

GuidePoint

Simplifying Reimbursement

Cardiac Rhythm Management
and Electrophysiology

This GuidePoint article outlines important coverage information for CRT-D therapy. Coverage varies among the Centers for Medicare & Medicaid Services (CMS) and private payers.

Medicare Coverage for CRT-D

Since the introduction of CRT therapy, CMS has never had a CRT National Coverage Determination^{††} (NCD). Today, as in the past, CRT-D patients who meet the criteria for CMS' National Coverage determination for ICDs are also covered provided that:

- CRT-D functionality is deemed reasonable and medically necessary[†]
- A CMS Local Coverage Determination (LCD) does not exist that limits CRT-D coverage (*As of August 25, 2011 there are no CMS LCDs that restrict CRT-D coverage to a subset of patients meeting the ICD NCD criteria.*)

MADIT-CRT Patients

Most MADIT-CRT patients continue to fall within the current CMS covered ICD indications.^{††} Note that NYHA Class I heart failure patients with LBBB must also have had a documented prior MI to meet the ICD indications. As always, physicians who implant CRT-D therapy into a MADIT-CRT FDA-indicated patient must continue to follow CMS coverage guidelines for ICD therapy and document medical necessity.

Please see Table 1 for the highlighted covered indications that address NYHA Class I and II heart failure patients.

Reasonable and Medically Necessary[†]

Physicians must provide explicit documentation that supports the decision to implant a CRT-D device rather than an ICD alone to meet the reasonable and medically necessary criteria required by CMS. The reasonable and medically necessary component is dependent on the physician documenting what was found as part of the patient's clinical evaluation and led to the physician's decision to implant a CRT-D device. This could include, but is not limited to, the following examples:

- The patient's diagnosis code
- The patient's measured EF (and the method used to measure the EF)
- LV function (level of dyssynchrony as indicated on echocardiogram or angiography)
- QRS width (as indicated on electrocardiography)
- Patient symptoms (How far can the patient walk without shortness of breath? Can they go up a flight of stairs? Have they decreased their general activity level because they are too tired?)

The need for documentation to support medical necessity has always been required by CMS. If the physician provides documentation that supports the reasonable and medically necessary criteria and is also implanting devices according to specific covered indications, there is an expectation of payment by CMS.

Table 1. CMS ICD National Coverage Determination (NCD)

MADIT CRT FDA Indication	CMS ICD National Coverage Determination
<ul style="list-style-type: none"> • Stable optimal pharmacologic therapy (OPT) for heart failure • Left bundle branch block (LBBB) • QRS width ≥ 130 ms • NYHA Class I ischemic or NYHA Class II ischemic or nonischemic • EF $\leq 30\%$ 	<p>Implantable Automatic Defibrillators (Various Effective Dates Below) (Rev. 29, Issued: 03-04-05, Effective: 01-27-05, Implementation: 01-27-05, Implementation QR Modifier: 04-04-05).</p> <p>A. General</p> <p>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.</p> <p>B. Covered Indications</p> <ol style="list-style-type: none"> 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). <p>Additional indications effective for services performed on or after October 1, 2003:</p> <ol style="list-style-type: none"> 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.) <p>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:</p> <ol style="list-style-type: none"> 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. <p>Additional indications effective for services performed on or after</p>

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 non-ischemic 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 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;^{†††}

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.

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;
- 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.
- (This NCD last reviewed February 2005.)

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

e. 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.**

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).

Private Payer Coverage for CRT-D

Coverage for CRT-D therapy will vary by non-Medicare private payers. As such, it is best to determine the coverage for each patient prior to rendering medical services. The most effective way to determine whether coverage for a non-Medicare patient is available for the hospital and physician is to research the payer's coverage policies. Coverage policies for CRT-D may be available on the payer's website.

Until recently many non-Medicare private payers limited their coverage for CRT-Ds to New York Heart Class (NYHA) Class III or IV heart failure patients with varying additional criteria such as an ejection fraction of (EF) < 35% and QRS duration > 120 ms.

In July of 2011, the Blue Cross Blue Shield Association (BCBSA) published a Technology Evaluation Center (TEC) Assessment on Cardiac Resynchronization Therapy for Mild Heart Failure. The complete BCBSA TEC Assessment can be found on the BCBSA website.¹ This assessment came to the following conclusion: "...the use of cardiac resynchronization for mild heart failure meets the TEC criteria for the following patient population:

- NYHA Class II heart failure
- Left-ventricular ejection fraction less than 30%
- QRS duration of 130 msec or greater"

In response to this BCBSA TEC Assessment some non-Medicare payers have expanded their coverage policy for CRT-Ds to mirror the above recommendation of the BCBSA.

Please see Table 2 for a listing of major private health plans that have expanded their coverage policy for CRT-Ds to include class II heart failure patients.

Preauthorization

In many cases, providers may be required to submit a formal request for preauthorization of benefits prior to scheduling procedures. Preauthorization helps to clarify benefits and payment rates in advance, allowing both the provider and patient to make informed decisions about their care. The one exception to this general rule is Medicare. Medicare does not preauthorize medical procedures.

Private payers have processes in place to render a decision for a preauthorization request. Boston Scientific offers a preauthorization template available for physician use at <http://www.bostonscientific.com/cardiac-rhythm-resources/Reimbursement-Home.html>

Table 2. Major private health plans with coverage policy for cardiac resynchronization therapy treatment for patients with Class II, III and IV heart failure

Table data accurate as of August 25, 2011; subject to change without notice

Plan	Membership	Class II-IV	Class II w/LBBB	Class II Effective Date	Coverage Area
Wellpoint (BCBS) ²	33,952,110	✓		4/13/11	Nationwide
UnitedHealth Group ³	32,824,278	✓		NP; in effect	Nationwide
BCBS of Alabama ⁴	3,570,223	✓		NP; in effect	Alabama
BCBS of Tennessee ⁵	2,468,015	✓		NP; in effect	Tennessee
BCBS of Minnesota ⁶	2,388,820	✓		9/26/11	Minnesota
Medica Health Plan ⁷	1,648,000	✓		8/1/11	Minnesota
Excellus BCBS ⁸	1,616,215	✓	✓	NP; in effect	New York
Premera BCBS ⁹	1,552,600	✓		6/13/11	AK and WA
Arkansas BCBS ¹⁰	898,957	✓		NP; in effect	Arkansas
BCBS of Kansas ¹¹	680,345	✓		NP; in effect	Kansas

NP = Not Published; No specific effective date for class II coverage provide in policy. Policy was effective at time of plan web site posting

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Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

- [†] Medicare, for example, defines medically necessary as "Services or supplies that are needed for the diagnosis or treatment of your medical condition and meet accepted standards of medical practice."
- ^{††} Centers for Medicare and Medicaid Services. National Coverage Determination for Implantable Automatic Defibrillators (20.4). In: Medicare Coverage Database. Effective January 27, 2005. Available at: http://www.cms.gov/mcd/viewncd.asp?ncd_id=20.4&ncd_version=3&basket=ncd%3A20.4%3A3%3AImplantable+Automatic+Defibrillators. Accessed January 3, 2011.
- ^{†††} Alpert and Thygesen et al., 2000. Criteria for acute, evolving or recent MI.
- ¹ Blue Cross Blue Shield Technology Evaluation Center, Volume 26, No. 1, July 2011, Cardiac Resynchronization Therapy for Mild Heart Failure, <http://www.bcbs.com/blueresources/tec/vols/26/cardiac-resynchronization-1.html> ; accessed August 25, 2011.
- ² Wellpoint; http://www.anthem.com/ca/medicalpolicies/policies/mp_pw_a053365.htm
- ³ UnitedHealth Group; <http://www.hrsonline.org/Policy/CodingReimbursement/reimbursement/coverage/upload/UnitedHealthcare-Cardiology-Notification-Program-Clinical-Criteria.pdf>
- ⁴ BCBS of Alabama; <https://www.bcbsal.org/providers/policies/final/055.pdf>
- ⁵ BCBS of Tennessee; http://www.bcbst.com/DraftMPs/BiVent_Pacemaker_TX_HF_Pol.pdf
- ⁶ BCBS of Minnesota; <http://notes.bluecrossmn.com/web/medpolman.nsf/8c1a3acb6f126e1862574ea0050a7f2/f44dc8215d542943862578b9005d4c19?OpenDocument>
- ⁷ Medica Health Plan; http://provider.medica.com/router/default.pdf?doc=/C1/CoveragePolicies/Document%20Library/Biventricular_InSync_CP.pdf
- ⁸ Excellus BCBS; https://www.excellusbcbs.com/wps/wcm/connect/ef7f84004e8eb76894a0bfe420b83c88/bivent_pacer.pdf?MOD=AJPERES and <https://www.excellusbcbs.com/wps/wcm/connect/953bee804e8eb77b94fabfe420b83c88/icd.pdf?MOD=AJPERES>
- ⁹ Premera BCBS; https://www.premera.com/stellent/groups/public/documents/medicalpolicy/cmi_062264.pdf and https://www.premera.com/stellent/groups/public/documents/medicalpolicy/cmi_003644.pdf
- ¹⁰ Arkansas BCBS; <http://www.arkansasbluecross.com/members/report.aspx?policyNumber=2002005> ICD <http://www.arkansasbluecross.com/members/report.aspx?policyNumber=1997018>
- ¹¹ BCBS of Kansas; http://www.bcbsks.com/Customerservice/Providers/MedicalPolicies/policies/policies/CardioverterDefibrillators_2011-04-22.pdf



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CRV-24308-AA SEP 2011