

MEDICAL POLICY

SUBJECT: CARDIAC RESYNCHRONIZATION THERAPY (BIVENTRICULAR PACEMAKERS) FOR THE TREATMENT OF HEART FAILURE

EFFECTIVE DATE: 11/21/02
REVISED DATE: 10/15/03, 08/19/04, 04/21/05, 01/19/06, 11/16/06, 09/20/07, 10/23/08, 09/17/09, 04/22/10, 06/16/11, 06/21/12, 06/20/13, 08/21/14, 07/16/15, 07/21/16, 07/20/17, 08/16/18

POLICY NUMBER: 7.01.58
CATEGORY: Technology Assessment

PAGE: 1 OF: 9

- *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*
- *If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT:

- I. Based upon our criteria and review of the peer-reviewed literature and the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) and the Heart Rhythm Society (HRS), biventricular pacing with or without an implantable cardiac defibrillator for the treatment of heart failure has been medically proven to be effective and therefore, is considered a medically appropriate treatment option in the management of persons with chronic heart failure and left bundle branch block pattern (LBBB) with the following indications:
- A. NY Heart Association Functional Class of II, III or IV; and
 - B. Sinus Rhythm; and
 - C. Left ventricular ejection fraction less than or equal to 35%; and
 - D. QRS duration of equal to or greater than 0.12 s; and
 - E. The patient remains symptomatic despite optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents. These agents include but are not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and diuretics.
- OR:
- F. NY Heart Association Functional Class of I; and
 - G. Sinus Rhythm; and
 - H. Left ventricular ejection fraction less than or equal to 30%; and
 - I. QRS duration of equal to or greater than 0.15 s; and
 - J. The patient remains symptomatic despite optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents. These agents include but are not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and diuretics.
- II. Based upon our criteria and review of the peer-reviewed literature, biventricular pacing with or without an implantable cardiac defibrillator for the treatment of heart failure has been medically proven to be effective and therefore, is considered a **medically appropriate** treatment option in the management of persons with chronic heart failure and *non-left bundle branch block pattern (non-LBBB)* with the following indications:
- A. NY Heart Association Functional Class of III or IV; and
 - B. Sinus Rhythm; and
 - C. Left ventricular ejection fraction less than or equal to 35%; and
 - D. QRS duration of equal to or greater than 0.12 s; and
 - E. The patient remains symptomatic despite optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents. These agents include but are not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and diuretics.
- OR:
- F. NY Heart Association Functional Class of II; and
 - G. Sinus Rhythm; and
 - H. Left ventricular ejection fraction less than or equal to 35%; and
 - I. QRS duration of equal to or greater than 0.15 s; and

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- J. The patient remains symptomatic despite optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents. These agents include but are not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and diuretics.
- III. Based upon our criteria and review of the peer-reviewed literature, biventricular pacing with or without an implantable cardiac defibrillator for the treatment of heart failure has been medically proven to be effective and therefore, is considered a **medically appropriate** treatment option in the management of persons with chronic heart failure and atrial fibrillation who meet criteria for CRT and *all* of the following indications:
- A. Left ventricular ejection fraction less than or equal to 35%; and
 - B. AV nodal ablation or pharmacologic rate control will allow near 100% ventricular pacing with CRT; and
 - C. The patient remains symptomatic despite optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents. These agents include but are not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and diuretics.
- IV. Based upon our criteria and review of the peer-reviewed literature, biventricular pacing with or without an implantable cardiac defibrillator for the treatment of heart failure has been medically proven to be effective and therefore, is considered a **medically appropriate** treatment option in the management of persons with chronic heart failure and undergoing new or replacement device placement who meet *all* of the following indications:
- A. Left ventricular ejection fraction less than or equal to 35%; and
 - B. Anticipated requirement for greater than 40% ventricular pacing; and
 - C. The patient remains symptomatic despite optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents. These agents include but are not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and diuretics.
- V. Based upon our criteria and review of the peer-reviewed literature, biventricular pacing is considered **investigational** for patients who do not meet the indications identified above.
- VI. Based upon our criteria and review of the peer-reviewed literature, an intrathoracic fluid monitoring sensor is considered **investigational** as a component of a biventricular pacemaker.

Refer to Corporate Medical Policy #6.01.26 regarding Cardiac Bioimpedance.

Refer to Corporate Medical Policy #7.01.06 regarding Implantable Cardiac Defibrillators (ICD).

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Approximately 30% of persons with chronic heart failure have intraventricular conduction disorders resulting in a disorganized contraction pattern and a wide QRS interval on the electrocardiogram (EKG). Studies suggest that this intraventricular conduction delay is associated with increased morbidity and mortality. Prolonged QRS duration in these patients contributes to abnormal septal wall motion, reduced cardiac contractility, decreased diastolic filling time and extended mitral valve regurgitation. Biventricular pacing or cardiac resynchronization therapy (CRT), along with optimal medical therapy, has demonstrated improved hemodynamic status in some persons with chronic heart failure. Evidence indicates that not all persons with heart failure respond to CRT, however the factors that predict response have not been studied completely.

The biventricular pacemaker provides specially timed electrical impulses to simultaneously stimulate the heart's right and left ventricles to contract. The system consists of a pulse generator that is implanted in the chest and connected to three leads that deliver the electrical impulses. One lead is placed in the right atrium and the other two in the right and left ventricles. A biventricular pacemaker may also include an automatic implantable cardioverter defibrillator (ICD) is a

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device designed to monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death.

RATIONALE:

The InSync® Biventricular Cardiac Pacing System (Medtronic) received premarket approval in 2001 for use in treating patients with New York Heart Association (NYHA) Class III or IV heart failure, on a stable pharmacologic regimen, who also have a QRS duration of greater than or equal to 130 msec and a left ventricular ejection fraction of less than or equal to 35%, based on clinical studies that showed improvement in either quality of life scores, distance they were able to walk or their heart failure classification as compared to the control group.

Several randomized clinical trials have found beneficial outcomes to support the use of biventricular pacemakers in the treatment of heart failure improving both hemodynamic and clinical performance. The evidence in the peer-reviewed literature supports the use of CRT to alleviate symptoms of severe heart failure in patients with ventricular dyssynchrony, decreased cardiac function and optimal drug therapy. The studies in general report improved cardiac function, exercise tolerance, and quality of life, as well as a decrease in heart failure related hospitalizations and a decrease in mortality in patients responding to CRT.

The 2013 ACCF/AHA guideline update for the Diagnosis and Management of Chronic Heart Failure in the Adult recommends that unless contraindicated, CRT may be considered for patients who have LVEF of 35% or less, sinus rhythm, a non-LBBB pattern with a QRS duration of 120 to 149 ms, and NYHA class III/ambulatory class IV on optimal drug therapy. (Level of Evidence: B) CRT may be considered for patients who have LVEF of 35% or less, sinus rhythm, a non-LBBB pattern with a QRS duration of 150 ms or greater, and NYHA class II symptoms on optimal drug therapy. (Level of Evidence: B) CRT may be considered for patients who have LVEF of 30% or less, ischemic etiology of HF, sinus rhythm, LBBB with a QRS duration of 150 ms or greater, and NYHA class I symptoms on optimal drug therapy. (Level of Evidence: C)

A 2009 TEC Assessment of CRT in mild heart failure summarized 5 of the larger trials of CRT for advanced heart failure, showing that CRT improves quality of life (QoL) and functional status for patients with class III and class IV CHF. Four of the 5 trials reported improvements in functional status for the CRT group. Similarly, 4 of the trials reported QoL measures, with all 4 showing significant improvements for the CRT group. Hospitalizations were reduced in 2 of the 4 trials, with an additional 2 trials reporting no difference in hospitalizations. The COMPANION trial, which had the highest enrollment and the longest follow-up, reported a significant improvement in mortality. The other trials reported lower mortality for the CRT group that did not reach statistical significance.

The 2009 TEC Assessment also evaluated 3 randomized, controlled trials enrolling 2,616 patients met the inclusion criteria, with follow-up ranging from 6 months to 2.4 years. The largest trial published to date was the MADIT-CRT trial, a single-blind trial that randomized 1,820 patients with NYHA class I/II CHF to an ICD alone or an ICD-CRT device. The MADIT-CRT trial reported a reduction for the ICD-CRT group on the primary outcome, i.e., death or acute heart failure exacerbation. The primary endpoint was reached by 17.2% of patients in the ICD-CRT group compared to 25.3% of patients in the ICD-alone group. The first component of the composite outcome, acute heart failure events, occurred in 22.8% of patients in the ICD-alone group compared with 13.9% of patients in the ICD-CRT group (relative risk reduction [RRR] 39%, absolute risk reduction [ARR] 8.9%, NNT=11.2). This difference in acute heart failure events accounted entirely for the difference on the primary composite outcome. The death rate was similar between groups.

A sub analysis of the MADIT-CRT trial data (Zareba, 2011) of patients with NYHA class I/II CHF demonstrated that compared with non-LBBB patients (those with RBBB or nonspecific intraventricular conduction disturbances), patients with LBBB QRS morphology showed significant clinical benefit from CRT-D therapy, as measured by reduced risk of heart failure event or death and risk of ventricular tachycardia/fibrillation or death. Non-LBBB patients did not benefit clinically despite a significant reduction in left ventricular volumes. These findings formed the basis for recent Food and Drug Administration approval of new broadened indications for CRT in mild or asymptomatic heart failure patients with

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LBBB. There is still a question as to whether CRT therapy should be used in non-LBBB patients even when advanced heart failure is present and which non-LBBB patients might still benefit clinically from CRT. Further research investigating the rationale, mechanisms, and clinical benefit is needed to determine whether CRT therapy should be pursued in non-LBBB patients.

The TEC assessment was revised in February 2011 prompted by publication in December 2010 of the results from the Resynchronization-Defibrillation for Ambulatory Heart Failure Trial or “RAFT” that showed a mortality benefit for NYHA class II heart failure patients treated with a CRT device. The RAFT trial randomized 1,798 patients with class II/III heart failure to ICD-CRT or ICD alone, with a mean follow-up 40 +/- 20 months. This trial met all quality indicators on formal quality assessment and was given a “good” quality rating. The primary outcome, death from any cause or hospitalization for heart failure, was reduced in the ICD-CRT group compared to the ICD-alone group (33.2% vs. 40.3%, p less than 0.001). There were significant reductions in both individual components of the primary outcome, overall mortality (20.8% vs. 26.1%, p=0.003) and hospitalizations (19.5% vs. 26.1%, p less than 0.001). When only the NYHA class II heart failure patients were analyzed, the mortality for class II patients in the ICD-CRT group was 15.5% versus 21.1% in the ICD-alone group (hazard ratio [HR] 0.71, 95% confidence interval [CI]: 0.56-0.91; p less than 0.006). Hospitalizations for class II patients occurred in 16.2% of patients in the ICD-CRT group compared to 21.1% in the ICD-alone group (HR 0.70, 95% CI: 0.55-0.89, p less than 0.003). There was a fairly large difference in overall mortality, with a relative risk reduction of 20.3% and an absolute risk reduction of 5.3%.

The REVERSE trial enrolled a total of 610 patients, all of whom received a CRT device. Patients were randomized to CRT-ON or CRT-OFF for a period of 12 months in double-blind fashion. The primary outcome was a composite measure that classified patients as improved, unchanged, or worse. There were no significant differences reported on this primary outcome. There was a decrease in hospitalizations for heart failure in the CRT-ON group (4.1%, 17/419) compared with the CRT-OFF group (7.9%, 15/191). Changes in functional status, as measured by the 6-minute walk, were similar between groups. Quality of life, as measured by the Minnesota Living with Heart Failure Questionnaire, was also similar between groups.

The MIRACLE ICD study was the smallest of the three studies, enrolling 186 patients with class II CHF and an indication for an ICD in an unblinded fashion. Patients were randomized to ICD/CRT-ON versus ICD/CRT-OFF and followed for 6 months. There was no difference in the primary outcome of peak oxygen uptake between groups. There were also no differences reported between groups on the secondary outcomes of functional status as measured by the 6-minute walk, QOL as measured by the Minnesota Living with Heart Failure Questionnaire, and New York Heart Association CHF class.

All 3 randomized, controlled trials reported significant improvements in echocardiographic measures of left-ventricular (LV) pump function. LV ejection fraction improved more in the CRT group in each trial, with a range of improvement of 3.0–11.0%, compared with the control group. There were also substantial improvements in LV end-systolic and end-diastolic volumes (LVESV, LVEDV) in all 3 trials. All 3 trials reported relatively large improvements in the LVESV and the LVEDV in favor of the CRT group.

Complications in these trials were not uniformly reported; however, each trial contained some information on short- and long-term complications. Short-term complication rates ranged from 4–22%, with lead dislodgement and hematoma at the access site most common. Long-term complications were reported by 2 of the trials, with rates of 16% and 35%. The majority of these long-term complications were lead dislodgement.

The 2012 ACCF/AHA/HRS focused update incorporated into the ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities Class I recommendations for cardiac resynchronization therapy in patients with severe systolic heart failure state: CRT is indicated for patients who have LVEF less than or equal to 35%, sinus rhythm, LBBB with a QRS duration greater than or equal to 150 ms, and NYHA class II, III, or ambulatory IV; symptoms on guideline directed medical therapy (Level of Evidence: A for NYHA class III/IV; Level of Evidence: B for NYHA class II).

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In 2004, the Agency for Healthcare Research and Quality (AHRQ) published a technology assessment to examine the success rate and safety of biventricular pacemaker implantation and the efficacy of CRT in patients with heart failure. This review included studies, reports, and conference proceedings from 1980 to 2004 that focused on cardiac resynchronization via implanted biventricular pacemakers in patients with symptomatic heart failure. The nine trials reviewed included 3,216 patients who had decreased ejection fraction and prolonged QRS duration. 85% of the patients had NYHA class III or class IV symptoms. The authors concluded that CRT improves functional and hemodynamic markers and reduces morbidity and mortality in patients with NYHA Class III or IV heart failure despite optimal medical management, reduced ejection fractions, and prolonged QRS duration.

Several recent studies have evaluated the relationship between QRS duration and left ventricular dyssynchrony in patients with end-stage heart failure. The studies suggest that from 30% to 40% of heart failure patients with QRS duration greater than 120 msec do not exhibit left ventricular dyssynchrony, which may explain the nonresponse to CRT. Alternatively, 20% to 30% of patients with heart failure and a narrow QRS complex show significant left ventricular dyssynchrony and may be candidates for CRT. Results of published trials are insufficient at this time to demonstrate that use of CRT in heart failure patients with a narrow QRS complex benefits patient outcomes.

The Guidant (CONTAK CD® CRT-D System) and Medtronic (InSync® ICD Model 7272) have received FDA approval for combined cardiac resynchronization therapy defibrillators for patients at high risk of sudden cardiac death due to ventricular arrhythmias and who have NYHA Class III or IV heart failure with left ventricular ejection fraction of 35% or less, QRS duration 130 msec or longer (120 msec or longer for the Guidant device) and remain symptomatic despite a stable, optimal heart failure drug therapy. In September 2010, the FDA expanded the indications for CRT to include patients with class I and II heart failure, and a left ventricular (LV) ejection fraction of less than 30% *and left bundle branch block with QRS duration of 130 msec or greater.*

In 2005, the InSync Sentry system received FDA approval through the supplemental PMA process. This combined biventricular pacemaker/AICD is additionally equipped to monitor intrathoracic fluid levels using bioimpedance technology, referred to as Optivol Fluid Status monitoring. Bioimpedance measures are performed using a vector from the right ventricular coil on the lead in the right side of the heart to the implanted pacemaker devices; changes in bioimpedance reflect intrathoracic fluid status and are evaluated based on a computer algorithm. Adding intrathoracic fluid status monitoring has been proposed as a more sensitive monitoring technique of the fluid status leading to prompt identification of impending heart failure, permitting early intervention and, it is hoped, a decreased rate of hospitalization. At this time there is insufficient evidence to evaluate the benefit of bioimpedance monitoring on the clinical management of patients with heart failure. Medtronic, the manufacturer of the OptiVol Fluid Status Monitoring feature of the InSync Sentry system, has announced several ongoing clinical trials of the device.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

<u>CPT:</u>	33202	Insertion of epicardial electrodes: open incision; (e.g., thoracotomy, median sternotomy, subxiphoid approach)
	33203	Insertion of epicardial electrodes: endoscopic approach (e.g., thoracoscopy, pericardioscopy)
	33207	Insertion or replacement of permanent pacemaker with transvenous electrode(s); ventricular

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- 33208 Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
- 33211 Insertion or replacement of temporary transvenous dual chamber pacing electrodes (separate procedure)
- 33213 Insertion or replacement of pacemaker pulse generator only; with existing dual leads
- 33224 Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable 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 implantable defibrillator or pacemaker pulse generator (e.g., upgrade to dual chamber system) (List separately in addition to code for primary procedure)
- 93281 Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed value with analysis, review and report by a physician or other qualified health care professional; multiple lead pacemaker system
- 93284 multiple lead implantable cardioverter-defibrillator system
- 93286 Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with physician analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system.
- 93288 Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system

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HCPCS: No specific code(s)

ICD10: I09.81 Rheumatic heart failure
I11.0-I11.9 Hypertensive heart disease (code range)
I50.1-I50.9 Heart failure (code range)

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<p>SUBJECT: CARDIAC RESYNCHRONIZATION THERAPY (BIVENTRICULAR PACEMAKERS) FOR THE TREATMENT OF HEART FAILURE</p> <p>POLICY NUMBER: 7.01.58</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/21/02</p> <p>REVISED DATE: 10/15/03, 08/19/04, 04/21/05, 01/19/06, 11/16/06, 09/20/07, 10/23/08, 09/17/09, 04/22/10, 06/16/11, 06/21/12, 06/20/13, 08/21/14, 07/16/15, 07/21/16, 07/20/17, 08/16/18</p> <p>PAGE: 7 OF: 9</p>
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<p>SUBJECT: CARDIAC RESYNCHRONIZATION THERAPY (BIVENTRICULAR PACEMAKERS) FOR THE TREATMENT OF HEART FAILURE</p> <p>POLICY NUMBER: 7.01.58</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/21/02</p> <p>REVISED DATE: 10/15/03, 08/19/04, 04/21/05, 01/19/06, 11/16/06, 09/20/07, 10/23/08, 09/17/09, 04/22/10, 06/16/11, 06/21/12, 06/20/13, 08/21/14, 07/16/15, 07/21/16, 07/20/17, 08/16/18</p> <p>PAGE: 8 OF: 9</p>
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<p>SUBJECT: CARDIAC RESYNCHRONIZATION THERAPY (BIVENTRICULAR PACEMAKERS) FOR THE TREATMENT OF HEART FAILURE</p> <p>POLICY NUMBER: 7.01.58</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/21/02</p> <p>REVISED DATE: 10/15/03, 08/19/04, 04/21/05, 01/19/06, 11/16/06, 09/20/07, 10/23/08, 09/17/09, 04/22/10, 06/16/11, 06/21/12, 06/20/13, 08/21/14, 07/16/15, 07/21/16, 07/20/17, 08/16/18</p> <p>PAGE: 9 OF: 9</p>
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*key article

KEY WORDS:

Bioimpedance, Cardiac Resynchronization Therapy, Heart failure, Resynchronization

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon review, cardiac resynchronization therapy is not addressed in a Regional or a National CMS coverage determination or policy.