

GuidePoint

Simplifying Reimbursement

Cardiac Rhythm Management and Electrophysiology

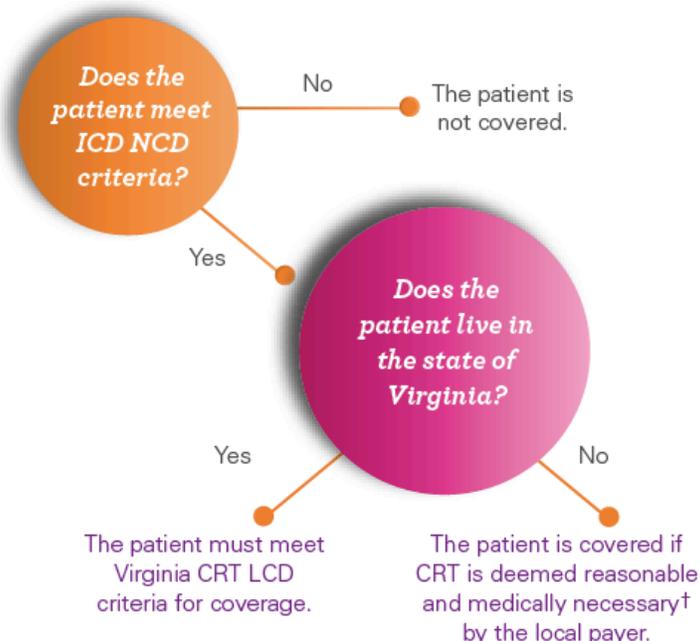
This GuidePoint article outlines important coverage information for CRT-D therapy. Coverage varies among the Centers for Medicare & Medicaid Services (CMS) and private payers.

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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^{†††}



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 to meet the reasonable and medically necessary criteria required by CMS. The reasonable and medically necessary component is dependent on the physician documenting what is found as part of the patient's clinical evaluation that led to the physician's determination 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><u>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:</u></p> <ol style="list-style-type: none"> <u>a. New York Heart Association (NYHA) classification IV;</u> <u>b. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;</u> <u>c. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months;</u> <u>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);</u> <u>e. Clinical symptoms or findings that would make them a candidate for coronary revascularization; or</u> <u>f. Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year.</u>

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 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 \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 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.

	<p>C. Other Indications</p>
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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).

Table 2. CMS Local Coverage Decisions (LCD)

Medicare Contractor	CRT-D
NATIONAL MEDICARE COVERAGE DETERMINATIONS (LCD)	
No NCD's- Local Contractor Discretion	
MEDICARE ADMINISTRATIVE CONTRACTORS (MAC)	
Jurisdiction 1 (CA, HI, NV) Palmetto GBA	No Published LCD
Jurisdiction 3 (AZ, MT, ND, SD, UT, WY) Noridian	No Published LCD
Jurisdiction 4 (CO, NM, OK, TX) Trailblazers	No Published LCD
Jurisdiction 5 (IA, KS, MO, NE) Wisconsin Physician Services (WPS)	No Published LCD
Jurisdiction 9 (FL) First Coast Service Options (FCSO)	No Published LCD
Jurisdiction 10 (AL, GA, TN) Cahaba GBA	No Published LCD
Jurisdiction 11 (NC, SC, WV) Palmetto GBA	No Published LCD

Medicare Contractor	CRT-D
<p>Jurisdiction 11 (VA) Palmetto GBA Policy is for VA only.</p>	<p><u>Resynchronization Therapy for Congestive Heart Failure (Bi-Ventricular Pacing)</u>¹</p> <p>Policy #: L31769 Effective: 3/19/2011</p> <p>Biventricular pacing or resynchronization therapy is a non-pharmacological treatment modality for patients with advanced heart failure. Its rationale is based on the observation that intraventricular conduction defects (IVCD) are associated with dyssynchronization between the left and the right ventricle resulting in decreased cardiac performance. In biventricular pacing, the right and left ventricle are activated simultaneously. In addition to the right atrial and right ventricular leads, a dedicated lead is required to pace the left ventricle. The latter is positioned via the coronary sinus.</p> <p>Resynchronization therapy will be considered as medically reasonable and necessary if:</p> <ol style="list-style-type: none"> 1) The patient is symptomatic despite optimal medical therapy with ACE (angiotensin converting enzyme) inhibitors and beta blockers as well as other appropriate pharmacologic measures, and 2) The patient has symptoms of moderate to severe congestive heart failure (NYHA Functional Class III or IV), and 3) The patient has a left ventricular ejection fraction of <35%, and 4) The QRS duration is ≥ 130 milliseconds. <p>All four provisions must be met and documented. Although patients with a left ventricular end diastolic diameter (LVEDD) of 55 mm or greater are the group for which data suggests optimum clinical improvement, this will not be used as an exclusionary criterion when all the other requirements have been satisfied. As long as documented in the medical record, a patient's intolerance or inability to take ACE inhibitors or beta blockers does not disqualify her/him for resynchronization therapy.</p> <p>For the initial implantation, a dedicated system must be used that is Food and Drug Administration (FDA) approved for this particular indication. Based on the individual patient situation, this carrier will consider the upgrade of previously implanted devices, as long as they are FDA approved.</p> <p>For the implantation of a biventricular pacing implantable cardiac defibrillator (ICD), all coverage criteria for the implantation of the ICD must be met first (CMS Manual System, Pub. 100-3, National Coverage Decisions, Ch. 1, section 20.4), in addition to all of the requirements for synchronized biventricular pacing. Documentation supporting this must be recorded in the medical record and available upon request.</p> <p>Resynchronization therapy is denied as not reasonable and necessary if these coverage criteria are not met.</p>
<p>Jurisdiction 12 (DC, DE, MD, NJ, PA) Highmark</p>	<p>No Published LCD</p>

Medicare Coverage for CRT-D

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Medicare Contractor	CRT-D
Jurisdiction 13 (CT,NY) National Government Services (NGS)	No Published LCD
Jurisdiction 14 (MA, ME, NH, RI, VT) National Heritage Insurance Company	No Published LCD
Medicare Part B Carriers	
Cigna Government Services (ID, NC, TN)	No Published LCD
Cahaba GBA (AL, GA, MS, TN)	No Published LCD
National Government Services (IN)	No Published LCD
NHIC (MA, ME, NH, RI, VT)	No Published LCD
Noridian (AZ, MT, ND, SD, UT, WY)	No Published LCD
Palmetto GBA (OH, SC, WV)	No Published LCD
Pinnacle (AR, LA)	No Published LCD
Wisconsin Phys Svcs (Part B: IL, MI, WI, MN)	No Published LCD

Private Payer Coverage for CRT-D

Coverage for CRT-D therapy will vary by non-Medicare private payer. 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 costs is for the provider to research the patient's coverage by contacting the payer regarding whether or not there is a coverage policy for CRT-D. Table 3 lists the coverage criteria for many of the top insurers in the United States for CRT-D therapy.

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 obtain prior-authorization. Boston Scientific offers a prior authorization template available for physician use at <http://www.bostonscientific.com/cardiac-rhythm-resources/reimbursement/Reimbursement-Coding-Coverage.html>.

Table 3. Private Payer Policies

(i) Private Payers	
<p>WellPoint, Inc. (licensed subsidiaries: CO, CT, GA, IN, KY, ME, MI, NV, NH, OH, VI, WI)</p>	<p><u>Cardiac Resynchronization Therapy (CRT) with or without an Implantable Cardioverter Difibrillator (CRT/ICD) for the Treatment of Heart Failure²</u></p> <p>Total Plan Enrollment: 33,952,110 Policy #: SURG.00064 Current Effective Date: 4/21/2010 Last Review Date: 2/25/2010</p> <p>Wellpoint Anthem considers FDA-approved biventricular pacemakers for cardiac resynchronization therapy (CRT) medically necessary for individuals who meet all of the following criteria:</p> <ol style="list-style-type: none"> 1. NYHA functional Class III or ambulatory Class IV symptoms, secondary to heart failure who remain symptomatic despite recommended, optimal medical therapy;* AND 2. Who have cardiac dyssynchrony, (which is currently defined as a QRS duration > 120 ms); AND 3. Left ventricular ejection fraction (LVEF) less than or equal to 35%; AND 4. Are in sinus rhythm. <p>The use of an FDA- approved ICD, in combination with cardiac resynchronization therapy (CRT/ICD), is considered medically necessary when the criteria listed above for CRT therapy AND the criteria within SURG.00033 Implantable Cardioverter Defibrillators (ICD) are met.</p> <p><u>Implantable Carioverter-Defibrillator (ICD)³</u></p> <p>Policy #: SURG.00033 Current Effective Date: 12/012010 Last Review Date: 11/18/2010</p> <p>Wellpoint Anthem considers implantable cardioverter-defibrillator (ICD) therapy medically necessary for the treatment of ventricular tachyarrhythmias and for the prevention of sudden cardiac death (SCD) in patients who are receiving optimal medical therapy and have a reasonable expectation of survival with a good functional</p>

	<p>status for more than 1 year when one of the following indications is present:</p> <ol style="list-style-type: none"> 1. After evaluation to define the cause of the event and to exclude any completely reversible causes in survivors of cardiac arrest due to ventricular fibrillation (VF) or hemodynamically unstable sustained ventricular tachycardia (VT); OR 2. Those with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable OR 3. Those with syncope of undetermined origin with either clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study; OR 4. Those with left ventricular ejection fraction (LVEF) less than 35% due to prior myocardial infarction (MI) who are at least 40 days post-MI and are in New York Heart Association (NYHA) functional Class II or III; OR 5. Those with nonischemic dilated cardiomyopathy (DCM) who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III; OR 6. Those with left ventricular (LV) dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than 30%, and are in NYHA functional Class I; OR 7. Those with nonsustained VT due to prior MI, LVEF less than 40%, and inducible VF or sustained VT at electrophysiological study; OR 8. Those with long-QT syndrome who are experiencing syncope or VT while receiving beta blockers. 9. Those with confirmed hypertrophic cardiomyopathy (HCM) with two (2) or more major risk factors for sudden cardiac death (SCD) which are: <ul style="list-style-type: none"> o Family history of HCM-related SCD in at least 1 first-degree relative; o At least 1 episode of unexplained syncope within the previous 12 months; o Nonsustained VT on ECG; o Abnormal blood pressure (BP) response during upright exercise testing; o Left ventricular (LV) wall thickness greater than or equal to 30 mm.
<p>UnitedHealth Group, Inc.</p>	<p><u>Cardiac Pacemakers, Defibrillators and Cardiac Resynchronization Therapy</u>⁴</p> <p>Total Plan Enrollment: 31,980,000 Policy #: C-SHO-001 Approval Date: 2/14/2008</p> <p>Cardiac Resynchronization Therapy for Congestive Heart Failure Cardiac Resynchronization Therapy (Biventricular Pacing) for Congestive Heart Failure is covered when criteria are met.</p>
<p>Aetna</p>	<p><u>Biventricular Pacing (Cardiac Resynchronization Therapy)/ Combination Resynchronization- Defibrillation Devices for Congestive Heart Failure</u>⁵</p> <p>Total Plan Enrollment: 18,557,996 Policy #: 0610 Last Review: 9/28/2010 Effective Date: 4/30/02 Next Review: 08/11/2011</p> <p>Aetna considers FDA-approved biventricular pacemakers (cardiac resynchronization therapy) medically necessary for the treatment of members with congestive heart</p>

	<p>failure (CHF) when all of the following criteria are met:</p> <ul style="list-style-type: none"> • New York Heart Association (NYHA) classification of heart failure III or IV; AND • Left ventricular ejection fraction less than or equal to 35%; AND • QRS duration greater than or equal to 120 msec; AND • Member is on a stable pharmacologic regimen before implantation, which may include any of the following, unless contraindicated; <ol style="list-style-type: none"> 1. Angiotensin-converting enzyme inhibitor; OR 2. Angiotensin receptor blocker; OR 3. Beta blocker; OR 4. Digoxin; OR 5. Diuretics <p>Aetna considers biventricular pacemakers experimental and investigational for all other indications (e.g., atrial fibrillation, mild heart failure, and antibradycardia pacing).</p> <p>Aetna considers FDA-approved combination resynchronization-defibrillator devices medically necessary for members who are at high risk for sudden cardiac death when the afore-mentioned criteria are fulfilled and any of the criteria listed below is met:</p> <ul style="list-style-type: none"> • Members have at least one episode of cardiac arrest as a result of ventricular tachyarrhythmias; OR • Members have recurring, poorly tolerated sustained ventricular tachycardia; OR • Members have a prior heart attack and a documented episode of non-sustained ventricular tachycardia, with an inducible ventricular tachyarrhythmia; OR • Members have a prior heart attack and a left ventricular ejection fraction of less than or equal to 30%.
<p>BCBS of Illinois, New Mexico, Oklahoma, & Texas</p>	<p><u>Biventricular Pacing</u>⁶</p> <p>Total Plan Enrollment: 12,400,000 Policy #: MED202.054 Effective Date: 5/1/09</p> <p>Biventricular pacing with biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (ID) (i.e., a combined biventricular pacemaker and ICD) may be considered medically necessary as a treatment of CHF (congestive heart failure) in patients who meet all the following requirement:</p> <ul style="list-style-type: none"> • New York Heart Association (NYHA) Class III or IV, AND • Left ventricular ejection fraction <= (less than or equal to) 35%, AND • QRS duration of >= (greater than or equal to) 120-130 msec, AND • Under treatment with a stable pharmacological medical regime prior to implant that includes appropriate combinations of Angiotensin-converting Enzyme (ACE inhibitor), an Angiotensin Receptor Blocker (ARB), beta blocker, digoxin, and diuretics. <p>Inclusion of an intrathoracic fluid monitoring sensor as a component of an implanted biventricular pacemaker is considered experimental, investigational and unproven.</p>

<p>CIGNA Healthcare</p>	<p><u>Biventricular Pacing/Cardiac Resynchronization Therapy</u>⁷</p> <p>Total Plan Enrollment: 11,131,599 Policy #: 0174 Effective Date: 8/15/10 Next Review Date: 8/15/11</p> <p>CIGNA covers the use of biventricular pacemakers alone or combined with an implantable cardioverter defibrillator for cardiac resynchronization therapy (CRT) as medically necessary for individuals with congestive heart failure (CHF) when ALL of the following criteria are met:</p> <ul style="list-style-type: none"> • New York Heart Association (NYHA) classification of heart failure III or IV • Left ventricular ejection fraction (LVEF) is less than or equal to 35% • QRS duration is greater than or equal to 120 milliseconds (ms) • Sinus rhythm or chronic atrial fibrillation (AF) • Individual on an optimal pharmacologic regimen before implantation, which may include the following, unless contraindicated: <ol style="list-style-type: none"> 1. Aldosterone antagonists 2. Angiotensin-converting enzyme (ACE) inhibitor 3. Angiotensin receptor blocker (ARB) 4. Beta blocker 5. Digoxin 6. Diuretics
<p>Humana</p>	<p><u>Cardioverter Defibrillators/ Cardiac Resynchronization Therapy</u>⁸</p> <p>Total Plan Enrollment: 8,359,031 Policy #: CLPD-0425-005* Effective Date: 2/24/2011 Revised Date: 2/24/2011</p> <p>Humana members may be eligible under the Plan for a Food and Drug Administration (FDA) approved AICD ONLY for the following indications:</p> <ol style="list-style-type: none"> 1. Episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause; OR 2. 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; OR 3. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy; OR 4. Coronary artery disease with a documented prior myocardial infarction (MI), a measured left ventricular ejection fraction (LVEF) $\leq 35\%$, 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); OR 5. Documented prior MI and a measured LVEF < 0.30 and a QRS duration of > 120 milliseconds. Patients must NOT have: <ul style="list-style-type: none"> • New York Heart Association (NYHA) Class IV; OR 6. With ischemic dilated cardiomyopathy (IDCM), documented prior MI, NYHA Class II and III, and measured LVEF $\leq 35\%$; OR 7. With non-ischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III, and measured LVEF $\leq 35\%$; OR <p>Indications 3 - 7 (primary prevention of sudden cardiac death) must also meet the following criteria:</p>

	<p>Patients must be able to give informed consent; AND Patients must NOT have:</p> <ul style="list-style-type: none"> ▪ Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; OR ▪ Coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within the past 3 months; OR ▪ Acute MI within the past 40 days; OR ▪ Clinical symptoms or finding that would make them a candidate for coronary revascularization; OR ▪ Any disease, other than cardiac (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year; AND <ul style="list-style-type: none"> • Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography; AND • 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. <p>8. NIDCM > 3 months, NYHA Class II or III, and measured LVEF < or = 35%, only if the following additional criteria are also met:</p> <ul style="list-style-type: none"> • Patients must be able to give informed consent; AND • Patient must NOT have: <ul style="list-style-type: none"> ▪ Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; OR ▪ CABG or PTCA within the past three months; OR ▪ Acute MI within the past 40 days; OR ▪ Clinical symptoms or findings that would make them a candidate for coronary revascularization; OR ▪ Irreversible brain damage from preexisting cerebral disease; OR ▪ Any disease, other than cardiac (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year; AND • Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography; AND • 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; AND • 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.
<p>Health Net</p> <p>*Changes to policy Class I & II changes</p>	<p><u>Biventricular Pacemakers/Combination Resynchronization-Defibrillation Devices for the Treatment of Congestive Heart Failure</u>⁹</p> <p>Total Medical Enrollment: 6,659,000 Policy #: NMP334 Effective Date: 4/2007 Updated: 12/2010*</p> <p>Biventricular Pacemakers / Cardiac Resynchronization Therapy (CRT) Health Net, Inc. considers FDA-approved biventricular pacemakers (cardiac resynchronization therapy (CRT), medically necessary when the following are met:</p> <ol style="list-style-type: none"> 1. LVEF less than or equal to 35%, a QRS duration greater than or equal to 0.12 seconds, and sinus rhythm, is indicated for the treatment of NYHA functional Class III or ambulatory Class IV heart failure symptoms with optimal recommended medical therapy, CRT with or without an ICD, unless contraindicated. OR

2. LVEF of less than or equal to 35%, a QRS duration of greater than or equal to 0.12 seconds, and atrial fibrillation (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.
3. Heart failure is stable, but individual continues to have advanced symptoms despite maximal medical therapy, which may include the following, unless not tolerated or contraindicated:
 - Angiotensin-converting enzyme (ACE) inhibitor
 - Angiotensin receptor blocker (ARB)
 - Beta blocker
 - Digoxin
 - Diuretics
4. LVEF of less than or equal to 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.

Health Net, Inc. considers FDA-approved combination resynchronization-defibrillator devices (CRT-D) medically necessary for members who are at high risk for sudden cardiac death when the afore-mentioned criteria are fulfilled and **any** of the criteria listed below is met: Biventricular Pacemaker Dec 10 2 Posted: December 2010

- Members have at least one episode of cardiac arrest due to ventricular fibrillation or hemodynamically unstable, sustained ventricular tachyarrhythmias, not due to reversible or transient causes; **OR**
- Non-sustained VT due to prior MI, left ventricular ejection fraction (LVEF) less than 40%, and inducible VF or sustained VT at electrophysiological study); **OR**
- LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 30%, and are in NYHA functional Class I.

***NOTE:** The Policy Statement noted above includes information from the American College of Cardiology (ACC) on Classification of Recommendation on Class I & Class IIa only, as noted below:

Class I – Procedure should be performed.

Class IIa – It is reasonable to perform procedure.

- Ischemic dilated cardiomyopathy (IDCM) with NYHA Class II or III heart failure, at least 30 days post MI, and measured LVEF is less than or equal to 35%; **OR**
- Non-ischemic dilated cardiomyopathy (NIDCM) of > 9 months duration, NYHA Class II or III heart failure, and measured LVEF is less than or equal to 35%.
- Patient has a prior heart attack and a LVEF of less than or equal to 30%.

Health Net, Inc. considers the following use of FDA approved combination resynchronization-defibrillator devices investigational and therefore not medically necessary:

- Asynchronous pacing in the presence or likelihood of competitive paced and intrinsic rhythms.
- For individuals whose heart failure or ventricular tachyarrhythmias may have transient or reversible causes and for patients with incessant ventricular tachycardia or ventricular fibrillation.

Health Net, Inc. considers combination resynchronization-defibrillator devices investigational and therefore **not** medically necessary for **all** other indications.

****NOTE:** ACC Recommendations Class IIB would need to be reviewed on a case-by-case basis.

	<p>Class IIB – Procedure may be considered. Class III – Conditions for which there is evidence and/or general agreement that procedure/treatment is not useful/effective and in some cases may be harmful.</p>
<p>Highmark</p>	<p><u>Biventricular Pacemakers for the Treatment of Congestive Heart Failure</u>¹⁰</p> <p>Total Medical Enrollment: 4,114,476 Policy #: S-153 Effective Date: 1/19/09 Issued Date: 1/19/09 Archived: 1/19/09</p> <p>This policy on Biventricular Pacemakers for the Treatment of Congestive Heart Failure has been archived as of January 19, 2009 and is no longer in effect. For services rendered prior to the archived date of this policy, please refer to the prior versions of the policy as follows:</p> <p>Effective Date: 1/1/08 Issued Date: 12/31/07</p> <p>Insertion of the biventricular pacemaker may be considered medically necessary as a treatment of congestive heart failure in patients who meet all of the following criteria:</p> <ul style="list-style-type: none"> • New York Heart Association Class III or IV • Left ventricular ejection fraction < 35% • QRS duration of greater than or equal to 120 msec • Patients treated with a stable pharmacological medical regimen prior to implant, including an ACE inhibitor (or an angiotensin receptor blocker) and a beta blocker (or angiotensin receptor blocker), digoxin, and diuretics. <p>If the insertion of a biventricular pacemaker for congestive heart failure is reported for any indication other than those listed, it should be denied as not medically necessary and, therefore, not covered. A participating, preferred, or network provider cannot bill the member for the denied service.</p>
<p>EmblemHealth, Inc</p>	<p><u>Resynchronization Therapy (biventricular pacing)</u>¹¹</p> <p>Total Medical Enrollment: 2,752,815 Policy #MG.MM.SU.41cC Last Review Date: 9/15/2010</p> <p><i>For implantable automatic defibrillators (also referred to as implantable cardioverter-defibrillators), the CMS NCD for Implantable Automatic Defibrillators may be referenced at:</i></p> <p>http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=20.4&ncd_version=3&basket=ncd%3A20%2E4%3A3%3AImplantable+Automatic+Defibrillators</p> <p>Members with moderate to severe symptomatic CHF (NYHA functional class III or IV) with IVCD may be eligible for coverage of resynchronization therapy when all of the following criteria are met:</p> <ol style="list-style-type: none"> 1. Presence of persistent symptoms despite optimal conventional therapy with any of the following pharmacological regimens, as appropriate, unless

	<p>contraindicated:</p> <ul style="list-style-type: none"> ○ Angiotensin-converting enzyme (ACE) inhibitors. ○ Angiotensin receptor blockers. ○ Beta blockers. <ol style="list-style-type: none"> 2. Left ventricular ejection fraction \leq 35%. 3. QRS \geq 120 milliseconds. 4. Must be in sinus rhythm. <p>Limitations/Exclusions Utilized devices must be FDA-approved.</p>
Medical Mutual of Ohio	No Policy Found Total Medical Enrollment: 3,154,334
WellCare Group of Companies	No Policy Found
Independence Blue Cross	No Policy Found Total Medical Enrollment: 3,599,371
Horizon BlueCross BlueShield	<p><u>Biventricular Pacemakers for Cardiac Resynchronization Therapy in Congestive Heart Failure</u>¹²</p> <p>Total Medical Enrollment: 2,831,119 Policy #: 062 Original Policy Date: 11/21/2005 Last Review Date: 9/14/2010</p> <p>FDA-approved biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD) are considered medically necessary for cardiac resynchronization therapy (CRT) in members with congestive heart failure who meet all of the following criteria:</p> <ul style="list-style-type: none"> • NYHA Class III or IV • Left ventricular ejection fraction \leq 35% • QRS duration of \geq120 msec • Members on optimal pharmacologic medical regimen prior to implant which may include (unless contraindicated) angiotensin-converting enzyme (ACE) inhibitor, angiotensin receptor blocker, beta blocker, digoxin, and/or diuretics. <p><i>[INFORMATIONAL NOTE: Please refer to the New York Heart Association Classification under the Description Section of this policy. Also refer to a separate policy on the use of Automatic Implantable Cardioverter Defibrillator (AICD) alone to treat patients at risk for ventricular arrhythmias – Policy #061 in the Surgery Section.]</i></p> <p>All other uses of biventricular pacemakers with or without an accompanying implantable cardiac defibrillator are considered investigational.</p>
BlueCross BlueShield of Massachusetts	<p><u>Biventricular Pacemakers for the Treatment of Congestive Heart Failure</u>¹³</p> <p>Total Medical Enrollment: 2,980,607 Policy #: 101 Original Policy Date: 6/1/09</p>

	<p>Revised Date: 12/01/2010</p> <p>We cover biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD) as a treatment of congestive heart failure in patients who meet all of the following criteria:</p> <ul style="list-style-type: none"> • NYHA (New York Heart Association) Class III or IV (heart failure) • Left ventricular ejection fraction $\leq 35\%$ (50-60 normal range) • Sinus rhythm • QRS duration of $\geq 120-130^*$ msec (wide QRS interval) • Patients treated with a stable pharmacological medical regimen prior to implant, such as an ACE inhibitor (or an angiotensin receptor blocker) and a beta blocker (or angiotensin receptor blocker), digoxin, and/or diuretics. <p>The FDA-labeled indication for the InSync device is limited to patients with a QRS duration of >130 msec, while the FDA-labeled indication for the CONTAK CD[®] CRT-D System is limited to patients with a QRS >120 msec.</p> <p>We do not cover an intrathoracic fluid monitoring sensor as a component of a biventricular pacemaker because it is considered investigational.</p> <p>All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature.</p>
<p>BlueCross BlueShield of Alabama</p>	<p><u>Bi-Ventricular Pacemakers for the Treatment of Congestive Heart Failure</u>¹⁴</p> <p>Total Medical Enrollment: 3,570,223 Policy #: 055 Last Review Date: 10/2009</p> <p>Biventricular Pacemakers meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the treatment of congestive heart failure (CHF) when all of the following criteria are met:</p> <ul style="list-style-type: none"> • New York Heart Association (NYHA) Class III or IV. • Left ventricular ejection fraction $\leq 35\%$. • QRS duration of ≥ 120 msec-130 msec.* • Patients who remain symptomatic despite stable pharmacological medical regimen prior to implant, including an ACE inhibitor (or an angiotensin receptor blocker) and a beta-blocker if tolerated, digoxin and diuretics. <p>*The FDA labeled indication for the InSync device is limited to patients with a QRS duration of > 130 msec, while the FDA-labeled indication for the CONTAK CD[®] CRT-D System is limited to patients with a QRS > 120 msec. Combination automatic implantable cardiac defibrillators (AICD) and biventricular pacemakers meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for <i>Proprietary Information of Blue Cross and Blue Shield of Alabama</i> 3 patients who meet criteria for BOTH a biventricular pacemaker and an AICD. Please see policy # 168 (Cardiac Defibrillators) for criteria for the AICD.</p> <p>Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator as a treatment of New York Heart Association class I or II heart failure do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered investigational. Biventricular Pacemakers do not</p>

	<p>meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational when performed in the following conditions:</p> <ul style="list-style-type: none"> • Unstable angina, myocardial infarction or prior coronary artery revascularization or angioplasty within the past 3 months.
<p>BlueCross BlueShield of Tennessee</p>	<p><u>Cardiac Resynchronization Therapy (CRT) for Heart Failure</u>¹⁵</p> <p>Total Medical Enrollment: 2,468,015</p> <p>Cardiac resynchronization therapy for the treatment of heart failure is considered medically necessary if the medical appropriateness criteria are met. (See Medical Appropriateness below.)</p> <ul style="list-style-type: none"> • Cardiac resynchronization therapy for the treatment of heart failure is considered medically necessary if the medical appropriateness criteria are met. (See Medical Appropriateness below.) • Cardiac resynchronization therapy for the treatment of conditions other than heart failure is considered investigational. • Any device utilized for this procedure must have FDA approval specific to the indication, otherwise it will be considered investigational. <p>MEDICAL APPROPRIATENESS</p> <p>Cardiac resynchronization therapy for the treatment of heart failure is considered medically appropriate if ALL of the following criteria are met:</p> <ul style="list-style-type: none"> • Has symptoms of moderate to severe congestive heart failure (NYHA Functional Class III or IV) • Left ventricular ejection fraction is equal to or less than 35% • QRS duration of equal to or greater than 130 msec • Remains symptomatic despite being treated with a stable pharmacological medical regimen prior to implant, including an ACE inhibitor (or an angiotensin receptor blocker) and a beta-blocker (or angiotensin receptor blocker), digoxin, and diuretics
<p>BlueCross BlueShield of North Carolina</p>	<p>No Policy Found</p> <p>Total Medical Enrollment: 2,800,519</p>
<p>BlueCross BlueShield of Florida</p>	<p>No Policy Found</p> <p>Total Medical Enrollment 2,893,373</p>
<p>Medica</p>	<p><u>Biventricular Pacing (Cardiac Resynchronization Therapy) for Heart Failure</u>¹⁶</p> <p>Effective Date: 6/1/08</p> <p>Biventricular pacing is covered for patients with chronic heart failure who demonstrate:</p> <ul style="list-style-type: none"> • Moderate to severe heart failure, as indicated by a New York Heart Association (NYHA) functional class status of III or IV, and • A left ventricular ejection fraction less than or equal to 35 percent, and • A prolonged QRS duration, and • Who remain symptomatic despite stable, optimal medical therapy.

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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/viewnacd.asp?ncd_id=20.4&ncd_version=3&basket=ncd%3A20.4%3A3%3AImplantable+Automatic+Defibrillators. Accessed January 3, 2011.
- ††† As of December 31, 2010, only Virginia has Medicare (CMS) LCDs that restrict CRT-D coverage to a subset of patients meeting the ICD NCD criteria.
- †††† Alpert and Thygesen et al., 2000. Criteria for acute, evolving or recent MI.
- 1 [http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?ContrNum=11302&ContrTypeld=9&LCDId=31769&ver=5&ContrlD=229&Cntrctr=229&name=Palmetto+GBA+\(11302,+MAC+-+Part+B\)&s=53&bc=BBAAAAEAAAA&](http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?ContrNum=11302&ContrTypeld=9&LCDId=31769&ver=5&ContrlD=229&Cntrctr=229&name=Palmetto+GBA+(11302,+MAC+-+Part+B)&s=53&bc=BBAAAAEAAAA&)
- 2 http://www.anthem.com/medicalpolicies/policies/mp_pw_a053365.htm
- 3 http://www.anthem.com/medicalpolicies/policies/mp_pw_a053321.htm
- 4 <https://www.unitedhealthcareonline.com/ccmcontent/Provider/II/JHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools and Resources/Policies and Protocols/UnitedHealthcare Medicare Coverage/Cardiac Pacemakers Defibrillator SH Ovations.pdf>
- 5 http://www.aetna.com/cpb/medical/data/600_699/0610.html
- 6 <http://medicalpolicy.hcsc.net/medicalpolicy/home?corpEntCd=IL1&path=/templatedata/m...>
- 7 http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/index.html
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- 13 https://www.bluecrossma.com/common/en_US/medical_policies/101 Biventricular Pacemakers for the Treatment of Congestive Heart Failure prn.pdf
- 14 <https://www.bcbsal.org/providers/policies/final/055.pdf>
- 15 http://www.bcbst.com/mpmanual/!SSL/!WebHelp/Cardiac_Resynchronization_Therapy_CRT_for_Heart_Failure.htm
- 16 <http://provider.medica.com/router/default.pdf?doc=C1/CoveragePolicies/Document Library/Biventricular InSync CP.pdf>



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