



Medtronic

Reimbursement Guide for ICD Implants

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Reimbursement Guide for ICD Implants

This guide has been developed to help you understand coverage and payment for implantable cardioverter defibrillator (ICD) and cardiac resynchronization defibrillator (CRT-D) therapies. This guide also incorporates information regarding the use of ICDs for patients with the expanded coverage indications reflected in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) and Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) studies.

The information contained in this guide does not replace seeking advice from your local payer for definitive interpretation of the appropriate coverage, coding, and payment guidelines. For more information regarding reimbursement-related issues, please call Medtronic at 1 (866) 877-4102, option 1.

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Overview

Implantable cardioverter defibrillator (ICD) therapy is a lifesaving therapy for individuals with ventricular arrhythmias and those at high risk of developing them. Defibrillation devices consist of an electrical generator implanted in a subcutaneous pocket, usually on the patient's chest, connected to one or more leads inserted at the chambers of the heart. When the device senses an arrhythmia, it sends an electrical signal through the leads to terminate the arrhythmia and restore normal heart rhythm.

Secondary Prevention

ICDs are used for "secondary prevention" in individuals with known arrhythmias and those who have survived an episode of sudden cardiac arrest. Medicare has covered ICD therapy in this population for a number of years through a national coverage decision. Medicare expanded coverage within this population on October 1, 2003 in response to the MADIT-II clinical trial results. This clinical trial demonstrated a 31% reduction in mortality in individuals with a prior myocardial infarction and left ventricular ejection fraction of 30% or lower.

Primary Prevention

ICDs are also used for "primary prevention" in individuals who have not had ventricular arrhythmias, or experienced sudden cardiac arrest, but have other significant risk factors. The landmark SCD-HeFT¹ clinical trial found that ICD therapy reduced mortality by 23% in individuals with heart failure, ischemic or nonischemic cardiomyopathy, and left ventricular ejection fraction (LVEF) of 35% or lower. Medicare then expanded coverage to the primary prevention population effective January 27, 2005 based on the SCD-HeFT trial results.

Medicare ICD Registry

With the expanded coverage in 2005, Medicare also introduced the requirement of an ICD registry to collect information about primary prevention patients.

An implant registry is currently maintained by the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR[®]). Hospitals must enter their Medicare primary prevention patients in the registry as a condition for Medicare coverage, with some exceptions. Hospitals have the option to enter all of their ICD and CRT-D patients into the registry. The existence of the ACC-NCDR registry, launched April 3, 2006, subsequently expanded Medicare coverage to patients diagnosed with:

- Nonischemic dilated cardiomyopathy (NIDCM) > 3 months and < 9 months
- NYHA Class II or III heart failure
- Measured LVEF \leq 35% if they participated in the ACC-NCDR ICD registry

For further clarification, visit the Medicare website: www.cms.hhs.gov or visit the ACC website: www.acc.org.

Overview, *continued*

Cardiac Resynchronization Therapy Defibrillator

Cardiac resynchronization therapy defibrillator (CRT-D) combines the benefits of defibrillation with synchronous biventricular pacing capabilities. Biventricular pacing re-coordinates mismatched contractions of the heart's ventricles to improve cardiac output in individuals. CRT-D therapy is used in individuals who qualify for an ICD and who also have moderate to severe heart failure. CRT-D is also indicated for individuals with poor pumping function, as expressed by a low left ventricular ejection fraction, and conduction delays to the ventricles, as expressed by long QRS duration.

Medicare does not have a national coverage determination specifically for CRT-D therapy. As CRT-D combines the benefits of defibrillation with synchronous biventricular pacing capabilities, it is important that the patient first and foremost meet the national coverage indications for an ICD. To determine if the biventricular pacing capabilities are warranted, the current indications for biventricular pacing and supporting literature should be considered. Please contact your local payer's medical director for more specific information regarding the coverage policies for your area.

Coverage for ICD Therapy

Medicare Coverage

Typically, Medicare does not provide prior authorization for services. The Medicare coverage policy for ICD implants occurring on or after January 27, 2005 is printed verbatim; it is, however, reformatted for easier readability. Note that in this policy, coverage has been extended to the SCD-HeFT population.

The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT),¹ a landmark clinical trial in heart failure (HF) and cardiology, compares the efficacy of implantable cardioverter defibrillators (ICDs), amiodarone, and placebo in treating 2,521 patients with low ejection fraction and mild-to-moderate HF. The National Institutes of Health's National Heart, Lung, and Blood Institute conducted the SCD-HeFT clinical study as an independent trial, with funding from Medtronic, Inc. and Wyeth Ayerst. The study found that ICD therapy reduced all-cause mortality by 23% as compared to placebo. This mortality benefit was observed in patients who were already optimally managed on drug therapy. Amiodarone had no significant effect on all-cause mortality. Patients with SCD-HeFT indications have not experienced a sudden cardiac arrest (SCA), and hence their treatment with ICD therapy is considered to be a "primary prevention" measure.

The Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II)² studied the benefit of ICD therapy in patients with a prior MI and LVEF of 30% or lower. The study demonstrated a 31% reduction in mortality in patients who had ICDs, compared to those in the optimized medical therapy group.

Medicare Coverage Policy

20.4 (previously 35-85) IMPLANTABLE AUTOMATIC DEFIBRILLATORS, Medicare National Coverage Determinations Manual (Chapter 1, Part I (Sections 10-80.12) Coverage Determinations)*

A. General

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.

B. Covered Indications

1. Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause (effective July 1, 1991)
2. Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause (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 left ventricular ejection fraction (LVEF) ≤ 0.35 , and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 40 days prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.)

*The coverage policy is available at <http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterByDID=-98&sortByDID=1&sortOrder=ascending&itemID=CMS014961>.

COVERAGE FOR ICD THERAPY, *continued*

5. Documented prior MI and a measured LVEF ≤ 0.30 and a QRS duration of > 120 milliseconds (the QRS restriction does not apply to services performed on or after January 27, 2005). Patients must not have:

- a. New York Heart Association (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 past month (Effective for services on or after January 27, 2005, patients must not have 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 $\leq 35\%$
7. Patients with nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF $\leq 35\%$
8. Patients who meet all current Centers for Medicare & Medicaid Services (CMS) coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure

All indications must meet the following criteria:

- a. Patients must not have irreversible brain damage from pre-existing 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 Infarction³

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

- 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
 - 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

COVERAGE FOR ICD THERAPY, *continued*

d. The beneficiary receiving the defibrillator implantation for primary prevention is enrolled in either a Food and Drug Administration (FDA) approved category B investigational device exemption (IDE) clinical trial (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 implantable cardiac defibrillator (ICD) database will be maintained using a data submission mechanism that is 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 who 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.

e. [Was not included in the original publication.]

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.

9. Patients with NIDCM > 3 months, NYHA Class II or III heart failure, and measured LVEF \leq 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 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

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 Infarction³

COVERAGE FOR ICD THERAPY, *continued*

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.

C. 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).

Coverage with Non-Medicare Payers

Non-Medicare payers typically determine coverage for procedures based on prior authorization. With ICD patients, unless you are aware of the payer's coverage policy for a specific patient population, we recommend that you contact the payer to seek prior authorization. Asking about coverage after implant may result in unpaid claims, leaving both the hospital and the physician without compensation. Be sure to allow sufficient time to obtain prior authorization.

Coding and Payment for ICD Therapy

Coding for ICD Therapy

These coding suggestions do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. All diagnosis and procedure codes must be supported by clear documentation within the medical record.

Physician Procedure Codes

The following CPT⁴ codes describe procedures associated with ICD Therapy implants. Depending on the type of ICD implanted, one or a combination of the following codes may be appropriate:

CPT Code	CPT Code Description
33202	Insertion of epicardial electrode(s); open incision (e.g., thoracotomy, median sternotomy, subxiphoid approach)
33203	Insertion of epicardial electrode(s); endoscopic approach (e.g., thoracoscopy, pericardioscopy)
33216	Insertion of a transvenous electrode; single chamber (one electrode) permanent pacemaker or single chamber pacing cardioverter-defibrillator
33217	Insertion of a transvenous electrode; dual chamber (two electrode) permanent pacemaker or dual chamber pacing cardioverter-defibrillator
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal, insertion and/or replacement of generator)
+33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33240	Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator
33241	Subcutaneous removal of single or dual chamber pacing cardioverter-defibrillator pulse generator
33249	Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator
71090-26	Insertion pacemaker, fluoroscopy and radiography, radiological supervision and interpretation <i>71090-26 is an additional code that may be appropriate at the time of the implant</i>

+ Add-on code

CODING AND PAYMENT FOR ICD THERAPY, *continued*

Hospital Inpatient Procedure Codes

The following ICD-9-CM codes describe procedures performed in a hospital inpatient setting. Depending on the type of ICD implanted, one or a combination of the following codes may be appropriate.

ICD-9-CM Procedure Code	ICD-9-CM Procedure Code Description
00.51	Implantation of cardiac resynchronization defibrillator, total system [CRT-D]
00.52	Implantation or replacement of transvenous lead [electrode] into left ventricular coronary venous system
00.54	Implantation or replacement of cardiac resynchronization defibrillator pulse generator device only [CRT-D]
37.74	Insertion or replacement of epicardial lead (electrode) into epicardium
37.94	Implantation or replacement of automatic cardioverter-defibrillator, total system [AICD]
37.95	Implantation of automatic cardioverter-defibrillator lead(s) only
37.96	Implantation of automatic cardioverter-defibrillator pulse generator only
37.97	Replacement of automatic cardioverter-defibrillator lead(s) only
37.98	Replacement of automatic cardioverter-defibrillator pulse generator only

ICD-9-CM Code for NIPS

Noninvasive programmed stimulation (NIPS) is follow-up testing of the ICD device. It is performed periodically to reassess the shock level needed, to check the device status and to identify any necessary programming. Using telemetry signals, the implanted generator is instructed to induce and terminate arrhythmias through the implanted leads. Although noninvasive, NIPS involves inducing potentially lethal arrhythmias and must be performed in a specially equipped suite.

ICD-9-CM Procedure Code	Used For	Description
37.26	Full scale EPS only	Catheter based invasive electrophysiologic testing
37.20	NIPS only	Noninvasive programmed electrical stimulation [NIPS]

CODING AND PAYMENT FOR ICD THERAPY, *continued*

Hospital Outpatient Procedure Codes

The following CPT⁴ codes describe procedures performed in the hospital outpatient setting associated with ICD implants.

CPT Code	CPT Code Description
33216	Insertion of a transvenous electrode; single chamber (one electrode) permanent pacemaker or single chamber pacing cardioverter-defibrillator
33217	Insertion of a transvenous electrode; dual chamber (two electrodes) permanent pacemaker or dual chamber pacing cardioverter-defibrillator
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal, insertion and/or replacement of generator)
+33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33240	Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator
33241	Subcutaneous removal of single or dual chamber pacing cardioverter-defibrillator pulse generator
33249	Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator

+ Add-on code

Use of C-Codes

Effective January 1, 2005, hospitals must submit Healthcare Common Procedure Coding System (HCPCS) II C-Codes for the devices used, in addition to the CPT/HCPCS codes for implantation procedures performed in an outpatient setting.

Claims with CPT/HCPCS codes for the implantation procedure that were billed without corresponding C-Codes for the devices are returned to the hospital for correction. This edit is necessary because CMS analyzes the claim data for rate-setting and needs to ensure that device costs are present and identifiable.

CODING AND PAYMENT FOR ICD THERAPY, *continued*

The following C-Codes relate to the implantation of an ICD. Depending on the type of ICD implanted and the specific components, one or a combination of the following codes may be appropriate:

HCPCS II Code (C-Codes)	HCPCS II Code Description
C1721	Cardioverter-defibrillator, Dual Chamber (Implantable)
C1722	Cardioverter-defibrillator, Single Chamber (Implantable)
C1777	Lead, Cardioverter-defibrillator, Endocardial Single Coil (Implantable)
C1779	Lead, Pacemaker, Transvenous VDD Single Pass
C1882	Cardioverter-defibrillator, Other Than Single or Dual Chamber (Implantable)
C1895	Lead, Cardioverter-defibrillator, Endocardial Dual Coil (Implantable)
C1896	Lead, Cardioverter-defibrillator, Other Than Endocardial Single or Dual Coil (Implantable)
C1898	Lead, Pacemaker, Other Than Transvenous VDD Single Pass
C1899	Lead, Pacemaker-Cardioverter-defibrillator Combination (Implantable)
C1900	Lead, Left Ventricular Coronary Venous System

Note: Medtronic will update C-Codes relating to electrophysiology procedures on a quarterly basis and post them online at: www.Medtronic.com/CRDMreimbursement.

ICD-9-CM Diagnosis Codes

A) Secondary Prevention Patients

Secondary prevention patients receive an ICD for documented arrhythmias or because they have survived an episode of sudden cardiac arrest. Medicare Transmittal 819 dated January 27, 2006, with an implementation date of April 3, 2006, includes the following diagnosis codes that indicate ventricular arrhythmias.

ICD-9-CM Diagnosis Code	ICD-9-CM Diagnosis Code Description
427.1	Ventricular tachycardia (Paroxysmal)
427.41	Ventricular fibrillation
427.42	Ventricular flutter
427.5	Cardiac arrest
427.9	Cardiac dysrhythmia, unspecified

CODING AND PAYMENT FOR ICD THERAPY, *continued*

B) Primary Prevention Patients

Primary prevention patients do not have ventricular arrhythmias but receive an ICD because they have a high risk of developing them, due to a variety of factors. There are several types of primary prevention patients, as identified below.

MADIT-II and SCD-HeFT Patients

MADIT-II and SCD-HeFT were two clinical trials that studied the impact of ICD therapy on specific patient populations. Both trials demonstrated decreased risk of death from sudden cardiac arrest for patients who received an ICD.

The MADIT-II study involved patients with reduced left ventricular function defined as ejection fraction of $\leq 30\%$. MADIT-II patients have survived a previous myocardial infarction (MI) and have impairment of the left ventricle, but no prior history of arrhythmia. In diagnostic terms, left ventricular impairment is seen as low ejection fraction and is usually expressed as heart failure. To properly communicate the indication for these patients, it is important to reflect the principal diagnosis as heart failure or prior MI rather than an arrhythmia.

MADIT-II Patient Population Summary

- Prior MI
- EF $\leq 30\%$

SCD-HeFT patients represent a patient population with either ischemic or nonischemic cardiomyopathy with NYHA Class II and III, chronic heart failure, and EF $\leq 35\%$. To fully communicate the indication, it is important to reflect a principal diagnosis that is not related to an arrhythmia, but rather heart failure or cardiomyopathy.

SCD-HeFT Patient Population Summary

- Ischemic or nonischemic cardiomyopathy
- NYHA Class II or III
- EF $\leq 35\%$

These two patient populations overlap. The SCD-HeFT population includes, but is broader than, the MADIT-II population. For example, a prior MI is a MADIT-II indication, but may or may not be present in a SCD-HeFT patient. Also, both MADIT-II and SCD-HeFT criteria may include abnormalities in QRS duration.

C) Heart Failure Patients (MADIT-II AND SCD-HeFT or CRT-D Patients)

Note that heart failure must be explicitly documented by the physician for this population; it cannot be assumed by the coder on the basis of the ejection fraction. Non-diagnostic and non-specific terms such as "low ejection fraction" and "ventricular dysfunction" should also be avoided. These either cannot be coded with precision or cannot be coded at all. Low ejection fraction is a characteristic of heart failure, and it is essential that physicians document the diagnosis clearly.

CODING AND PAYMENT FOR ICD THERAPY, *continued*

Heart Failure

ICD-9-CM Diagnosis Code	ICD-9-CM Diagnosis Code Description
402.01	Hypertensive heart disease, malignant, with heart failure
402.11	Hypertensive heart disease, benign, with heart failure
402.91	Hypertensive heart disease, unspecified, with heart failure
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic kidney disease stage V or end stage renal disease
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease
428.0	Congestive heart failure, unspecified
428.1	Left heart failure
428.20	Systolic heart failure, unspecified
428.21	Acute systolic heart failure
428.22	Chronic systolic heart failure
428.23	Acute on chronic systolic heart failure
428.30	Unspecified diastolic heart failure
428.31	Acute diastolic heart failure
428.32	Chronic diastolic heart failure
428.33	Acute on chronic diastolic heart failure
428.40	Unspecified combined systolic and diastolic heart failure
428.41	Acute combined systolic and diastolic heart failure
428.42	Chronic combined systolic and diastolic heart failure
428.43	Acute on chronic combined systolic and diastolic heart failure
428.9	Unspecified heart failure

CODING AND PAYMENT FOR ICD THERAPY, *continued*

Prior Myocardial Infarction

The ICD-9-CM diagnosis codes for myocardial infarction vary depending on when the MI occurred and whether it still presents symptoms. The myocardial infarction codes in the 410 series indicate an MI that occurred more recently than 8 weeks ago.

For patients who had an MI more than 8 weeks ago, codes 412 or 414.8 can be used. Code 412 is for a remote MI that is currently presenting no symptoms. If the MI occurred more than 8 weeks ago and is no longer acute but is still symptomatic, and the patient is out of the initial episode of care, code 414.8 is used.

Note that the presence of the prior myocardial infarction cannot be assumed by the coder from ECGs or other studies without confirmation in the primary physician documentation. It is essential that physicians document the presence of the prior myocardial infarction clearly. The following diagnosis codes indicate a myocardial infarction:

ICD-9-CM Diagnosis Code	ICD-9-CM Diagnosis Code Description
410.00-410.92	Acute myocardial infarction
412	Old myocardial infarction
414.8	Other specified forms of chronic ischemic heart disease

QRS Duration, Wide and Narrow

ICD-9-CM does not have specific codes for undiagnosed variations or abnormalities in QRS duration, such as prolonged QT interval on electrocardiogram. This can only be shown with a general code:

ICD-9-CM Diagnosis Code	ICD-9-CM Diagnosis Code Description
794.31	Abnormal electrocardiogram

If the patient has a documented diagnosis of Long QT syndrome, this is shown with a specific code:

ICD-9-CM Diagnosis Code	ICD-9-CM Diagnosis Code Description
426.82	Long QT syndrome

CODING AND PAYMENT FOR ICD THERAPY, *continued*

Cardiomyopathy, Ischemic and Nonischemic Patients

ICD-9-CM has one diagnosis code for ischemic cardiomyopathy, and this code is also used when the diagnosis is ischemic congestive cardiomyopathy.

ICD-9-CM Diagnosis Code	ICD-9-CM Diagnosis Code Description
414.8	Other specified forms of chronic ischemic heart disease

Nonischemic cardiomyopathy is generally assigned to just one code:

ICD-9-CM Diagnosis Code	ICD-9-CM Diagnosis Code Description
425.4	Other primary cardiomyopathies

This code includes almost all other forms of primary cardiomyopathy such as idiopathic, hypertrophic, dilated, congestive (nonischemic), obstructive, constrictive, and restrictive forms of cardiomyopathy. One exception is hypertrophic obstructive cardiomyopathy, which is coded 425.1.

Familial or Inherited Conditions Patients

Familial or inherited conditions are cardiac conditions with a high risk of a life-threatening arrhythmia that are coded as the indication for receiving an ICD. These types of conditions include hypertrophic obstructive cardiomyopathy and Long QT syndrome.

The following diagnosis codes indicate a familial or inherited condition:

ICD-9-CM Diagnosis Code	ICD-9-CM Diagnosis Code Description
425.1	Hypertrophic obstructive cardiomyopathy
426.82	Long QT syndrome

CODING AND PAYMENT FOR ICD THERAPY, *continued*

Medicare Payment for ICD Therapy

Medicare continues to reimburse hospitals for inpatient services under Medicare Severity (MS) DRGs. Effective October 1, 2008, DRG 245 was changed to only include ICD generator procedures, and a new DRG 265 was created for ICD lead procedures. Accurate and detailed physician documentation is essential with severity adjusted DRG payments.

DRG Description	National DRG Payment Rate ⁵ Effective October 1, 2008	National DRG Payment Rate ⁶ Effective October 1, 2007
DRG 222 Cardiac defibrillator implant with cardiac catheterization with acute myocardial infarction/heart failure/shock with MCC*	\$48,011	\$43,459
DRG 223 Cardiac defibrillator implant with cardiac catheterization with acute myocardial infarction/heart failure/shock without MCC	\$34,906	\$37,270
DRG 224 Cardiac defibrillator implant with cardiac catheterization without acute myocardial infarction/heart failure/shock with MCC	\$44,155	\$39,637
DRG 225 Cardiac defibrillator implant with cardiac catheterization without acute myocardial infarction/heart failure/shock without MCC	\$32,764	\$34,100
DRG 226 Cardiac defibrillator implant without cardiac catheterization with MCC	\$37,267	\$32,024
DRG 227 Cardiac defibrillator implant without cardiac catheterization without MCC	\$27,741	\$27,305
DRG 245 AICD generator procedures	\$22,122	\$16,831
DRG 265 AICD lead procedures	\$12,268	Not applicable

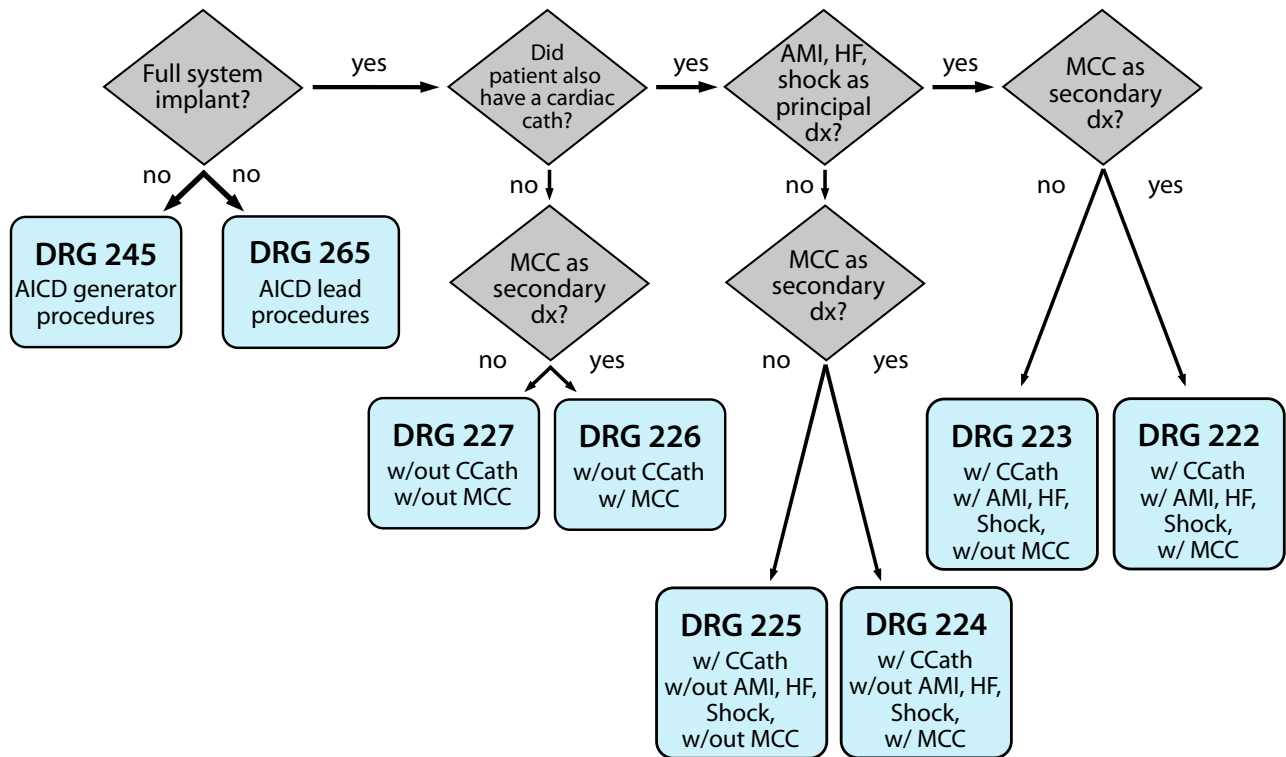
* MCC = Major Complication or Comorbidity

CODING AND PAYMENT FOR ICD THERAPY, *continued*

MS-DRGs for ICDs

Medicare has created eight MS-DRGs for ICD implants. The following chart illustrates the mapping of procedures to the MS-DRGs.

Mapping for Defibrillator MS-DRGs



Physician Documentation

Physician documentation for MS-DRGs is critical. All primary and secondary diagnoses must be clearly identified in the patient's record to facilitate appropriate payment.

Heart Failure as a CC (Complication or Comorbidity) or MCC (Major Complication or Comorbidity)

Under the MS-DRG system, heart failure can be considered both a chronic and acute condition. Documentation about the specific type of heart failure is critical to determine if the condition is considered a CC or a MCC.

For heart failure to be considered a CC, it must be specified as:

- Left heart
- Systolic, diastolic, or combined systolic and diastolic

For heart failure to be considered a MCC, it must be specified as:

- Acute
- or
- Acute on chronic

CODING AND PAYMENT FOR ICD THERAPY, *continued*

Heart Failure CCs and MCCs by diagnosis code:

Code	Description	Class
398.91	Rheumatic heart failure (congestive)	CC
402.01	Malignant hypertensive heart disease, with heart failure	CC
402.11	Hypertensive heart disease, benign, with heart failure	Not a CC
402.91	Hypertensive heart disease, unspecified, with heart failure	Not a CC
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	CC
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease	CC
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	CC
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic kidney disease stage V or end stage renal disease	CC
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	CC
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease	CC
428.0	Congestive Heart Failure, unspecified	Not a CC
428.1	Left Heart Failure	CC
428.20	Unspecified Systolic heart failure	CC
428.21	Acute systolic heart failure	MCC
428.22	Chronic systolic heart failure	CC
428.23	Acute on chronic systolic heart failure	MCC
428.30	Unspecified diastolic heart failure	CC
428.31	Acute diastolic heart failure	MCC
428.32	Chronic diastolic heart failure	CC
428.33	Acute on chronic diastolic heart failure	MCC
428.40	Unspecified combined systolic and diastolic HF	CC
428.41	Acute combined systolic and diastolic HF	MCC
428.42	Chronic combined systolic and diastolic HF	CC
428.43	Acute on chronic combined diastolic and systolic HF	MCC
428.9	Unspecified heart failure	Not a CC

Medicare Implant Registry

Patients who are enrolled in an FDA-approved Category B Investigational Device Exemption (IDE) clinical trial or a trial receiving coverage under the Medicare Routine Costs in Clinical Trials policy do not need to have their data submitted to this registry.

Registry participation is mandatory to obtain Medicare coverage for both inpatient and outpatient ICD services for primary prevention patients. Other trials or registries not previously mentioned may submit information about their data collection to CMS to determine if the data collection requirement is satisfied. For purposes of this coverage decision, CMS will determine whether specific registries or clinical trials meet these criteria.

This registry is a collaboration between the American College of Cardiology Foundation and the Heart Rhythm Society, and is formally referred to as the American College of Cardiology's National Cardiovascular Data Registry's (ACC-NCDR) ICD Registry. The purpose of the registry is to meet Medicare's data requirements.

This registry measures:

- a) Patient, facility, and provider characteristics
- b) Device type and characteristics
- c) Device interrogation for firing data
- d) Adverse events, etc.

Note: The enrollment instructions to participate in the NCDR® ICD Registry include the associated fees.

Date of Enrollment	Participation Dues	Implementation Fee	Total Due
January 1, 2009 – June 30, 2009	\$3,395	\$1,000	\$4,395
July 1, 2009 – December 31, 2009	\$1,700	\$1,000	\$2,700

Hospitals can choose to enter all ICD patients that would include primary and secondary prevention patients for both Medicare and non-Medicare patients.

More information can be found at <http://www.accncdr.com> or by calling the American College of Cardiology toll-free at 1 (866) 877-4102, extension 451.

Frequently Asked Questions

Answers to Frequently Asked Questions about Coverage

Does Medicare grant prior authorization for services?

No. Medicare does not typically require or grant prior authorization for services. However, Medicare will answer provider coverage questions about new devices and therapies. Please contact your local contractor for instructions. Medicare's website address is: <http://www.cms.hhs.gov>.

Have there been any changes to Medicare's covered indications since January 27, 2005?

No, there are no changes to the national coverage determination. However, as mentioned on page 2, patients with nonischemic dilated cardiomyopathy (NICDM) > 3 months, NYHA Class II and III heart failure, and measured LVEF < 35% will be covered as a result of the ACC-NCDR registry.

What is the effect of excluding all primary prevention patients including SCD-HeFT and MADIT-II indications if they have a PTCA or CABG within the past 3 months?

Even if a patient has met the other indications, an ICD implant would not be covered by Medicare for a patient who has had a PTCA or CABG procedure within the past 3 months. With sufficient passage of time, such a patient would later become eligible for Medicare coverage of an ICD implant. This same requirement is for all primary prevention patients (Indications 3-8) as reported in the Coverage section (see page 4).

Do non-Medicare payers have the same indications as Medicare for ICD implants?

Non-Medicare payers typically determine coverage through the prior authorization process. Contact the patient's payer to determine how you should proceed.

Does Medicare cover ICD therapy for the treatment of atrial fibrillation in patients who do not have a corresponding ventricular indication?

No. As of October 1, 2003, Medicare coverage is not available for ICD therapy for the treatment of atrial fibrillation in patients who do not have a corresponding ventricular indication, unless the patients are receiving ICD therapy under Category B IDE trial (42 CFR §405.201) or the CMS routine clinical trials policy (CIM 30-1, NCD 130.1).

Are there national CMS QRS requirements for NYHA Class IV heart failure CRT-D patients?

No, but Medicare local contractors may have developed local coverage decisions to CRT-D. Some of these local coverage decisions (LCDs) may require a strict adherence for FDA labeling (e.g., patients must have a QRS duration > 120 ms or 130 ms, etc.) in order for coverage to be granted. Contact your local Medicare contractor for more information regarding these and other policy requirements. Local Medicare coverage can be researched at <http://www.cms.hhs.gov/mcd/search.asp>.

FREQUENTLY ASKED QUESTIONS, *continued*

Does Medicare automatically cover the indications included in the ACC/AHA/HRS 2008 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death?

No. Medicare should cover an ICD implant if they meet any one of the national coverage determination indications outlined on pages 4-7. The 2008 ACC/AHA/HRS Guidelines for Implantable Defibrillator and Cardiac Resynchronization Therapy for Cardiac Rhythm Abnormalities⁷ are as follows:

Class I Recommendations for ICD Therapy

ICD therapy is indicated in patients*:

Level of Evidence: A

- With LVEF \leq 35% due to prior MI who are at least 40 days post-MI and are in NYHA Functional Class II or III
- With LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF \leq 30%, and are in NYHA Functional Class I
- Who are survivors of cardiac arrest due to VF or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes

Level of Evidence: B

- With nonischemic DCM who have an LVEF \leq 35% and who are in NYHA Functional Class II or III
- With nonsustained VT due to prior MI, LVEF $<$ 40%, and inducible VF or sustained VT at electrophysiological study
- With structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable
- With syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study

Class IIa Recommendations for ICD Therapy

ICD implantation is reasonable for patients*:

Level of Evidence: B

- To reduce SCD in patients with Long QT Syndrome who are experiencing syncope and/or VT while receiving beta blockers

Level of Evidence: C

- With unexplained syncope, significant LV dysfunction, and nonischemic DCM
- With sustained VT and normal or near-normal ventricular function
- With catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers
- For the prevention of SCD in patients with ARVD/C who have one or more risk factors for SCD
- With HCM who have one or more major risk factors for SCD
- With Brugada syndrome who have had syncope or documented VT that has not resulted in cardiac arrest
- With cardiac sarcoidosis, giant cell myocarditis, or Chagas' disease
- For non-hospitalized patients awaiting transplantation

* Assuming patients are on chronic, optimal medical therapy and have a reasonable expectation of survival with good functional status for $>$ 1 year.

FREQUENTLY ASKED QUESTIONS, *continued*

Class I Recommendations for CRT

CRT with or without ICD therapy is indicated for the treatment of heart failure in patients with*:

- NYHA Functional Class III or ambulatory Class IV heart failure symptoms
- LVEF \leq 35%
- QRS duration \geq 120 ms
- Sinus rhythm
- Optimal recommended medical therapy

(Level of Evidence: A)

Class IIa Recommendations for CRT

CRT with or without an ICD is reasonable for treatment of heart failure in patients with*:

- NYHA Functional Class III or ambulatory Class IV heart failure symptoms
- LVEF \leq 35%
- QRS duration \geq 120 ms
- Atrial fibrillation
- Optimal recommended medical therapy

(Level of Evidence: B)

CRT with or without an ICD is reasonable for treatment of heart failure in patients with*:

- NYHA Functional Class III or ambulatory Class IV heart failure symptoms
- LVEF \leq 35%
- Frequent dependence on ventricular pacing
- Optimal recommended medical therapy

(Level of Evidence: C)

Class I Recommendations for EF Measurement

Echocardiography is recommended:

- In patients with ventricular arrhythmias who are suspected of having structural heart disease (Level of Evidence: B)
- For the subset of patients at high risk for development of serious ventricular arrhythmias or SCD, such as:
 - Those with dilated hypertrophic, or RV cardiomyopathies
 - Acute MI survivors
 - or
 - Relatives of patients with inherited disorders associated with SCD (Level of Evidence: B)

Class IIa Recommendations for EF Measurement

1. Magnetic resonance imaging (MRI), cardiac computed tomography (CT), or radionuclide angiography can be useful in patients with ventricular arrhythmias when echocardiography does not provide accurate assessment of LV and RV function and/or evaluation of structural changes. (Level of Evidence: B)
2. LV imaging can be useful in patients undergoing CRT. (Level of Evidence: C)

* Assuming patients are on chronic, optimal medical therapy and have a reasonable expectation of survival with good functional status for > 1 year.

FREQUENTLY ASKED QUESTIONS, *continued*

Classification of Recommendations

- Class I** Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective
- Class II** Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment
Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy
Class IIb: Usefulness/efficacy is less well established by evidence/opinion
- Class III** Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective in some cases may be harmful

Level of Evidence

- Level A** Data derived from multiple randomized clinical trials or meta-analyses
- Level B** Data derived from a single randomized trial or nonrandomized studies
- Level C** Only consensus opinion of experts, case studies, or standard-of-care

What is the Q0 (zero) modifier, and does this apply to hospital or physician billing?

Effective January 1, 2008, the Q0 modifier replaced the QR modifier. Physicians must report the Q0 modifier on Medicare claims submitted on or after April 1, 2005 for primary prevention patients. The Q0 modifier must be appended to the primary procedure code describing the service on the claim. This modifier is also applicable to Medicare Hospital Outpatient Medicare claims (OPPS) effective April 1, 2005. CMS has stated that they have the ability to match claims to registry participation on a post-pay review basis.

If the hospital has chosen to enter all patients (all insurers and secondary prevention patients) into the ACC-NCDR Registry, they can also include the Q0 modifier on all of these patients.

If an individual does not have any heart conditions, what would we expect their QRS duration to be?

A normal QRS duration is less than 120 ms.

FREQUENTLY ASKED QUESTIONS, *continued*

Answers to Frequently Asked Questions about Coding and Payment

For a SCD-HeFT or MADIT-II ICD indication, a cardiac catheterization is not generally provided. What DRG would be assigned?

When a cardiac catheterization is not performed during the same admission as an ICD implant, either MS-DRG 226 (ICD/CRT-D system implant without cardiac cath with MCC) or MS-DRG 227 (ICD/CRT-D system implant without cardiac cath without MCC) would be assigned.

What procedure codes fall under ICD generator replacement MS-DRG 245?

ICD-9-CM Procedure Code	ICD-9-CM Procedure Code Description
00.54	Implantation or replacement of cardiac resynchronization defibrillator pulse device only [CRT-D]
37.96	Implantation of automatic cardioverter-defibrillator pulse generator only
37.98	Replacement of automatic cardioverter-defibrillator pulse generator only

What procedure codes fall under ICD lead replacement MS-DRG 265?

ICD-9-CM Procedure Code	ICD-9-CM Procedure Code Description
00.52	Implantation or replacement of transvenous lead [electrode] into left ventricular coronary venous system
37.95	Implantation of automatic cardioverter-defibrillator lead(s) only
37.97	Replacement of automatic cardioverter-defibrillator lead(s) only

Do secondary diagnosis codes make a difference in DRG assignment?

Yes. With the MS-DRG payment structure, secondary diagnoses codes can affect the DRG assignment. The secondary diagnosis will determine if the patient has a (major) complication or comorbidity.

Are there any other important diagnosis codes that may pertain to ICD patients that are classified as a CC or a MCC?

Yes.

V85.0 Body Mass Index less than 19, adult – CC

V85.4 Body Mass Index 40 and over, adult – CC

Can CC or MCC codes be excluded for MS-DRG assignment in particular situations?

Yes. Certain CC codes will not be applicable when submitted with particular principal diagnosis codes. Some MCC codes are only valid if the patient is discharged alive. This list includes:

427.41 Ventricular fibrillation

427.5 Cardiac arrest

785.51 Cardiogenic shock

785.59 Other Shock

799.1 Respiratory arrest

For additional information, please contact:

CRDM

healthcare
economics

Visit our website:

www.Medtronic.com/CRDMreimbursement

Email us:

rs.healthcareeconomics@Medtronic.com

Call our Coding Hotline:

1 (866) 877-4102, option 1

References

¹ Bardy GH, Lee KL, Mark DB, et al, for the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure [published correction appears in *N Engl J Med*. May 19, 2005;352(20):2146]. *N Engl J Med*. January 20, 2005;352(3):225-237.

² Moss AJ, Zareba W, Hall WJ, et al, for the Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med*. March 21, 2002;346(12):877-883.

³ Alpert JS, Thygesen K, Antman E, Bassand JP. Myocardial infarction redefined – a consensus document of The Joint European Society of Cardiology/American College of Cardiology Committee for the redefinition of myocardial infarction. *J Am Coll Cardiol*. September 2000;36(3):959-969.

Criteria for acute, evolving, or recent MI:

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

Criteria for established MI:

Any one 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

⁴ *Current Procedural Terminology (CPT®)*. Copyright 2008, American Medical Association. All Rights Reserved.

⁵ FY09 National Payment for large urban hospital with wage index and geographic adjustment factor of 1.00. Does not include IME or DSH. Assumes full market basket update for hospitals reporting quality data (3.6%) for FY09.

⁶ FY08 National Payment for large urban hospital with wage index and geographic adjustment factor 1.00. Does not include IME or DSH. Assumes a full market basket update of hospitals reporting quality data (3.3%) for FY08.

⁷ Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities [published correction appears in *J Am Coll Cardiol*. January 6, 2009;53(1):147]. *J Am Coll Cardiol*. May 27, 2008;51(21):e1-62.

www.medtronic.com

World Headquarters

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for
physicians and medical professionals)



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