardiac resynchronization therapy or biventricular pacing and standard ICD therapy.	• Receiving optimized and stable CHF drug therapy • Symptomatic CHF (NYHA Class III/IV and LVEF <35%); and • Intraventricular conduction delay (QRS duration >130 ms) The Tupos LV/ATx is also indicated for patients who, in addition to an indication for a CRT-D device, have atrial tachyarrhythmia or are at risk of developing atrial tachyarrhythmia.
ST JUDE MEDICAL EPIC HF SYSTEM ST. JUDE MEDICAL, INC. June 30, 2004	The St. Jude Medical Epic HF V-338 and Atlas + HF V-340 dual-chamber ICD systems are multi-programmable, ICDs with biventricular pacing for CRT that monitor and regulate a patient's heart rate by providing ventricular tachyarrhythmia therapy and single- or dual-chamber bradycardia pacing with rate adaptive response (DDD(R)).	Provides ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Provides a reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy (as defined in the clinical trials section), and have a left ventricular ejection $\leq$ 35% and a prolonged QRS duration.
INSYNC(TM) ICD MODEL 7272 MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT June 26, 2002	The InSync ICD Model 7272 Dual Chamber ICD System is a multi-programmable ICD with biventricular pacing for CRT that monitors and regulates a patient's heart rate by providing ventricular tachyarrhythmia therapy and single- or dua-chamber bradycardia pacing.	Provides ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias Reduction of symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy (as defined in the clinical trials section), and have a left ventricular ejection fraction $\leq$ 35% and a QRS duration $\geq$ 130 ms.
CONTAK CD/EASYTRAK LEAD SYSTEM GUIDANT CORP. May 02, 2002	The Guidant CONTAK CD CRT-D pulse generator, Model 1823, provides ventricular tachyarrhythmia and cardiac resynchronization therapies. Ventricular tachyarrhythmia therapy is for the treatment of VT and ventricular fibrillation VF, rhythms that are associated with SCD. CRT uses simultaneous biventricular electrical stimulation to synchronize ventricular contractions.	For patients at high risk of sudden cardiac death caused by ventricular arrhythmias who have moderate to severe heart failure NYHA Class III/IV] including left ventricular dysfunction (EF $\leq$35%) and QRS duration >120 ms and remain symptomatic despite stable, optimal heart failure drug therapy. Patient populations at high risk of sudden cardiac death caused by ventricular arrhythmias including, but not limited to, those with: --Survival of at least one episode of cardiac arrest (manifested by loss of consciousness) caused by a VT. --Recurrent, poorly tolerated sustained VT. --Prior myocardial infarction, left ventricular ejection fraction of $\leq$35%, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia.

Summary: Implications for CMV Drivers

Current guidance from the FMCSA on physical qualifications for commercial drivers with ICDs prohibit them from obtaining medical certification to drive a CMV in interstate commerce. The primary rationale for this recommendation is summarized below:

- While ICDs are effective in preventing sudden cardiac death, they do not completely eliminate this risk.
- Individuals with an ICD continue to be at risk of experiencing a syncopal or near-syncopal episode during an arrhythmic event.
- ICD discharges, whether appropriate or not, can startle or temporarily incapacitate a patient and thereby disrupt safe motor vehicle operation.

In recent years, however, the functioning of these devices has improved dramatically, expanding the indications to include prophylactic treatment or primary prevention of various CVDs. Similarly, the use of pacemakers combined with an ICD (CRT-D therapy) for the treatment of various stages of heart failure has become a growing option.

Several seminal clinical trials (Abraham, et al., 2002; Bristow, et al., 2004) have demonstrated that cardiac resynchronization therapy using biventricular pacemakers (CRT-P) or ICDs (CRT-D) can improve symptoms of heart failure over and above the use of optimized medical therapy. In addition, a recent systematic evidence review commissioned by AHRQ (McAlister, et al., 2007) has also found that CRT (including both CRT-P and CRT-D) does improve ejection fraction, quality of life, function, and survival in patients with left ventricular systolic dysfunction and heart failure symptoms.

As a result of these trials and accumulating evidence of effectiveness, medical specialty societies such as the American College of Cardiology Foundation, the AHA, and the HRS have revised recommendations for the use of CRT-P and CRT-D for individuals meeting specific criteria. Similarly, Medicare has also expanded coverage for the use CRT-P and CRT-D in certain patients using FDA-approved devices.

Questions of Interest to FMCSA

There are two question of interest to the FMCSA regarding recent advancements in ICD technology, specifically CRT using biventricular ICDs (CRT-D). Each is addressed in turn below. They are:

1. How do the indications of CRT-D devices affect current medical fitness requirements for driving? Have the indications for the use of these devices expanded to include conditions under which FMCSA's current regulations or guidance would not be disqualifying? Would the current disqualifying criteria of an ICD be considered too strict, given current indications for the use of these devices?

2. Are there conditions or circumstances under which an individual with a dual-functioning ICD-pacemaker (CRT-D) would be implanted with the device but not use the ICD portion? Are there circumstances under which the ICD portion would not be configured or turned on in individuals in whom they have been implanted?

To answer these questions, we have examined the indications for which the use of these devices:

- Have been approved by the FDA,
- Have been studied in clinical trials,
- Are recommended in evidence-based guidelines from the relevant medical specialty societies, and
- Are covered under current Medicare or Medicaid reimbursement policies.

Question 1

There is some heterogeneity in the characteristics of patients included in original seminal trials of CRT-D effectiveness. However, in large part, patients enrolled in these trials have had advanced HF as defined by a NYHA classification III or IV, a LVEF ≤35% and a QRS interval of ≥120 ms.

The use of these devices has not expanded to included significantly earlier stages of HF. Traditional ICDs, while highly effective in reducing mortality associated with sudden cardiac arrest that may result from progressive HF, do not generally correct the underlying pathology in the individuals for whom they are indicated. Rather, they are largely intended to prevent life-threatening arrhythmias by detecting and responding to them. CRT, on the other hand, is specifically indicated for the purpose of helping correct or suppress ongoing deterioration of a chronic heart condition and improve quality of life and functional class.

Individuals currently approved for use of dual-functioning ICD-pacemakers (CRT-D) devices are essentially no different from those for whom traditional devices have been approved. As outlined in the Medicare coverage policy, CRT-P is considered medically reasonable and necessary in the treatment of patients who meet all the following criteria:

- Moderate to severe chronic HF (NYHA Functional Class III or IV);
- Symptomatic despite stable, optimal heart failure drug therapy;
- Left ventricular ejection fraction ≤35%; and
- QRS duration ≥120ms.

Furthermore, if the patient is at high risk for SCD, CRT-D can be considered. The Medicare policy goes on to highlight the criteria under which CRT-D is considered reasonable, including:

Secondary prevention

- Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) caused by a VT, ***or***

Primary prevention

- Recurrent, poorly tolerated sustained VT, ***or***
- Prior myocardial infarction and a documented episode of non-sustained VT, with an inducible ventricular tachyarrhythmia, ***or***
- Prior myocardial infarction and a left ventricular ejection fraction of ≤30%.

Thus, individuals indicated for this relatively new treatment are still at significant risk for sudden cardiac death, and are likely to continue to pose a significant risk to driving safety.

Question 2

From our review of available information, we conclude that it is unlikely that individuals would receive a dual-functioning ICD-pacemaker or CRT-D with a defibrillator that has not been configured or is turned off.

According to current recommendations, individuals are either indicated for CRT, in which case they would receive a biventricular pacemaker (CRT-P), which lacks defibrillator capabilities, or they are indicated for CRT-D because of their increased risk for sudden cardiac death, and would thus receive a biventricular ICD (CRT-D).

Owing to the complexity and increased complications of implanting an ICD or CRT-D and the high cost and the medical indications required to receive one, a person will only receive one if it is medically indicated (i.e., he or she meets requirements for an ICD).

Moreover, current Medicare coverage explicitly states that individuals indicated for the use of these devices are to receive only those devices that have been FDA-approved. FDA currently approves both CRT-P and CRT-D devices. CRT-D devices are only to be used in individuals medically indicated for CRT with defibrillation capabilities.

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APPENDIX A

Medicare Indications and Limitations of Coverage for ICDs and Pacemakers

Medicare has national coverage determinations (NCDs) for pacemakers and ICDs. Below are descriptions of these NCDs. At this time there is no NCD for CRT-P or CRT-D.

Medicare National Coverage Decision for Pacemakers		
Publication Number 100-3	Manual Section Number 20.8	Version Number 2
Effective Date of this Version 4/30/2004	Implementation Date 4/30/2004	Benefit Category Inpatient Hospital Services Physicians' Services Prosthetic Devices
Coverage Topic Prosthetic Devices		
Item/Service Description	Cardiac pacemakers are self-contained, battery-operated units that send electrical stimulation to the heart. They are generally implanted to alleviate symptoms of decreased cardiac output related to abnormal heart rate or rhythm. Pacemakers are generally used for persistent, symptomatic second- or third-degree atrioventricular (AV) block and symptomatic sinus bradycardia.	

Indications and Limitations of Coverage

Cardiac pacemakers are covered as prosthetic devices under the Medicare program and are subject to the conditions and limitations. While cardiac pacemakers have been covered under Medicare for many years, there were no specific guidelines for their use other than the general Medicare requirement that covered services be reasonable and necessary for the treatment of the condition. Services rendered for cardiac pacing on or after the effective dates of this instruction are subject to these guidelines, which are based on certain assumptions of the clinical goals of cardiac pacing. While some uses of pacemakers are relatively certain or unambiguous, many others require considerable expertise and judgment.

Consequently, the medical necessity for permanent cardiac pacing must be viewed in the context of overall patient management. The appropriateness of such pacing may be conditional on other diagnostic or therapeutic modalities having been undertaken. Although significant complications and adverse side effects of pacemaker use are relatively rare, they cannot be ignored when considering the use of pacemakers for dubious medical conditions or marginal clinical benefit.

These guidelines represent current concepts of medical circumstances in which permanent cardiac pacing may be appropriate or necessary. As with other areas of medicine, advances in knowledge and techniques in cardiology are expected. Consequently, judgments about the medical necessity and acceptability of new uses for cardiac pacing in new classes of patients may change as more conclusive evidence becomes available. This instruction applies only to permanent cardiac pacemakers, and does not address the use of temporary, non-implanted pacemakers.

The two groups of conditions outlined below deal with the necessity for cardiac pacing for patients in general. These are intended as guidelines in assessing the medical necessity for pacing therapies and taking into account the particular circumstances in each case. However, as a general rule, the two groups of current medical concepts may be viewed as representing:

Group I. Single-Chamber Cardiac Pacemakers: a) conditions under which single-chamber pacemaker claims may be considered covered without further claims development; and b) conditions under which single-chamber pacemaker claims would be denied unless further claims development shows they fall into the covered category, or special medical circumstances exist of the sufficiency to convince the contractor that the claim should be paid.

Group II: Dual-Chamber Cardiac Pacemakers: a) conditions under which dual-chamber pacemaker claims may be considered covered without further claims development, and b) conditions under which dual-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered categories for single- and dual-chamber pacemakers, or special medical circumstances exist sufficient to convince the contractor that the claim should be paid.

CMS opened the NCD on cardiac pacemakers to afford the public an opportunity to comment on the proposal to revise the language contained in the instruction. The revisions transfer the focus of the NCD from the actual pacemaker implantation procedure itself to the reasonable and necessary medical indications that justify cardiac pacing. This is consistent with our findings that pacemaker implantation is no longer considered routinely harmful or an experimental procedure.

Group I: Single-Chamber Cardiac Pacemakers (Effective March 16, 1983)

A. Nationally Covered Indications

Conditions under which cardiac pacing is generally considered acceptable or necessary, provided the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity.)

1. Acquired complete (also referred to as third-degree) AV heart block.
2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms caused by the bradycardia.
3. Second-degree AV heart block of Type II (i.e., *no* progressive prolongation of P-R interval prior to each blocked beat. P-R interval indicates the time taken for an impulse to travel from the atria to the ventricles on an electrocardiogram.
4. Second-degree AV heart block of Type I (i.e., progressive prolongation of P-R interval prior to each blocked beat) with significant symptoms from hemodynamic instability associated with the heart block.
5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, CHF); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
6. In selected and few patients, sinus bradycardia of lesser severity (heart rate of 50–59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
7. Sinus bradycardia is the consequence of long-term necessary drug treatment for which there is no acceptable alternative when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block (i.e., the bradycardia-tachycardia syndrome, sino-atrial block, sinus arrest) when accompanied by significant symptoms (e.g., syncope, seizures, CHF, dizziness, or confusion).
9. Sinus node dysfunction with or without symptoms when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature

ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).

10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high-degree AV block that is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, CHF, dizziness or confusion).
11. The occasional patient with hypersensitive carotid sinus syndrome with syncope caused by bradycardia and unresponsive to prophylactic medical measures.
12. Bifascicular or trifascicular block accompanied by syncope attributed to transient complete heart block after other plausible causes of syncope have been reasonably excluded.
13. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third-degree) or Mobitz Type II second-degree AV block in association with bundle branch block.
14. In patients with recurrent and refractory ventricular tachycardia, "overdrive pacing" (pacing above the basal rate) to prevent ventricular tachycardia.

(Effective May 9, 1985)

15. Second-degree AV heart block of Type I with the QRS complexes prolonged.

B. *Nationally Noncovered Indications*

Conditions which, although used by some physicians as a basis for permanent cardiac pacing, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for single-chamber pacemakers in the absence of the above indications. Contractors should review claims for pacemakers with these indications to determine the need for further claims development prior to denying the claim, since additional claims development may be required. The object of such further development is to establish whether the particular claim actually meets the conditions in a) above. In claims where this is not the case or where such an event appears unlikely, the contractor may deny the claim for the following reasons:

1. Syncope of undetermined cause.
2. Sinus bradycardia without significant symptoms.
3. Sino-atrial block or sinus arrest without significant symptoms.
4. Prolonged P-R intervals with atrial fibrillation (without third-degree AV block) or with other causes of transient ventricular pause.
5. Bradycardia during sleep.
6. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block).
7. Asymptomatic second-degree AV block of Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His bundle (a component of the electrical conduction system of the heart).
8. Asymptomatic bradycardia in post-mycardial infarction patients about to initiate long-term beta-blocker drug therapy.

Effective October 1, 2001

Group II: Dual-Chamber Cardiac Pacemakers – (Effective May 9, 1985)

A. *Nationally Covered Indications*

Conditions under dual-chamber cardiac pacing are considered acceptable or necessary in the general medical community unless conditions 1 and 2 under Group II B are present:

1. Patients in whom single-chamber (ventricular pacing) at the time of pacemaker insertion elicits a definite drop in blood pressure, retrograde conduction, or discomfort.
2. Patients in whom the pacemaker syndrome (atrial ventricular asynchrony), with significant symptoms, has already been experienced with a pacemaker that is being replaced.
3. Patients in whom even a relatively small increase in cardiac efficiency will significantly improve the quality of life, e.g., patients with CHF despite adequate other medical measures.
4. Patients in whom the pacemaker syndrome can be anticipated, e.g., in young and active people, etc.

Dual-chamber pacemakers may also be covered for the conditions listed in Group I A if medical necessity is sufficiently justified through adequate claims development. Expert physicians differ in their judgments about what constitutes appropriate criteria for dual-chamber pacemaker use. The judgment that such a pacemaker is warranted in the patient meeting accepted criteria must be based on the individual needs and characteristics of that patient, weighing the magnitude and likelihood of anticipated benefits against the magnitude and likelihood of disadvantages to the patient.

B. *Nationally Noncovered Indications*

Whenever the following conditions (which represent overriding contraindications) are present, dual-chamber pacemakers are not covered:

1. Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium.
2. Frequent or persistent supraventricular tachycardias, *except* where the pacemaker is specifically for the control of the tachycardia.
3. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged, e.g., the occasional patient with hypersensitive carotid sinus syndrome with syncope caused by bradycardia and unresponsive to prophylactic medical measures.
4. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third-degree) and/or Type II second-degree AV block in association with bundle branch block.

C. *Other*

All other indications for dual-chamber cardiac pacing for which the Centers for Medicare & Medicaid Services has not specifically indicated coverage remain nationally noncovered, except for Category B IDE clinical trials, or as routine costs of dual-chamber cardiac pacing associated with clinical trials, in accordance with section 310.1 of the NCD Manual.

(This NCD was last reviewed June 2004.)

Medicare National Coverage Decision for Implantable Automatic Defibrillators

Publication Number 100-3	Manual Section Number 20.4	Version Number 3
Effective Date of this Version 1/27/2005	Implementation Date 1/27/2005	Benefit Category Prosthetic Devices
Coverage Topic Prosthetic Devices		
Item/Service Description	The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating.	

Indications and Limitations of Coverage

A. Covered Indications

1. Documented episode of cardiac arrest caused by VF, not a transient or reversible cause (effective July 1, 1991).
2. Documented sustained VT, either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause (effective July 1, 1999).
3. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy (effective July 1, 1999).

   Additional indications effective for services performed on or after October 1, 2003:

4. Coronary artery disease with a documented prior MI, a measured LVEF < .35, and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 40 days prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.)
5. Documented prior MI and a measured LVEF < .30 and a QRS duration of > 20 ms (the QRS restriction does not apply to services performed on or after January 27, 2005).

   Patients must not have:

   a. NYHA classification IV;
   b. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
   c. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months;
   d. Had an enzyme positive MI within the past month (Effective for services on or after January 27, 2005, patients must not have had an acute MI in the past 40 days);
   e. Clinical symptoms or findings that would make them a candidate for coronary revascularization; or
   f. Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year.

   Additional indications effective for services performed on or after January 27, 2005:

6. Patients with ischemic dilated cardiomyopathy (IDCM), documented prior MI, NYHA Class II and III heart failure, and measured LVEF < 35%;
7. Patients with non-ischemic dilated cardiomyopathy (NIDCM) >9 months, NYHA Class II and III heart failure, and measured LVEF < 35%;

8. **Patients who meet all current CMS coverage requirements for a CRT device and have NYHA Class IV heart failure;**

   All indications must meet the following criteria:

   a. Patients must not have irreversible brain damage from preexisting cerebral disease;
   b. MIs must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction;[2]

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

   c. Patients must be able to give informed consent;
   d. Patients must not have:
      - Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
      - Had a 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;
      - Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year;

   e. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography;
   f. The beneficiary receiving the defibrillator implantation for primary prevention is enrolled in either an FDA-approved category B investigational device exemption (IDE) clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (National Coverage Determination (NCD) Manual §310.1) or a qualifying data collection system, including approved clinical trials and registries. Initially, an ICD database will be maintained using a data submission mechanism already in use by Medicare participating hospitals to submit data to the Iowa Foundation for Medical Care (IFMC)—a Quality Improvement Organization (QIO) contractor—for determination of reasonable and necessary and quality improvement. Initial hypothesis and data elements are specified in this decision (Appendix VI) and are the minimum necessary to ensure that the device is reasonable and necessary. Data collection will be completed using the ICDA (ICD Abstraction Tool) and transmitted via QNet (Quality Network Exchange) to the IFMC, which will collect and maintain the database. Additional stakeholder-developed data collection systems to augment or replace the initial QNet system, addressing at a minimum the hypotheses specified in this decision, must meet the following basic criteria:

      - Written protocol on file;
      - Institutional review board review and approval;
      - Scientific review and approval by two or more qualified individuals who are not part of the research team;
      - Certification that investigators have not been disqualified.

      For purposes of this coverage decision, CMS will determine whether specific registries or clinical trials meet these criteria.

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[2] Alpert and Thygesen, et al., 2000. Criteria for acute, evolving or recent MI.

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

9. Patients with NIDCM > 3 months, NYHA Class II or III heart failure, and measured LVEF < 35%, only if the following additional criteria are also met:

    a. Patients must be able to give informed consent;
    b. Patients must not have:

        - Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
        - Had a 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 preexisting cerebral disease;
        - Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year;

    c. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography;
    d. MIs must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction;
    e. The beneficiary receiving the defibrillator implantation for this indication is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1), or a prospective data collection system meeting the following basic criteria:

        - Written protocol on file;
        - Institutional Review Board review and approval;
        - Scientific review and approval by two or more qualified individuals who are not part of the research team;
        - Certification that investigators have not been disqualified.

        For purposes of this coverage decision, CMS will determine whether specific registries or clinical trials meet these criteria.

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

B. Other Indications

All other indications for implantable automatic defibrillators not currently covered in accordance with this decision will continue to be covered under Category B IDE trials (42 CFR §405.201) and the CMS routine clinical trials policy (NCD §310.1).

(This NCD was last reviewed February 2005.)

Either one of the following criteria satisfies the diagnosis for an acute, evolving or recent MI:

1. Typical rise and gradual fall (troponin) or more rapid rise and fall (CK-MB) of biochemical markers of myocardial necrosis with at least one of the following:

a. ischemic symptoms;
b. development of pathologic Q waves on the ECG;
c. ECG changes indicative of ischemia (ST segment elevation or depression); or
d. coronary artery intervention (e.g., coronary angioplasty).

2. Pathologic findings of an acute MI.

Any of the following criteria satisfies the diagnosis for established MI:

1. Development of new pathologic Q waves on serial ECGs. The patient may or may not remember previous symptoms. Biochemical markers of myocardial necrosis may have normalized, depending on the length of time that has passed since the infarct developed.
2. Pathologic findings of a healed or healing MI.