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I. POLICY

Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD) may be considered medically necessary as a treatment of heart failure in patients who meet all of the following criteria:

**New York Heart Association (NYHA) Class III or IV:**
- Left ventricular ejection fraction ≤ (less than or equal to) 35%;
- Sinus rhythm
- QRS duration of ≥ (greater than or equal to) 120-130 msec*; and
- Patients treated with a stable and maximal pharmacological medical regimen prior to implant, such as an angiotensin converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker, digoxin, and/or diuretics.

**New York Heart Association class II**
- Left ventricular ejection fraction ≤30%
- Sinus rhythm
- QRS duration of ≥120–130* msec, and
- Patients treated with a stable pharmacological medical regimen prior to implant, such as an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker, digoxin, and/or diuretics.

*The FDA-labeled indications for QRS duration vary by device. For some devices, FDA approval is based on QRS duration of ≥130 (e.g., InSync® device) while for others, it is based on QRS duration ≥120 msec (e.g., CONTAK CD® CRT-D System). These differences in QRS duration arise from differences in the eligibility criteria in the trials on which the FDA approval is based.

Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator are considered investigational as a treatment of NYHA class I heart failure. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD), are considered investigational as a treatment for heart failure in patients with atrial fibrillation unless through medications (AV nodal blocking agents) or AV node ablation, the patient would be expected to be predominantly (>90%) pacemaker dependent. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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An intrathoracic fluid-monitoring sensor is considered *investigational* as a component of a biventricular pacemaker, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Triple-site (triventricular) CRT, using an additional pacing lead, is considered *investigational*. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

The use of pacemakers or pacemaker monitoring for conditions other than those described in the policy section is considered *investigational*, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

**Cross-references:**
- MP-1.081 Cardioverter-Defibrillators (Implantable and External)
- MP-2.051 Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting
- MP-5.002 MRI of the Breast With or Without Computer-Aided Detection of Malignancy (Cancer and Breast Implant Indications)

**II. PRODUCT VARIATIONS**

\[N\] = *No product variation, policy applies as stated*

\[Y\] = *Standard product coverage varies from application of this policy, see below*

- [N] PPO
- [N] HMO
- [N] CHIP
- [Y] SeniorBlue HMO*
- [Y] SeniorBlue PPO*
- [N] SpecialCare
- [N] POS
- [N] Indemnity
- [Y] FEP PPO**

* Refer to Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) 20.8, Cardiac Pacemakers and 20.8.3 Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers for additional pacemaker indications.

** For biventricular pacemakers refer to the FEP Medical Policy Manual MP-2.02.10 Biventricular Pacemakers for Treatment of Heart Failure. The FEP Medical Policy manual can be found at: [www.fepblue.org](http://www.fepblue.org)
III. DESCRIPTION/BACKGROUND

Cardiac pacemakers can be external or implanted in the chest wall and can be temporary or permanent. Pacemakers electronically stimulate a heart by periodically emitting electrical discharges and are used to treat patients with slow heart rates, long pauses between beats, heart block and arrhythmias.

Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure

Cardiac resynchronization therapy (CRT), which consists of synchronized pacing of the left and right ventricles, is intended to treat patients with heart failure and dyssynchronous ventricular contractions. Treatment involves placement of a device that paces both ventricles and which coordinates ventricular pacing to maximize cardiac pumping function and left ventricular ejection fraction (LVEF).

It is estimated that 20–30% of patients with heart failure have intraventricular conduction disorders resulting in a contraction pattern that is not coordinated and a wide QRS interval on the electrocardiogram (ECG). This abnormality appears to be associated with increased morbidity and mortality. Biventricular pacemakers using 3 leads (1 in the right atrium and 1 in each ventricle) have been investigated as a technique to coordinate the contraction of the ventricles, thus improving patients’ hemodynamic status. Two strategies are being explored: incorporating biventricular pacing into automatic implantable cardiac defibrillators and the development of stand-alone biventricular pacemakers.

One stand-alone biventricular pacemaker (InSync® Biventricular Pacing System, Medtronic) has received approval by the U.S. Food and Drug Administration (FDA) for the treatment of 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 130 msec or longer and a left-ventricular ejection fraction (LVEF) of 35% or less. Biventricular pacemakers have also been combined with automatic implantable cardiac defibrillators (ICDs). Both 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 LVEF 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 cardiac resynchronization therapy (CRT) to include patients with class I and II heart failure. In addition to NYHA class I/II heart failure, indications for CRT in mild heart failure include a LVEF of less than 30% and a QRS duration of 130 msec or greater.

In 2005, the InSync Sentry system received FDA approval through the supplemental premarket approval (PMA) process. This combined biventricular pacemaker/ICD is also equipped to
monitor intrathoracic fluid levels using bioimpedance technology, referred to as OptiVol Fluid Status monitoring. Bioimpedance measures, defined as the electrical resistance of tissue to flow of current, are performed many times per day 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. For example, changes in a patient’s daily average of intrathoracic bioimpedance can be monitored; differences in the daily average compared to a baseline are reported as the OptiVol Fluid Index. It has been proposed that these data may be used as an early warning system of cardiac decompensation or to provide additional feedback enabling a physician to further tailor medical therapy.

IV. RATIONALE

This policy is updated periodically with literature review. The most recent update covers the period from February 2011 through February 2012.

Literature Review

Biventricular pacemakers and combined biventricular pacemakers/cardiac defibrillators

Efficacy of CRT (cardiac resynchronization therapy) in advanced heart failure (New York Heart Association [NYHA] class III/IV)

Use of biventricular pacemakers with or without accompanying implantable cardiac defibrillator (ICD) for selected patients with advanced heart failure is supported by a large body of clinical trial evidence. For patients with the following characteristics, this treatment receives a class I recommendation in the 2005 American College of Cardiology/American Heart Association (ACC/AHA) guidelines for the diagnosis and management of patients with heart failure, (1) supported by the “A” level of evidence:

- Left-ventricular ejection fraction ≤35%
- Sinus rhythm
- New York Heart Association (NYHA) functional class III or IV despite optimal medical therapy
- Cardiac dyssynchrony as defined as a QRS >120 msec
- No contraindications for biventricular pacing

The current ACC/AHA guideline is accompanied by a review of the evidence, which states that more than 4,000 patients have been evaluated in randomized, clinical trials (RCTs) and that these trials establish benefit for CRT in this patient population in improving functional status and exercise capacity.

A 2009 TEC Assessment of cardiac resynchronization therapy (CRT) in mild heart failure (2) 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 heart failure. 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 Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial, (3) 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, which did not reach statistical significance.

A systematic review of 9 RCTs of CRT in class III/IV heart failure was published in 2004. (4) This quantitative analysis revealed the following conclusions: 1) improvement of 3.5% in left-ventricular ejection fraction (LVEF); 2) improved QoL, with weighted mean difference on the Minnesota Living with Heart Failure Questionnaire of 7.6 points (0–100 scale); 3) improved functional capacity and a reduction in all-cause mortality of 21%. This analysis also found some evidence that cardiac morphology may be improved, suggesting that CRT may prevent, delay, or even reverse the changes in morphology resulting from chronic heart failure (reverse remodeling).

**Efficacy of CRT in mild heart failure (NYHA class I/II)**

Evaluation of CRT in mild heart failure was originally based on a 2009 TEC Assessment. (2) There is less evidence on treatment of mild heart failure compared to that for advanced heart failure, but clinical trial evidence is available. At least 4 RCTs enrolling over 3,000 patients, with follow-up ranging from 6 months to 2.4 years, have been published to date. A summary of the major RCTs in mild heart failure is provided.

**MADIT-CRT trial.** The largest trial published to date was the Multicenter Automatic Implantation Trial – Cardiac Resynchronization (MADIT-CRT) trial, (5) a single-blind trial that randomized 1,820 patients with NYHA class I/II heart failure 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%; number needed to treat [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 follow-up publication from the MADIT-CRT trial was published in 2011 and analyzed the reduction in recurrent heart failure events. (6) This analysis supplemented the original MADIT-CRT outcome of time to first heart failure event, by comparing total heart failure events during an average follow-up of 2.6 years. Over this time period, there was a 38%
relative reduction in heart failure events in the CRT group (HR: 0.62; 95% CI: 0.45-0.85; p=0.003). On subgroup analysis, the benefit was evident in patients with left bundle branch block (HR: 0.50; 95% CI: 0.33-0.76; p=0.001) but not in patients without left bundle branch block (HR: 0.99; 95% CI: 0.58-1.69; p=0.96).

RAFT trial. A second, large RCT was the Resynchronization-Defibrillation for Ambulatory Heart Failure Trial or (RAFT) trial, (7) which randomized 1,798 patients with class II/III heart failure to ICD-CRT or ICD alone, with a mean follow-up 40 +/- 20 months. Unlike most previous trials, this trial did not confine enrollment to patients with sinus rhythm but allowed patients with atrial arrhythmias to participate. However, the number of patients who were not in sinus rhythm was only 12.8% (229/1,798). The RAFT trial was included in a 2011 TEC Assessment. On formal quality assessment as part of the TEC Assessment, this trial met all quality indicators 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%, respectively; p<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%, all respectively; p<0.001). When restricted to patients with NYHA class II heart failure, the improvements in the outcomes of mortality and hospitalizations remained significant. The mortality for class II patients in the ICD-CRT group was 15.5% versus 21.1% in the ICD-alone group (HR: 0.71; 95% CI: 0.56-0.91; p<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<0.003).

Subgroup analyses from the RAFT trial reported that female gender, QRS duration equal to or greater than 150 msec, LVEF less than 20%, and QRS morphologic features were predictive of benefit. Of these factors, the QRS duration was the strongest factor. Patients with a QRS duration equal to or greater than ≥150 msec had a relative risk (RR) for the primary outcome of approximately 0.50, compared with a RR of approximately 1.0 for patients with a QRS duration less than 150 msec (p=0.003 for difference between RRs). There was a trend for greater improvement in patients with sinus rhythm compared to patients with atrial arrhythmias, but this difference did not reach statistical significance.

REVERSE trial. The Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction (REVERSE) trial (8) 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.
MIRACLE ICD trial. The Multicenter InSync ICD Randomized Clinical Evaluation MIRACLE ICD study (9) was the smallest of the 3 studies, enrolling 186 patients with class II heart failure 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 NYHA heart failure class.

Systematic Reviews. Numerous systematic reviews and meta-analyses have been published on CRT for heart failure. (4, 10-15) The majority compare CRT to medical management and report that outcomes are improved for patients with advanced heart failure and for patients with mild heart failure. For example, a meta-analysis of 25 trials of CRT was published in February 2011 by Al-Majed et al. (11) This study focused on the analysis of trials with class I/II heart failure patients, identifying 6 trials treating 4,572 patients. There was a significant mortality benefit associated with CRT on combined analysis (6 trials, 4,572 participants; RR: 0.83 [95% CI: 0.72 to 0.96]). This mortality benefit was driven largely by the results of the RAFT trial, which had the most number of events and was given the greatest weight in combined analysis. There was also a significant reduction in heart failure hospitalizations associated with CRT use (4 trials, 4,349 participants; RR: 0.71 [CI: 0.57 to 0.87]). There were no significant benefits reported for quality of life, functional status, or progression to more advanced stages of heart failure.

Adverse Effects of CRT placement

Complications in the main RCTs 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 the most common. Long-term complications were reported by 2 of the trials, (8, 9) with rates of 16% and 35%, respectively. The majority of these long-term complications were lead dislodgement.

A systematic review and meta-analysis was published in 2011 that focused on complications from CRT treatment. (16) This review included 7 trials of CRT treatment that reported on in-hospital mortality and complications related to device placement. In all 7 CRT trials, the device was placed percutaneously without a thoracotomy. In-hospital mortality occurred at a rate of 0.3%, and 30-day mortality was 0.7%. The most common complications were related to placement of the left ventricular (LV) lead. Lead dislodgement occurred in 5.9% of patients. Other LV lead placement complications included coronary vein dissection in 1.3% and coronary vein perforation in 1.3%. Pneumothorax occurred in 0.9% of patients, and hematoma at the insertion site occurred in 2.4% of patients.

Conclusions. There is a large body of clinical trial evidence that supports the use of CRT in patients with NYHA class II/IV heart failure. These trials establish that CRT treatment leads to reduced mortality, improved functional status, and improved QoL.
For patients with milder heart failure, at least 4 RCTs of CRT have been published in the literature. A mortality benefit was reported by one of the 4 trials, the RAFT trial. This trial was free of major bias and reported a fairly large absolute difference in overall mortality of 5.3%. None of the other 3 RCTs reported a mortality difference. While 2 of the other 3 trials were underpowered to detect differences in mortality, the MADIT-CRT was approximately the same size as the RAFT trial and did not show any improvement in mortality. It is possible that the sicker patient population and longer follow-up in RAFT accounted for the mortality difference. Among other outcome measures, hospitalizations for heart failure showed consistent improvements, but quality of life and functional status did not.

Use of CRT in patients with atrial fibrillation

There is controversy about whether CRT leads to health outcome benefits for patients with atrial fibrillation (AF). Many experts feel that if CRT is to be used, it needs to be combined with ablation of the atrioventricular node, in order to avoid transmission of atrial impulses through the node that might result in rapid ventricular rates, thus undermining the efficacy of CRT.

An RCT was published in 2011 (17) that compared CRT to right ventricular pacing alone in patients with atrial fibrillation. A total of 186 patients had atrioventricular nodal ablation and implantation of a CRT device. Patients were then randomized to echo-optimized CRT or right ventricular pacing alone and followed for a median of 20 months. The primary outcome measure was a composite of death from heart failure, hospitalization for heart failure, or worsening heart failure. This combined endpoint occurred in 11% of the CRT group compared with 26% of the right ventricular (RV) pacing group (HR: 0.37; 95% CI: 0.18-0.73; p=0.005). For the individual outcome measures, there was not a significant reduction in mortality (HR: 1.57; 95% CI: 0.58-4.27; p=0.37), but there were significant reductions in hospitalizations (HR: 0.20; 95% CI: 0.06-0.72; p=0.013) and worsening heart failure (HR: 0.27; 95% CI: 0.12-0.58; p=0.37). There were no differences in outcomes on subgroup analysis, including analysis by ejection fraction, NYHA class, and/or QRS duration.

A post-hoc analysis of patients with atrial fibrillation (AF) enrolled in the RAFT RCT was published by Healey et al. in 2012. (18) Randomization in the RAFT trial was stratified for the presence of AF, resulting in 114 patients with AF in the CRT plus defibrillator group and 115 patients with AF in the defibrillator group alone. There was no difference between groups in the primary outcome of death or hospitalization due to heart failure (HR: 0.96, 95% CI: 0.65-1.41, p=0.82). There were also no differences in cardiovascular death or functional status. There was a trend for patients in the CRT group to have fewer hospitalizations for heart failure compared to the defibrillator-alone group, but the difference did not reach statistical significance.

A systematic review published in 2011 (19) compared outcomes of CRT in patients with and without AF. This analysis included 23 observational studies enrolling 7,495 patients, 1,912 of whom had AF. Outcomes in patients with AF were less favorable on all measures. This
included overall mortality (RR: 1.5; 95% CI: 1.08 to 2.09; p=0.015), nonresponse to CRT (RR: 1.32; 95% CI: 1.12 to 1.55; p=0.001), change in the Minnesota Living with Heart Failure QoL score (mean difference: -4.1; 95% CI: -1.7 to -6.6; p=0.001), and change in the 6-minute walk distance (mean difference: -14.1 meters, 95% CI: -28.2 to 0.0; p=0.05). Five studies compared outcomes of patients with AF who had AV nodal ablation to patients who did not have ablation. Pooled analysis from these studies indicated that AV nodal ablation was associated with a lower rate of non-response (RR: 0.40; 95% CI: 0.28 to 0.58; p<0.001).

A second systematic review that evaluated the role of AV node ablation in patients with atrial fibrillation (AF) treated with CRT was published in 2012. (20) This review included non-randomized studies that reported outcomes of CRT and medical therapy. Six studies were included, enrolling a total of 768 patients, 339 of whom underwent atrioventricular (AV) node ablation and 429 who did not. AV nodal ablation was associated with improvements in the outcomes of all-cause mortality (RR: 0.42; 95% CI: 0.26 to 0.68), cardiovascular mortality (RR: 0.44; 95% CI: 0.24 to 0.81), and change in NYHA class (mean difference: -0.34; 95% CI: -0.56 to -0.13; p=0.002).

Conclusions. There is insufficient evidence to determine whether CRT improves outcomes for patients with AF and heart failure. Data from two RCTs report different results, with one reporting improvements for patients with AF and another reporting no significant improvements. One systematic review of observational studies suggests that patients with AF do not achieve the same degree of benefit as do patients with sinus rhythm. For patients with AF who are undergoing CRT, a systematic review of non-randomized studies conclude that when CRT is used in patients with AF, AV nodal ablation is associated with improved outcomes compared to no AV nodal ablation.

Selecting patients for CRT treatment

For patients who meet indications for CRT treatment, there is a large variability in the magnitude of response. Some patients do not respond at all, while others have very substantial benefit. As a result, there is interest in better defining the clinical features that predict response in order to better target therapy toward those who will benefit most.

The Predictors of Response to Cardiac Resynchronization Therapy (PROSPECT) study (21) was a prospective, multicenter study that evaluated the ability of echocardiographic parameters to predict response to CRT. Results of this trial indicated that the 12 individual echocardiographic parameters varied widely in their ability to predict response. (22) The sensitivity of these individual measures ranged from 6-74% and the specificity ranged from 35-91%. The authors concluded that it was unlikely that these echocardiographic measures could improve patient selection for CRT.

Ventricular dyssynchrony. A small randomized controlled trial (RCT) that compared outcomes of CRT in patients with ventricular dyssynchrony versus those without was published in 2011. (23) A total of 73 patients with class II/IV were evaluated, 44 of whom were found to have dyssynchrony on echocardiography. These 44 patients were randomized to
a combined CRT-defibrillator or a defibrillator alone. Outcomes measures were peak O2 consumption (VO2max), NYHA class, and echocardiographic parameters. At 6 months of follow-up, more patients in the CRT group had an increase of at least 1 mL/kg/min in VO2max (62% vs. 50% p=0.04). There were significant within-group improvements in NYHA class and echocardiographic measures, but the between-group comparisons with the no-CRT group did not reach statistical significance.

Several observational studies of patients who meet criteria for treatment have shown that measures of dyssynchrony measured by various methods are correlated with treatment response, as defined by improvements in left-ventricular end-systolic volume, ejection fraction, or clinical criteria. (24) Although correlations have been found, studies vary due to the method used to measure dyssynchrony, the cutoff value used, and the criteria used for clinical response. Without clinical trial evidence, it is not possible to determine which method and which cutoff will select patients who otherwise meet criteria for therapy who would be better off without a biventricular pacemaker.

**QRS duration.** Two RCTs were identified that selected patients who had a narrow QRS complex on EKG and echocardiographic evidence (Doppler and M-mode) of dyssynchrony. (25, 26) The Resynchronization Therapy in Normal QRS Trial (RethiNQ study) (25) randomized 172 patients to receive a CRT device, turned on or not, and followed up for 6 months. CRT-treated patients were not more likely to have improvement than non-CRT patients (46 vs. 41%, respectively, met endpoint of improvement in exercise capacity [peak VO2]). A subset of patients with QRS duration greater than or equal to 120–130 msec showed improvement (p=0.02), whereas patients with QRS less than 120 msec did not (p=0.45). The LESSER-EARTH trial (26) was an RCT designed to compare CRT versus no CRT in patients with a QRS complex <120 msec. This trial was terminated early after 85 patients had been enrolled. Interim analysis revealed futility in achieving benefit on the primary outcomes, and a trend toward greater adverse events. These studies confirm that patients with a QRS duration less than 120 msec do not benefit from CRT.

Several meta-analyses of the association of QRS duration with outcomes have been published. The first of these was published in 2011 and evaluated whether patients with modest prolongations of the QRS complex benefited from CRT. (27) This study identified 5 trials enrolling 5,813 patients that reported on outcomes stratified by QRS duration. There was some variability in the definition of QRS categories, but the authors were able to categorize studies into those with moderately prolonged QRS, generally 120-149 msec, and severely prolonged QRS, generally 150 msec or greater. For patients with a moderately prolonged QRS, there was no significant benefit for CRT in reducing composite outcomes of adverse cardiac events (RR: 0.95; 95% CI: 0.82 to 1.10; p=0.49). In contrast, for patients with a severely prolonged QRS, there was a 40% relative reduction in the composite outcomes (RR: 0.60; 95% CI: 0.53 to 0.67; p<0.001). There were no differences in outcomes on sensitivity analysis according to NYHA class and implantable cardiac defibrillator (ICD) status.

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Other meta-analyses have come to similar conclusions, reporting benefit in patients with a QRS >150, and little to no benefit in patients with shorter QRS duration. (28-30) In one of these studies, (30) the benefit of CRT was confined to patients with left bundle-branch block (LBBB). There was no benefit demonstrated for patients with right bundle-branch block (RBBB) or intraventricular conduction delay. These authors suggest that QRS morphology may be as important, or more important, than QRS duration in prediction response to CRT.

Conclusions. The optimal selection of patients for CRT treatment remains an active area of investigation. The presence of dyssynchrony on echocardiography may risk-stratify patients, but is not a good discriminator of responders versus non-responders. In contrast, a QRS duration of greater than 150 msec, or the presence of left bundle-branch block, appears to discriminate well between responders and non-responders and represents another potential factor on which patients may be selected for CRT treatment. The evidence on this question is primarily from subgroup analyses of RCTs but is consistent across multiple studies and is supported by quantitative pooling of these subgroup analyses in a meta-analysis.

**Triple-site CRT (Triventricular Pacing)**

Triple-site CRT, or triventricular pacing, is a variation of conventional CRT that uses an additional pacing lead. The rationale behind triventricular pacing is that a third pacing lead may improve electromechanical synchrony, thereby leading to better outcomes. Two RCTs have been published that compared triple-site CRT with conventional CRT. Rogers et al. performed a double-blind RCT in 43 patients referred for CRT. (31) All patients had 3 leads implanted, but patients in the conventional CRT arm had their device programmed to biventricular pacing. The triventricular group had greater improvements in the 6-minute walk distance compared to the conventional CRT group (increase of 91 m vs. 65 m, p=0.008), and greater improvement on the Minnesota Living with Heart Failure scale (reduction of 24 points vs. 18 points, p<0.0001). Complications did not differ between groups; however, since all patients had 3 leads implanted, this was not a valid comparison of complications for biventricular versus triventricular pacing.

A second RCT was published by Lenarczyk et al. in 2012. (32) This was a report of the first 100 patients randomized to triple-site or conventional CRT in the Triple-Site versus Standard Cardiac Resynchronization Therapy Randomized Trial (TRUST CRT). After a follow-up of 1 year, more patients in the conventional arm were in NYHA class III or IV heart failure compared to the triple-site CRT group (30% vs. 12.5%, p<0.05). Implantation success was similar in the triple-site and conventional groups (94% vs. 98%, respectively, p=NS), but the triple-site implantation was associated with longer time for implantation and a higher fluoroscopic exposure. In addition, more patients in the triple-site group required additional procedures (33% vs. 16%, p<0.05).

Conclusions. Two small RCTs with limited follow-up report improved functional status and quality of life with triple-site CRT compared to conventional CRT. However, triple-site CRT was also associated with higher radiation exposure and a greater number of additional

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procedures post-implantation. Further studies are needed to better define the benefit/risk ratio for triple-site CRT compared to conventional CRT.

**Combined automatic implantable cardiac defibrillators/biventricular pacemakers/intrathoracic fluid monitors**

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. There is a lack of evidence from RCTs on the efficacy of fluid monitoring compared to usual care. The available evidence consists of uncontrolled studies that evaluate the correlation of fluid status information with cardiac events.

A prospective cohort of 558 patients from 34 centers identified the number of “threshold crossing events” and the percent of days with such events as predictors of hospitalization for severe heart failure using multivariate regression. (33) Over a mean of 326 days, 953 threshold crossing events in 351 patients resulted in 63 hospitalizations among 49 patients. Each subsequent event was associated with a 36% increased risk of hospitalization; however, the extent to which the presence of threshold crossing events influenced the decision to hospitalize is not known.

A similar retrospective study, that evaluated “threshold crossings” as a predictor of arrhythmogenic events, was published in 2011. (34) This analysis included 282 patients with NYHA class III or IV heart failure followed for a mean of 10 months. Patients were categorized into those who had “threshold crossings” (n=145, 51%) and those who did not (n=137, 49%). Tachyarrhythmic events were more common in patients with threshold crossings than in patients without (3,241 vs. 1,484 events; p<0.0001).

Medtronic, the manufacturer of the OptiVolÔ Fluid Status Monitoring feature of the InSync Sentry system, has announced several ongoing clinical trials of the device as follows. The Optilink HF trial (35) is designed to evaluate fluid status monitoring with the OptiVolÔ device combined with wireless transmission through the CareLink Network. Patients with NYHA class II or III heart failure are eligible, and the target enrollment is 1,000 patients. The primary outcome is a composite of all-cause death or cardiovascular hospitalization. The trial is scheduled to report the first results in May 2014.

The Medtronic Impedance Diagnostics in Heart Failure (MID-HeFT) study was a retrospective study designed to investigate the feasibility of predicting heart failure hospitalization based on intrathoracic bioimpedance and to validate impedance measurements as a surrogate measure of pulmonary congestion based on pulmonary capillary wedge pressure. The device that was used was a modified pacemaker and thus was not incorporated into a biventricular pacemaker/ICD. A total of 9 abstracts are derived from this study. One abstract included 33 patients. (36) Among the 10 patients with 26 hospitalizations for heart failure during an 18-month follow-up, thoracic bioimpedance gradually decreased prior to the hospitalization, in many instances before the onset of clinical symptoms.

[Note: Final page is signature page and is kept on file, but not issued with Policy.]
The Fluid Accumulation Status Trial (FAST) is a prospective trial investigating the use of the algorithm used to analyze the collected bioimpedance data. The early results of this trial have been presented at the 13th Heart Failure Society meeting in September 2009. (37) Data presented at that time reported that fluid monitoring was more sensitive in predicting acute heart failure exacerbations, compared to weight monitoring. To date, there have not been any publications in the peer-reviewed literature on this study, and no data on other health outcomes are available at this time.

The Sensitivity of the InSync Sentry for Prediction of Heart Failure (SENSE-HF) study is designed to prospectively evaluate the sensitivity of the OptiVol fluid trends feature in predicting heart failure hospitalizations with signs and/or symptoms of pulmonary congestion and then to define OptiVol clinical guidelines for patient management. The SENSE-HF study was completed in March 2009. Baseline characteristics of the PARTNERS-HF study (38) have been published; study outcomes have not been published in the peer-reviewed literature.

The Combined Heart Failure Diagnostics Identify Patients at Higher Risk of Subsequent Heart Failure Hospitalization (PARTNERS-HF) is a prospective, nonrandomized postmarketing study conducted in up to 100 U.S. centers that was completed in March 2008. (39) The goal of the trial is to characterize the relationship between a variety of diagnostic data derived from the implanted biventricular/ICD devices. Data from this study were presented at the 2008 Annual Heart Failure Society Meeting. Researchers reported at this time that patients with a fluid index that crossed threshold were twice as likely to develop acute heart failure events, compared to patients whose fluid index did not cross the threshold.

Conclusions. The evidence is not sufficient to determine whether intrathoracic fluid monitoring improves outcomes for patients who receive a CRT device. The available evidence indicates that intrathoracic monitoring may be a more sensitive measure for predicting heart failure exacerbations compared to weight monitoring. However, there is no published data that report improved outcomes associated with fluid monitoring. Although numerous trials have been undertaken, as of April 2012, there were no RCT publications in the peer-reviewed literature that report on outcomes and/or the utility of intrathoracic fluid monitoring in the management of patients with heart failure.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 8 academic medical centers while this policy was under review in 2012. There was consensus agreement with the medically necessary statements. For patients with class I heart failure, there was mixed input as to whether cardiac resynchronization therapy (CRT) should be medically
necessary. Regarding the duration of the QRS complex, there was acknowledgement that the literature supported use mainly in patients with a QRS greater than 150 msec, but most reviewers disagreed with restricting CRT use to patients with a QRS greater than 150 msec because that was not currently the accepted standard of care. For patients with atrial fibrillation, the input was mixed on whether biventricular pacing improves outcomes.

**Summary**

Evidence from clinical trials and systematic reviews supports the benefit of cardiac resynchronization therapy (CRT) treatment for patients with New York Heart Association (NYHA) class III/IV heart failure. For this group, there are improvements in mortality, functional status and quality of life. As a result, CRT treatment may be considered medically necessary for patients with NYHA class III/IV heart failure when criteria are met.

For patients with milder heart failure, RCT evidence from at least one large, high-quality trial reports a mortality benefit for patients with class II heart failure, but other RCTs do not report a mortality benefit. Several studies report a decrease in hospitalizations for class II patients, but no studies provide evidence of treatment benefit on functional status or QOL outcomes. Despite the lower level of evidence available for mild compared to advanced heart failure, it can be concluded that the benefit of CRT outweighs the risk for these patients. Therefore, CRT treatment may be considered medically necessary for class II heart failure patients who meet other clinical criteria for treatment. The evidence on class I heart failure is not sufficient to permit conclusions, as only a small number of class I patients have been included in some of the trials, and no benefit has been demonstrated for this specific subgroup. As a result, CRT is considered investigational for class I heart failure. Triple-site (triventricular) CRT, using an additional pacing lead, is in preliminary testing with only a small amount of available evidence and is considered investigational as an alternative to conventional CRT.

Treatment of patients with atrial fibrillation and heart failure is controversial. Available evidence establishes that patients with heart failure probably do not derive the same magnitude of benefit as do patients with sinus rhythm and that CRT with atrioventricular (AV) nodal ablation is probably superior to CRT without AV nodal ablation in patients with heart failure. However, the evidence is insufficient to determine whether CRT treatment is superior to no treatment for this patient group. In addition, clinical input in 2012 was mixed as to whether patients with atrial fibrillation should be treated with CRT. Therefore, CRT remains investigational for patients with atrial fibrillation.

The optimal selection of patients for CRT treatment remains uncertain. Accumulating evidence indicates that benefit is concentrated in patients with a QRS duration of greater than 150 msec. This factor offers a potential method to better select patients for CRT and potentially avoid treatment in patients who will not benefit. Clinical input in 2012 demonstrated support for continued use of QRS threshold of 120 msec, rather than restricting treatment to patients with QRS greater than 150 msec. Other factors for selecting patients,
such as ventricular dyssynchrony on echocardiography, have not been shown to be good discriminators of responders versus non-responders.

**Practice Guidelines and Position Statements**

Guidelines for device-based treatment of cardiac rhythm abnormalities were published jointly by ACC/AHA/HRS in 2008. (40) These guidelines included the following recommendations on CRT for heart failure:

**Class I recommendations**

- For patients who have LVEF [left ventricular ejection fraction] less than or equal to 35%, a QRS duration greater than or equal to 0.12 seconds, and sinus rhythm, CRT with or without a ICD is indicated for the treatment of NYHA functional Class III or ambulatory Class IV heart failure symptoms with optimal recommended medical therapy. *(Level of Evidence: A)*

**Class IIa recommendations**

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

- For patients with LVEF 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, CRT is reasonable. *(Level of Evidence: C)*

**Class IIb recommendations**

- For patients with LVEF less than or equal to 35% with NYHA functional Class I or II symptoms who are undergoing implantation of a permanent pacemaker and/or ICD with anticipated frequent ventricular pacing, CRT may be considered. *(Level of Evidence: C)*

The 2005 AHA/ACC guidelines (41) suggest that patients with atrial fibrillation (AF) and complete atroventricular (AV) block may benefit from CRT. A prospective cohort of 162 patients indicated for CRT with permanent AF found that CRT without AV ablation was associated with less favorable outcomes than CRT with AV ablation. (42) Response to pacing
was defined as 85% biventricular capture at 2 months and 42% of patients responded; non-responders underwent ablation. Evidence of reverse remodeling (reduction of left ventricular end-systolic volume [LVE\textsubscript{SV}] of $\geq 10\%$ from baseline at 6 and 12 months) was 3 times more likely in ablated compared to nonablated patients. Controlled trials addressing this issue are underway and are needed before recommending the “ablate and pace” pathway that would render many patients pacemaker dependent.

V. DEFINITIONS

ARRHYTHMIA refers to irregularity, or loss of rhythm, of the heart.

NEW YORK HEART ASSOCIATION CLASS I-Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.

NEW YORK HEART ASSOCIATION CLASS II-Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.

NEW YORK HEART ASSOCIATION CLASS III-Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.

NEW YORK HEART ASSOCIATION CLASS IV-Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases.

PREMARKET APPROVAL (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s
individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. REFERENCES


2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Cardiac Resynchronization Therapy for Mild Congestive Heart Failure. TEC Assessments 2009; Volume 24, Tab 8.


## MEDICAL POLICY

<table>
<thead>
<tr>
<th>POLICY TITLE</th>
<th>BIVENTRICULAR PACEMAKERS (CARDIAC RESYNCHRONIZATION THERAPY) FOR THE TREATMENT OF HEART FAILURE</th>
</tr>
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<tbody>
<tr>
<td>POLICY NUMBER</td>
<td>MP-2.007</td>
</tr>
</tbody>
</table>


[Note: Final page is signature page and is kept on file, but not issued with Policy.]

34. Sekiguchi Y, Tada H, Yoshida K et al. Significant increase in the incidence of ventricular arrhythmic events after an intrathoracic impedance change measured with a cardiac resynchronization therapy defibrillator. Circ J 2011; 75(11):2614-20.


38. Whellan DJ, O’Connor CM, Ousdigian KT et al. Rationale, design, and baseline characteristics of a Program to Assess and Review Trending INformation and Evaluate CorRelation to Symptoms in Patients with Heart Failure (PARTNERS HF). Am Heart J 2008; 156(5):833-9, 39 e2.


Other Sources

IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

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# Medical Policy

## Policy Title

**Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure**

## Policy Number

MP-2.007

### HCPCS Code

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<th>Description</th>
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<td>C1722</td>
<td>CARDOVERTER-DEFIBRILLATOR, SINGLE CHAMBER (IMPLANTABLE)</td>
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<td>LEAD, CARDOVERTER-DEFIBRILLATOR, ENDOCARDIAL SINGLE COIL (IMPLANTABLE)</td>
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<td>C1882</td>
<td>CARDOVERTER-DEFIBRILLATOR, OTHER THAN SINGLE OR DUAL CHAMBER (IMPLANTABLE)</td>
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<td>C1895</td>
<td>LEAD, CARDOVERTER-DEFIBRILLATOR, ENDOCARDIAL DUAL COIL (IMPLANTABLE)</td>
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<td>C1896</td>
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<td>LEAD, PACEMAKER/CARDOVERTER-DEFIBRILLATOR COMBINATION (IMPLANTABLE)</td>
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### ICD-9-CM Diagnosis Code*

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<th>Code</th>
<th>Description</th>
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<tr>
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<td>MALIGNANT HYPERTENSIVE HEART DISEASE WITH HEART FAILURE</td>
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<td>410.00 – 410.92</td>
<td>ACUTE MYOCARDIAL INFARCTION</td>
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<td>412</td>
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<td>414.8</td>
<td>OTHER SPECIFIED FORMS OF CHRONIC ISCHEMIC HEART DISEASE</td>
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<td>CARDIOMYOPATHY</td>
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<td>426.2 – 426.3</td>
<td>Left bundle branch hemiblock</td>
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<td>426.6 – 426.7</td>
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<td>426.50 – 426.54</td>
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### ICD-9-CM Diagnosis Codes

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<td>746.84</td>
<td>Congenital Obstructive Anomalies Of Heart, Not Elsewhere Classified</td>
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<td>Nonspecific Abnormal Unspecified Cardiovascular Function Study</td>
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<td>794.31</td>
<td>Nonspecific Abnormal Electrocardiogram (Ecg) (Ekg)</td>
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<td>996.01</td>
<td>Mechanical Complication Due To Cardiac Pacemaker (Electrode)</td>
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<td>996.04</td>
<td>Mechanical Complication Due To Automatic Implantable Cardiac Defibrillator</td>
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<td>996.61</td>
<td>Infection And Inflammatory Reaction Due To Cardiac Device, Implant, And Graft</td>
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<td>996.72</td>
<td>Other Complications Due To Other Cardiac Device, Implant, And Graft</td>
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*If Applicable, Please See Medicare LCD Or NCD For Additional Covered Diagnoses.

The Following ICD-10 Diagnosis Codes Will Be Effective October 1, 2014:

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<td>I21.09</td>
<td>St Elevation (Stemi) Myocardial Infarction Involving Other Coronary Artery Of Anterior Wall</td>
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<td>I25.2</td>
<td>Old Myocardial Infarction</td>
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<td>Ischemic Cardiomyopathy</td>
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<td>Silent Myocardial Ischemia</td>
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<td>Atrioventricular and left bundle-branch block</td>
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X. POLICY HISTORY

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<td><strong>CAC 5/27/08</strong></td>
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<tr>
<td><strong>CAC 3/31/09</strong> Consensus</td>
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<tr>
<td><strong>CAC 3/30/10</strong> Minor revision. Statement added that Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator are considered investigational as a treatment of NYHA class I or II heart failure.</td>
</tr>
<tr>
<td><strong>CAC 11/22/11</strong> Minor revision. Biventricular pacemakers now considered medically necessary for NYHA class II indications, remaining investigational for class I. The term “congestive” in reference to the use of biventricular pacemakers was removed.</td>
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<tr>
<td><strong>CAC 10/30/12</strong> BCBSA criteria adopted for biventricular pacemakers. For this review, a new investigational indication was added for the use of biventricular pacemakers for the treatment for heart failure in patients with atrial fibrillation. Policy title revised to “Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure”. The indication as a treatment for heart failure in patients with atrial fibrillation is considered investigational unless through medications or ablation, the patient would be expected to be pacemaker dependent was added to the policy. Rationale for this use of CRT in patients with atrial fibrillation were also added to the policy background. Criteria for temporary and permanent pacemakers and cardiac pacemaker monitoring removed from the policy. FEP variation revised for biventricular pacemakers to refer to the FEP policy.</td>
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Codes reviewed 9/18/12 klr

CAC 11/26/13 Additional investigational policy statement added for triple-site (triventricular) CRT. Added Rationale section. All rationale information now contained in that section. Deleted Medicare variation addressing NCD 220.2 Magnetic Resonance Imaging and L30529 - Cardiac Rhythm Device Evaluation. The CBC policy does not address services described within these documents. Added reference to NCD 20.8.3 in Medicare variation.

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