



Louisiana

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

Policy # 00009

Original Effective Date: 06/05/2002

Current Effective Date: 04/13/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Automatic Implantable Cardioverter Defibrillator (AICD) is addressed separately in medical policy 00008.

Note: Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting is addressed separately in medical policy 00287.

Based on review of available data, the Company may consider biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (ICD) (i.e., a combined biventricular pacemaker plus cardiac defibrillator) as a treatment of heart failure to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for biventricular pacemakers with or without an accompanying ICD as a treatment of heart failure for New York Heart Association (NYHA) class II, III or IV will be considered in patients who meet ALL of the following criteria:

- Left ventricular ejection fraction (LVEF) $\leq 35\%$, AND
- Sinus rhythm, AND
- Patients treated with guideline-directed medical therapy before implant, such as an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker, digoxin, and/or diuretics, AND
- Either left bundle branch block (LBBB) OR QRS duration ≥ 150 ms***

****The Food and Drug Administration (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 ms (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.*

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Based on review of available data, the Company may consider biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (ICD [i.e., a combined biventricular pacemaker plus ICD]) for patients who do not meet the criteria outlined above, but who have an indication for a ventricular pacemaker to be **eligible for coverage**** as an alternative to a right ventricular pacemaker.

Patient Selection Criteria

Coverage eligibility for biventricular pacemakers with or without an accompanying ICD (i.e., a combined biventricular pacemaker plus ICD) as an alternative to a right ventricular pacemaker for patients who do not meet the criteria outlined above, but who have an indication for a ventricular pacemaker will be considered when the following criteria are met:

- NYHA class I, II, III or IV heart failure; AND
- Left ventricular ejection fraction (LVEF) $\leq 50\%$; AND
- The presence of atrioventricular (AV) block with requirement for a high percentage of ventricular pacing (See Policy Guidelines); AND
- Patients treated with guideline-directed medical therapy before implant, such as an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker, digoxin, and/or diuretics.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator (ICD [i.e., a combined biventricular pacemaker plus ICD]) as a treatment for patients with NYHA class II, III or IV heart failure when patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers the use of biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator (ICD [i.e., a combined biventricular pacemaker plus ICD]) as a treatment for patients with NYHA class I heart failure who do not meet the above criteria to be **investigational.***

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Based on review of available data, the company considers biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator (ICD [i.e., a combined biventricular pacemaker plus ICD]), as a treatment for heart failure in patients with atrial fibrillation (AF) who do not meet the above criteria to be **investigational**.*

Based on review of available data, the Company considers triple-site (triventricular) cardiac resynchronization therapy (CRT), using an additional pacing lead, to be **investigational**.*

Based on review of available data, the Company considers an intrathoracic fluid monitoring sensor is considered to be **investigational*** as a component of a biventricular pacemaker.

Based on review of available data, the Company considers cardiac resynchronization therapy (CRT) with wireless left ventricular (LV) endocardial pacing is considered to be **investigational***.

Policy Guidelines

Definitions

Atrioventricular block with a requirement for a high percentage of ventricular pacing is considered to be present when there is either:

- Third-degree atrioventricular block; OR
- Second-degree atrioventricular block or a PR interval of ≥ 300 ms when paced at 100 beats per minute.

Guideline-directed medical therapy for heart failure is outlined in 2013 American College of Cardiology Foundation and American Heart Association guidelines for the management of heart failure (Yancy et al [2013]).

Table 1. NYHA Functional Classification

NYHA Class	Patients with Cardiac Disease (Description of HF Related Symptoms)
Class I (Mild)	Patients with cardiac disease but without resulting in limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation (rapid or pounding heart beat), dyspnea (shortness of breath), or anginal pain (chest pain).

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Class II (Mild)	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
Class III (Moderate)	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.
Class IV (Severe)	Patients with cardiac disease resulting in the 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 is increased.

The Criteria Committee of the New York Heart Association. *Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels*. 9th ed. Boston, Mass: Little, Brown & Co; 1994:253-256.

Background/Overview

Heart Failure

It is estimated that 20% to 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. This abnormality appears to be associated with increased morbidity and mortality.

Treatment

Biventricular pacemakers using three leads (one in the right atrium, one endocardial in the right ventricle, one epicardial for the left ventricle), also known as cardiac resynchronization therapy (CRT), have been investigated as a technique to coordinate the contraction of the ventricles, thus improving patients' hemodynamic status. Originally developed CRT devices typically used two ventricular leads for biventricular pacing. Devices and implantation techniques have been developed to allow for multisite pacing, with the goal of improving CRT response. This may be accomplished in one of two ways: through the use of multiple leads within the coronary sinus (triventricular pacing) or through the use of multipolar left ventricular pacing leads, which can deliver pacing stimuli at multiple sites. Wireless left ventricular endocardial pacing is also being evaluated for patients who are not candidates for or do not respond to standard epicardial pacing leads.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

There are numerous CRT devices, combined implantable cardioverter defibrillator (ICD) plus CRT devices (CRT-D), and combined CRT plus fluid monitoring devices. Some devices are discussed here. For example, in 2001, the InSync Biventricular Pacing System (Medtronic), a stand-alone biventricular pacemaker, was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process 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 ms or longer and a left ventricular ejection fraction (LVEF) of 35% or less. Devices by Guidant (CONTAK-CD CRT-D System) and Medtronic (InSync ICD Model 7272) have been approved by the FDA through the premarket approval process for combined CRT 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 a LVEF of 35% or less, QRS interval 130 ms or longer (≥ 120 ms for the Guidant device), and remain symptomatic despite a stable, optimal heart failure drug therapy. In 2006, Biotronik Inc. received premarket approval from the FDA for its combined ICD-D device with ventricular pacing leads (Tupos LV/ATx CRT-D/Kronos LV-T CRT-D systems,); in 2013, the company received the FDA approval for updated ICD-D devices (Ilesto/Iforia series).

In September 2010, the FDA expanded indications for some CRT devices to include patients with class I and II heart failure. Based on data from the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy study, indications for 3 Guidant CRT-D (Cognis[®]‡, Livian[®]‡, and Contak Renewal; Boston Scientific) devices were expanded to include patients with heart failure who receive stable optimal pharmacologic therapy for heart failure and who meet any of the following classifications:

- Moderate-to-severe heart failure (NYHA class III-IV) with an ejection fraction less than 35% and QRS interval greater than 120 ms.
- Left bundle branch block with a QRS interval greater than or equal to 130 ms, ejection fraction less than 30%, and mild (NYHA class II) ischemic or nonischemic heart failure or asymptomatic (NYHA class I) ischemic heart failure.

In April 2014, the FDA further expanded indications for multiple Medtronic CRT devices to include patients with NYHA class I, II, or III heart failure, who have a LVEF of 50% or less on stable, optimal heart failure medical therapy, if indicated, and have atrioventricular block that is expected

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to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. The expanded indication was based on data from the BLOCK HF study, a Medtronic-sponsored randomized controlled trial that evaluated the use of CRT in patients with NYHA class I, II, or III heart failure, LVEF of 50% or less, and atrioventricular block.

Several CRT devices have incorporated a fourth lead, providing quadripolar pacing. The Medtronic Viva^{™‡} Quad XT and the Viva Quad S have a fourth lead, and the Medtronic Attain Performa^{®‡} has a left ventricular lead, which received clearance for marketing from the FDA in August 2014. The Dynagen^{™‡} X4 and Inogen^{™‡} X4 devices (Boston Scientific) also incorporate a fourth lead. Other CRT devices with quadripolar leads have been approved for use outside of the U. S. (eg, St. Jude Quartet^{™‡} left ventricular lead).

Multiple devices manufactured by Medtronic combine a CRT with the OptiVol^{™‡} monitoring system. For example, in 2005, the InSync Sentry^{®‡} system was approved by the FDA through the supplemental premarket approval process. This combined biventricular pacemaker plus 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 a 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 using a computer algorithm. For example, changes in a patient's daily average of intrathoracic bioimpedance can be monitored; differences in the daily average are compared with a baseline and 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 may provide feedback that enables a physician to tailor medical therapy. Medical policy 00287 addresses the use of external bioimpedance devices as stand-alone devices to assess cardiac output noninvasively.

The WiSE-CRT (EBR Systems) provides CRT with a small wireless electrode that is implanted within the left ventricle and controlled by ultrasound. It has European CE approval and is being studied in a multicenter pivotal trial.

FDA product code: NIK.

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Rationale/Source

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 coordinates ventricular pacing to maximize cardiac pumping function and left ventricular ejection fraction.

For individuals who have New York Heart Association (NYHA) class III or IV heart failure with a left ventricular ejection fraction of 35% or less who are in sinus rhythm, treated with guideline-directed medical therapy, and have either left bundle branch block (LBBB) or a QRS interval of 150 ms or more who receive CRT with or without defibrillator, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. The relevant outcomes are overall survival (OS), symptoms, functional outcomes, quality of life (QOL), hospitalizations, and treatment-related morbidity. There is a large body of clinical trial evidence supporting the use of CRT in patients with NYHA class III or IV heart failure. The RCTs have consistently reported that CRT reduces mortality, improves functional status, and improves QOL for patients with NYHA class III or IV heart failure. Multiple subgroup analyses of RCTs have demonstrated that the benefit of CRT is mainly restricted to patients with LBBB or QRS interval greater than 150 ms. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have NYHA class II heart failure with a left ventricular ejection fraction of 30% or less who are in sinus rhythm, treated with guideline-directed medical therapy, and have either LBBB or a QRS interval of 150 ms or more who receive CRT with or without defibrillator, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are OS, symptoms, functional outcomes, QOL, hospitalizations, and treatment-related morbidity. For patients with NYHA class II heart failure, at least four RCTs assessing CRT have been published. A mortality benefit was reported in one of the four trials, the Resynchronization-Defibrillation for Ambulatory Heart Failure Trial. None of the other three RCTs reported a mortality difference, but a subgroup analysis of the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy trial reported a mortality benefit for patients with LBBB. Among other outcome measures, hospitalizations for heart failure showed consistent reductions, but QOL and functional status did not improve. Multiple subgroup analyses of RCTs have demonstrated that the benefit of CRT is mainly restricted to patients with LBBB or a QRS interval greater than 150 ms.

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The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have NYHA class I heart failure, who receive CRT with or without defibrillator, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are OS, symptoms, functional outcomes, QOL, hospitalizations, and treatment-related morbidity. Few patients with NYHA class I heart failure have been included in RCTs. The Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy trial included 265 patients with class I. While the treatment effect on death and hospitalization favored combined implantable cardiac defibrillator plus CRT devices vs implantable cardiac defibrillator alone for class I patients, the confidence interval was large and included a 25% to 30% increase in events. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have NYHA class I, II, III or IV heart failure with left ventricular ejection fraction of 50% or less and the presence of atrioventricular block with requirement for a high percentage of ventricular pacing, treated with guideline-directed medical therapy, who receive CRT with or without defibrillator, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are OS, symptoms, functional outcomes, QOL, hospitalizations, and treatment-related morbidity. For patients who have atrioventricular nodal block, some degree of left ventricular dysfunction, and who would not necessarily meet conventional criteria for CRT but would require ventricular pacing, a large RCT has demonstrated improvements in heart failure-related hospitalizations and urgent care visits among patients treated with CRT instead of RV pacing alone. For patients who require ventricular pacing but have no left ventricular dysfunction, results of a small RCT have suggested that biventricular pacing is associated with improved measures of cardiac function, but the trial was small and underpowered to detect differences in clinical outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have heart failure and atrial fibrillation who receive CRT with or without defibrillator, the evidence includes four RCTs and observational studies. The relevant outcomes are OS, symptoms, functional outcomes, QOL, hospitalizations, and treatment-related morbidity. Results from RCTs have been conflicting, with one reporting improvements for patients with atrial fibrillation and others reporting no significant improvements. Results from observational studies are

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also conflicting. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure and atrioventricular nodal block who receive CRT, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are OS, symptoms, functional outcomes, QOL, hospitalizations, and treatment-related morbidity. One large RCT demonstrated that CRT led to reductions in heart failure-related hospitalizations and urgent care visits among patients with heart failure and atrioventricular block but who would not necessarily meet conventional criteria for CRT. For patients who require ventricular pacing but have no left ventricular dysfunction, results of a small RCT have suggested that biventricular pacing is associated with improvement in cardiac function, but the trial was small and underpowered to detect differences in clinical outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have heart failure who receive triple-site CRT, the evidence includes small RCTs and a meta-analysis that included nonrandomized studies. The relevant outcomes are OS, symptoms, functional outcomes, QOL, hospitalizations, and treatment-related morbidity. The available RCTs have reported improved outcomes on at least one measure of functional status or QOL with triple-site CRT compared with conventional CRT. However, the trials were small and had methodologic limitations. Also, outcomes reported differed across studies. Triple-site CRT was also associated with higher radiation exposure and a greater number of additional procedures post implantation. Larger, high-quality RCTs are needed to define better the benefit-risk ratio for triple-site CRT compared with conventional CRT. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure who receive CRT combined with remote fluid monitoring, the evidence includes three RCTs. The relevant outcomes are OS, symptoms, functional outcomes, QOL, hospitalizations, and treatment-related morbidity. Three RCTs have reported no improvement in outcomes associated with remote fluid monitoring for patients with heart failure. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Supplemental Information

Clinical Input from 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 with the medically necessary statements. For patients with class I heart failure, there was mixed input as to whether cardiac resynchronization therapy should be medically necessary. Regarding the duration of the QRS complex, commentators acknowledged that the literature supported use mainly in patients with a QRS interval greater than 150 ms, but most reviewers disagreed with restricting cardiac resynchronization therapy use to patients in that group because that duration was not currently the accepted standard of care. For patients with atrial fibrillation, the input was mixed on whether biventricular pacing improves outcomes.

Practice Guidelines and Position Statements

American College of Cardiology et al

The ACC and American Heart Association and Heart Rhythm Society (2019) published joint guidelines on the evaluation and management of patients with bradycardia and cardiac conduction delay. These guidelines included the following recommendations on CRT (see Table 2).

Table 2. Joint Guidelines on Treatment of Cardiac Rhythm Abnormalities

Recommendation	COR	LOE
"In patients with atrioventricular block who have an indication for permanent pacing with a LVEF between 36% and 50% and are expected to require ventricular pacing more than 40% of the time, it is reasonable to choose pacing methods that maintain physiologic ventricular activation (e.g., cardiac resynchronization therapy [CRT] or His bundle pacing) over right ventricular pacing."	IIa	B-R ^{SR}
"In patients with atrioventricular block who have an indication for permanent pacing with a LVEF between 36% and 50% and are expected to require ventricular	IIa	B-R

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Recommendation	COR	LOE
pacing less than 40% of the time, it is reasonable to choose right ventricular pacing over pacing methods that maintain physiologic ventricular activation (e.g., CRT or His bundle pacing)."		

COR: class of recommendation; LOE: level of evidence; LVEF: left ventricular ejection fraction.

The ACC and American Heart Association (2013) published guidelines for the management of heart failure. These guidelines made recommendations on cardiac resynchronization therapy (CRT) for heart failure that are in line with those made by the ACC, American Heart Association, and Heart Rhythm Society related to CRT for heart failure outlined next.

A focused update to 2008 guidelines for device-based treatment of cardiac rhythm abnormalities was published jointly by American College of Cardiology Foundation, American Heart Association, and Heart Rhythm Society in 2012. These guidelines included the following recommendations on CRT for heart failure (see Table 3).

Table 3. Joint Guidelines on Treatment of Cardiac Rhythm Abnormalities

Recommendation	COR	LOE
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 GDMT	I	A ^a B ^b
CRT can be useful for patients who have LVEF less than or equal to 35%, sinus rhythm, LBBB with a QRS duration 120 to 149 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT	IIa	B
CRT can be useful for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with a QRS duration greater than or equal to 150 ms and NYHA class III/ambulatory class IV symptoms on GDMT	IIa	A
CRT can be useful in patients with atrial fibrillation and LVEF less than or equal to 35% on GDMT if a) the patient requires ventricular pacing or otherwise meets CRT criteria and b) AV nodal ablation or pharmacologic rate control will allow near 100 % ventricular pacing with CRT	IIa	B

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Recommendation	COR	LOE
CRT can be useful for patients on GDMT who have LVEF less than or equal to 35 % and are undergoing new or replacement device placement with anticipate requirement for significant (>40%) ventricular pacing	IIa	C
CRT may be considered for patients who have LVEF less than or equal to 30%, ischemic etiology of heart failure, sinus rhythm, LBBB with a QRS duration of greater than or equal to 150 ms, and NYHA class I symptoms on GDMT	IIb	C
CRT may be considered for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with QRS duration 120 to 149 ms, and NYHA class III/ambulatory class IV on GDMT	IIb	B
CRT may be considered for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with a QRS duration greater than or equal to 150 ms, and NYHA class II symptoms on GDMT	IIb	B
CRT is not recommended for patients with NYHA class I or II symptoms and non-LBBB pattern with QRS duration less than 150 ms	III ^c	B
CRT is not indicated for patients whose comorbidities and/or frailty limit survival with good functional capacity to less than 1 year	III ^c	C

AV: atrioventricular; COR: class of recommendation; CRT: cardiac resynchronization therapy; GDMT: guideline-directed medical therapy; LBBB: left bundle branch block; LOE: level of evidence; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association.

^a For NYHA class III or IV heart failure.

^b For NYHA class II heart failure.

^cNo benefit.

Heart Failure Society of America

The Heart Failure Society of America (2010) released comprehensive guidelines on the management of heart failure. The guidelines included the following recommendations on the use of CRT (see Table 4).

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Table 4. Guidelines on Management of Heart Failure

Recommendation	LOE
Biventricular pacing therapy is recommended for patients in sinus rhythm with a widened QRS interval (≥ 120 ms) and severe LV systolic dysfunction (LVEF $\leq 35\%$) who have persistent, moderate to severe HF (NYHA III) despite optimal medical therapy.	A
Biventricular pacing therapy may be considered for patients with atrial fibrillation with a widened QRS interval (≥ 120 ms) and severe LV systolic dysfunction LVEF $\leq 35\%$ who have persistent, moderate to severe HF (NYHA III) despite optimal medical therapy.	B
Selected ambulatory NYHA IV patients in sinus rhythm with QRS ≥ 120 ms and LV systolic dysfunction may be considered for biventricular pacing therapy.	B
Biventricular pacing therapy may be considered in patients with reduced LVEF and QRS ≥ 150 ms who have NYHA I or II HF symptoms.	B
In patients with reduced LVEF who require chronic pacing and in whom frequent ventricular pacing is expected, biventricular pacing may be considered.	C

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence's (2014) guidance provided recommendations on CRT for heart failure. The recommendations for patients with left ventricular ejection fraction of 35% or less are list in Table 5.

Table 5. Guidelines on Management of Cardiac Resynchronization Therapy for Heart Failure

Indication	Recommendation
NYHA class I-IV with QRS interval < 120 ms	CRT not recommended
NYHA class IV with QRS interval 120 to 149 ms and without LBBB	CRT-P recommended
NYHA class II-III with QRS interval 120 to 149 ms and with LBBB	CRT-D recommended
NYHA class III-IV with QRS interval 120 to 149 ms and with LBBB	CRT-P recommended
NYHA class I-III with QRS interval ≥ 150 ms (with or without LBBB)	CRT-D recommended
NYHA class III-IV with QRS interval ≥ 150 ms (with or without LBBB)	CRT-P recommended

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Louisiana

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

Policy # 00009

Original Effective Date: 06/05/2002

Current Effective Date: 04/13/2020

CRT-D: cardiac resynchronization therapy with implantable cardiac defibrillator; CRT-P: cardiac resynchronization therapy with pacemaker; LBBB: left bundle branch block; NYHA: New York Heart Association.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 6.

Table 6. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT01994252	Resynchronization/Defibrillation for Ambulatory Heart Failure Trial in Patients With Permanent Atrial Fibrillation (RAFT-PerMAF)	200	Dec 2020
NCT02137187	A Randomized Controlled Trial of Atrioventricular (AV) Junction Ablation and Biventricular Pacing Versus Optimal Pharmacological Therapy in Patients With Permanent Atrial Fibrillation	1830	Jul 2021
NCT02962791	Prospective Randomized Trial Comparing TRIPLE Site ventricular Stimulation Versus Conventional Pacing in CRT candidates: TRIPLEAD Trial	166	Oct 2021

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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02922036a	Stimulation Of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy in Non-Responders and Previously Untreatable Patients (SOLVE CRT)	350	Sep 2020
NCT01522898 ^a	Cardiac Resynchronization Therapy and AV Nodal Ablation Trial in Atrial Fibrillation (CAAN-AF)	590	Jan 2022
<i>Unpublished</i>			
NCT00187278	Biventricular Pacing for Atrioventricular Block in Left Ventricular Dysfunction to Prevent Cardiac Desynchronization	1833	Oct 2014 (completed)
NCT02454439	Assessment of Cardiac Resynchronization Therapy in Patients With Wide QRS and Non-specific Intraventricular Conduction Delay: a Randomized Trial	200	Nov 2018 (unknown)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure”, Policy 2.02.10, June 2019.
2. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure. JACC Oct 15 2013; 62(16):147-239; <http://dx.doi.org/10.1016/j.jacc.2013.05.0193>.
3. The Criteria Committee of the New York Heart Association. *Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels*. 9th ed. Boston, Mass: Little, Brown & Co; 1994:253-256.

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Louisiana

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

Policy # 00009

Original Effective Date: 06/05/2002

Current Effective Date: 04/13/2020

4. Food and Drug Administration. Summary of Safety and Effectiveness Data: Tupos LV/ATx CRT-D, Kronos LV-T CRT-D. 2006;
https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050023b.pdf.
5. Food and Drug Administration. Approval Order: Biotronic PMA P050023. 2013;
https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050023S058A.pdf.
6. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Cardiac Resynchronization Therapy Defibrillator (CRT-D). 2010;
https://www.accessdata.fda.gov/cdrh_docs/pdf/P010012S230b.pdf.
7. Yu CM, Abraham WT, Bax J, et al. Predictors of response to cardiac resynchronization therapy (PROSPECT)-- study design. *Am Heart J.* Apr 2005;149(4):600-605. PMID 15990740.
8. Chung ES, Leon AR, Tavazzi L, et al. Results of the Predictors of Response to CRT (PROSPECT) trial. *Circulation.* May 20 2008;117(20):2608-2616. PMID 18458170.
9. Al-Majed NS, McAlister FA, Bakal JA, et al. Meta-analysis: cardiac resynchronization therapy for patients with less symptomatic heart failure. *Ann Intern Med.* Mar 15 2011;154(6):401-412. PMID 21320922.
10. Ezekowitz JA, Rowe BH, Dryden DM, et al. Systematic review: implantable cardioverter defibrillators for adults with left ventricular systolic dysfunction. *Ann Intern Med.* Aug 21 2007;147(4):251-262. PMID 17709759.
11. McAlister FA, Ezekowitz JA, Wiebe N, et al. Systematic review: cardiac resynchronization in patients with symptomatic heart failure. *Ann Intern Med.* Sep 7 2004;141(5):381-390. PMID 15353430.
12. Adabag S, Roukoz H, Anand IS, et al. Cardiac resynchronization therapy in patients with minimal heart failure: a systematic review and meta-analysis. *J Am Coll Cardiol.* Aug 23 2011;58(9):935-941. PMID 21851882.
13. Bertoldi EG, Polanczyk CA, Cunha V, et al. Mortality reduction of cardiac resynchronization and implantable cardioverter-defibrillator therapy in heart failure: an updated meta-analysis. Does recent evidence change the standard of care? *J Card Fail.* Oct 2011;17(10):860-866. PMID 21962425.
14. Nery PB, Ha AC, Keren A, et al. Cardiac resynchronization therapy in patients with left ventricular systolic dysfunction and right bundle branch block: a systematic review. *Heart Rhythm.* Jul 2011;8(7):1083-1087. PMID 21300176.
15. Tu R, Zhong G, Zeng Z, et al. Cardiac resynchronization therapy in patients with mild heart failure: a systematic review and meta-analysis of randomized controlled trials. *Cardiovasc Drugs Ther.* Aug 2011;25(4):331-340. PMID 21750900.

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Louisiana

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

Policy # 00009

Original Effective Date: 06/05/2002

Current Effective Date: 04/13/2020

16. Santangeli P, Di Biase L, Pelargonio G, et al. Cardiac resynchronization therapy in patients with mild heart failure: a systematic review and meta-analysis. *J Interv Card Electrophysiol*. Nov 2011;32(2):125-135. PMID 21594629.
17. Wells G, Parkash R, Healey JS, et al. Cardiac resynchronization therapy: a meta-analysis of randomized controlled trials. *CMAJ*. Mar 8 2011;183(4):421-429. PMID 21282316.
18. Chen S, Ling Z, Kiuchi MG, et al. The efficacy and safety of cardiac resynchronization therapy combined with implantable cardioverter defibrillator for heart failure: a meta-analysis of 5674 patients. *Europace*. Jul 2013;15(7):992-1001. PMID 23419662.
19. Woods B, Hawkins N, Mealing S, et al. Individual patient data network meta-analysis of mortality effects of implantable cardiac devices. *Heart*. Nov 2015;101(22):1800-1806. PMID 26269413.
20. Sun WP, Li CL, Guo JC, et al. Long-term efficacy of implantable cardiac resynchronization therapy plus defibrillator for primary prevention of sudden cardiac death in patients with mild heart failure: an updated meta-analysis. *Heart Fail Rev*. Jul 2016;21(4):447-453. PMID 27043219.
21. Ali-Hassan-Sayegh S, Mirhosseini SJ, Karimi-Bondarabadi AA, et al. Cardiac resynchronization therapy in patients with mild heart failure is a reversal therapy. *Indian Heart J*. Jan - Feb 2017;69(1):112-118. PMID 28228294.
22. Lozano I, Bocchiardo M, Achtelik M, et al. Impact of biventricular pacing on mortality in a randomized crossover study of patients with heart failure and ventricular arrhythmias. *Pacing Clin Electrophysiol*. Nov 2000;23(11 Pt 2):1711-1712. PMID 11139906.
23. Cazeau S, Leclercq C, Lavergne T, et al. Effects of multisite biventricular pacing in patients with heart failure and intraventricular conduction delay. *N Engl J Med*. Mar 22 2001;344(12):873-880. PMID 11259720.
24. Garrigue S, Bordachar P, Reuter S, et al. Comparison of permanent left ventricular and biventricular pacing in patients with heart failure and chronic atrial fibrillation: prospective haemodynamic study. *Heart*. Jun 2002;87(6):529-534. PMID 12010933.
25. Leclercq C, Walker S, Linde C, et al. Comparative effects of permanent biventricular and right-univentricular pacing in heart failure patients with chronic atrial fibrillation. *Eur Heart J*. Nov 2002;23(22):1780-1787. PMID 12419298.
26. Abraham WT, Fisher WG, Smith AL, et al. Cardiac resynchronization in chronic heart failure. *N Engl J Med*. Jun 13 2002;346(24):1845-1853. PMID 12063368.

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Louisiana

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Policy # 00009

Original Effective Date: 06/05/2002

Current Effective Date: 04/13/2020

27. Auricchio A, Stellbrink C, Sack S, et al. Long-term clinical effect of hemodynamically optimized cardiac resynchronization therapy in patients with heart failure and ventricular conduction delay. *J Am Coll Cardiol.* Jun 19 2002;39(12):2026-2033. PMID 12084604.
28. Auricchio A, Stellbrink C, Butter C, et al. Clinical efficacy of cardiac resynchronization therapy using left ventricular pacing in heart failure patients stratified by severity of ventricular conduction delay. *J Am Coll Cardiol.* Dec 17 2003;42(12):2109-2116. PMID 14680736.
29. Higgins SL, Hummel JD, Niazi IK, et al. Cardiac resynchronization therapy for the treatment of heart failure in patients with intraventricular conduction delay and malignant ventricular tachyarrhythmias. *J Am Coll Cardiol.* Oct 15 2003;42(8):1454-1459. PMID 14563591.
30. Young JB, Abraham WT, Smith AL, et al. Combined cardiac resynchronization and implantable cardioversion defibrillation in advanced chronic heart failure: the MIRACLE ICD Trial. *Jama.* May 28 2003;289(20):2685-2694. PMID 12771115.
31. Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. *N Engl J Med.* May 20 2004;350(21):2140-2150. PMID 15152059.
32. Abraham WT, Young JB, Leon AR, et al. Effects of cardiac resynchronization on disease progression in patients with left ventricular systolic dysfunction, an indication for an implantable cardioverter-defibrillator, and mildly symptomatic chronic heart failure. *Circulation.* Nov 2 2004;110(18):2864-2868. PMID 15505095.
33. Cleland JG, Daubert JC, Erdmann E, et al. The effect of cardiac resynchronization on morbidity and mortality in heart failure. *N Engl J Med.* Apr 14 2005;352(15):1539-1549. PMID 15753115.
34. Food and Drug Administration. Summary of Safety and Effectiveness Data: PMA P030054. 2004; https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030054b.pdf.
35. Food and Drug Administration. Summary of Safety and Effectiveness Data: Cardiac Resynchronization Therapy - Pacemaker (CRT-P) System. PMA P030035. 2005; https://www.accessdata.fda.gov/cdrh_docs/pdf3/p030035s003b.pdf.
36. Gasparini M, Bocchiardo M, Lunati M, et al. Comparison of 1-year effects of left ventricular and biventricular pacing in patients with heart failure who have ventricular arrhythmias and left bundle-branch block: the Bi vs Left Ventricular Pacing: an International Pilot Evaluation on Heart Failure Patients with Ventricular Arrhythmias (BELIEVE) multicenter prospective randomized pilot study. *Am Heart J.* Jul 2006;152(1):155.e151-157. PMID 16824846.
37. Kindermann M, Hennen B, Jung J, et al. Biventricular versus conventional right ventricular stimulation for patients with standard pacing indication and left ventricular dysfunction: the

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Current Effective Date: 04/13/2020

- Homburg Biventricular Pacing Evaluation (HOBIPACE). *J Am Coll Cardiol.* May 16 2006;47(10):1927-1937. PMID 16697307.
38. Piccirillo G, Magri D, di Carlo S, et al. Influence of cardiac-resynchronization therapy on heart rate and blood pressure variability: 1-year follow-up. *Eur J Heart Fail.* Nov 2006;8(7):716-722. PMID 16513420.
 39. Rao RK, Kumar UN, Schafer J, et al. Reduced ventricular volumes and improved systolic function with cardiac resynchronization therapy: a randomized trial comparing simultaneous biventricular pacing, sequential biventricular pacing, and left ventricular pacing. *Circulation.* Apr 24 2007;115(16):2136-2144. PMID 17420340.
 40. Leclercq C, Cazeau S, Lellouche D, et al. Upgrading from single chamber right ventricular to biventricular pacing in permanently paced patients with worsening heart failure: The RD-CHF Study. *Pacing Clin Electrophysiol.* Jan 2007;30(Suppl 1):S23-30. PMID 17302711.
 41. Beshai JF, Grimm RA, Nagueh SF, et al. Cardiac-resynchronization therapy in heart failure with narrow QRS complexes. *N Engl J Med.* Dec 13 2007;357(24):2461-2471. PMID 17986493.
 42. Brignole M, Auricchio A, Baron-Esquivias G, et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: the Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). *Eur Heart J.* Aug 2013;34(29):2281-2329. PMID 23801822.
 43. Linde C, Abraham WT, Gold MR, et al. Randomized trial of cardiac resynchronization in mildly symptomatic heart failure patients and in asymptomatic patients with left ventricular dysfunction and previous heart failure symptoms. *J Am Coll Cardiol.* Dec 2 2008;52(23):1834-1843. PMID 19038680.
 44. Moss AJ, Hall WJ, Cannom DS, et al. Cardiac-resynchronization therapy for the prevention of heart-failure events. *N Engl J Med.* Oct 1 2009;361(14):1329-1338. PMID 19723701.
 45. Pinter A, Mangat I, Korley V, et al. Assessment of resynchronization therapy on functional status and quality of life in patients requiring an implantable defibrillator. *Pacing Clin Electrophysiol.* Dec 2009;32(12):1509-1519. PMID 19765233.
 46. Boriani G, Kranig W, Donal E, et al. A randomized double-blind comparison of biventricular versus left ventricular stimulation for cardiac resynchronization therapy: the Biventricular versus Left Univentricular Pacing with ICD Back-up in Heart Failure Patients (B-LEFT HF) trial. *Am Heart J.* Jun 2010;159(6):1052-1058.e1051. PMID 20569719.

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Policy # 00009

Original Effective Date: 06/05/2002

Current Effective Date: 04/13/2020

47. Martinelli Filho M, de Siqueira SF, Costa R, et al. Conventional versus biventricular pacing in heart failure and bradyarrhythmia: the COMBAT study. *J Card Fail.* Apr 2010;16(4):293-300. PMID 20350695.
48. Tang AS, Wells GA, Talajic M, et al. Cardiac-resynchronization therapy for mild-to-moderate heart failure. *N Engl J Med.* Dec 16 2010;363(25):2385-2395. PMID 21073365.
49. Thibault B, Ducharme A, Harel F, et al. Left ventricular versus simultaneous biventricular pacing in patients with heart failure and a QRS complex ≥ 120 milliseconds. *Circulation.* Dec 20 2011;124(25):2874-2881. PMID 22104549.
50. Van Geldorp IE, Vernoooy K, Delhaas T, et al. Beneficial effects of biventricular pacing in chronically right ventricular paced patients with mild cardiomyopathy. *Europace.* Feb 2010;12(2):223-229. PMID 19966323.
51. Foley PW, Patel K, Irwin N, et al. Cardiac resynchronisation therapy in patients with heart failure and a normal QRS duration: the RESPOND study. *Heart.* Jul 2011;97(13):1041-1047. PMID 21339317.
52. Gillis AM, Kerr CR, Philippon F, et al. Impact of cardiac resynchronization therapy on hospitalizations in the Resynchronization-Defibrillation for Ambulatory Heart Failure trial. *Circulation.* May 20 2014;129(20):2021-2030. PMID 24610807.
53. Goldenberg I, Hall WJ, Beck CA, et al. Reduction of the risk of recurring heart failure events with cardiac resynchronization therapy: MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial With Cardiac Resynchronization Therapy). *J Am Coll Cardiol.* Aug 9 2011;58(7):729-737. PMID 21816309.
54. Goldenberg I, Kutiyafa V, Klein HU, et al. Survival with cardiac-resynchronization therapy in mild heart failure. *N Engl J Med.* May 1 2014;370(18):1694-1701. PMID 24678999.
55. Hosseini SM, Moazzami K, Rozen G, et al. Utilization and in-hospital complications of cardiac resynchronization therapy: trends in the United States from 2003 to 2013. *Eur Heart J.* Jul 14 2017;38(27):2122-2128. PMID 28329322.
56. Thibault B, Harel F, Ducharme A, et al. Cardiac resynchronization therapy in patients with heart failure and a qrs complex < 120 milliseconds: the evaluation of resynchronization therapy for heart failure (LESSER-EARTH) Trial. *Circulation.* Feb 26 2013;127(8):873-881. PMID 23388213.
57. Sipahi I, Carrigan TP, Rowland DY, et al. Impact of QRS duration on clinical event reduction with cardiac resynchronization therapy: meta-analysis of randomized controlled trials. *Arch Intern Med.* Sep 12 2011;171(16):1454-1462. PMID 21670335.

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

Policy # 00009

Original Effective Date: 06/05/2002

Current Effective Date: 04/13/2020

58. Bryant AR, Wilton SB, Lai MP, et al. Association between QRS duration and outcome with cardiac resynchronization therapy: a systematic review and meta-analysis. *J Electrocardiol.* Mar-Apr 2013;46(2):147-155. PMID 23394690.
59. Stavrakis S, Lazzara R, Thadani U. The benefit of cardiac resynchronization therapy and QRS duration: a meta- analysis. *J Cardiovasc Electrophysiol.* Feb 2012;23(2):163-168. PMID 21815961.
60. Sipahi I, Chou JC, Hyden M, et al. Effect of QRS morphology on clinical event reduction with cardiac resynchronization therapy: meta-analysis of randomized controlled trials. *Am Heart J.* Feb 2012;163(2):260-267 e263. PMID 22305845.
61. Kang SH, Oh IY, Kang DY, et al. Cardiac resynchronization therapy and QRS duration: systematic review, meta- analysis, and meta-regression. *J Korean Med Sci.* Jan 2015;30(1):24-33. PMID 25552880.
62. Shah RM, Patel D, Molnar J, et al. Cardiac-resynchronization therapy in patients with systolic heart failure and QRS interval. *2015 Feb*;17(2):267-273. PMID25164431.
63. Stockburger M, Moss AJ, Klein HU, et al. Sustained clinical benefit of cardiac resynchronization therapy in non- LBBB patients with prolonged PR-interval: MADIT-CRT long-term follow-up. *Clin Res Cardiol.* Nov 2016;105(11):944-952. PMID 27318807.
64. Ruschitzka F, Abraham WT, Singh JP, et al. Cardiac-resynchronization therapy in heart failure with a narrow QRS complex. *N Engl J Med.* Oct 10 2013;369(15):1395-1405. PMID 23998714.
65. Kalscheur MM, Saxon LA, Lee BK, et al. Outcomes of cardiac resynchronization therapy in patients with intermittent atrial fibrillation or atrial flutter in the COMPANION trial. *Heart Rhythm.* Jun 2017;14(6):858-865. PMID 28323173.
66. Healey JS, Hohnloser SH, Exner DV, et al. Cardiac resynchronization therapy in patients with permanent atrial fibrillation: results from the Resynchronization for Ambulatory Heart Failure Trial (RAFT). *Circ Heart Fail.* Sep 1 2012;5(5):566-570. PMID 22896584.
67. Khazanie P, Greiner MA, Al-Khatib SM, et al. Comparative effectiveness of cardiac resynchronization therapy among patients with heart failure and atrial fibrillation: findings from the National Cardiovascular Data Registry's Implantable Cardioverter-Defibrillator Registry. *Circ Heart Fail.* Jun 2016;9(6). PMID 27296396.
68. Curtis AB, Worley SJ, Adamson PB, et al. Biventricular pacing for atrioventricular block and systolic dysfunction. *N Engl J Med.* Apr 25 2013;368(17):1585-1593. PMID 23614585.
69. Curtis AB, Worley SJ, Chung ES, et al. Improvement in clinical outcomes with biventricular versus right ventricular pacing: the BLOCK HF Study. *J Am Coll Cardiol.* May 10 2016;67(18):2148-2157. PMID 27151347.

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Louisiana

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

Policy # 00009

Original Effective Date: 06/05/2002

Current Effective Date: 04/13/2020

70. Yu CM, Chan JY, Zhang Q, et al. Biventricular pacing in patients with bradycardia and normal ejection fraction. *N Engl J Med*. Nov 26 2009;361(22):2123-2134. PMID 19915220.
71. Chan JY, Fang F, Zhang Q, et al. Biventricular pacing is superior to right ventricular pacing in bradycardia patients with preserved systolic function: 2-year results of the PACE trial. *Eur Heart J*. Oct 2011;32(20):2533- 2540. PMID 21875860.
72. Yu CM, Fang F, Luo XX, et al. Long-term follow-up results of the pacing to avoid cardiac enlargement (PACE) trial. *Eur J Heart Fail*. Sep 2014;16(9):1016-1025. PMID 25179592.
73. Doshi RN, Daoud EG, Fellows C, et al. Left ventricular-based cardiac stimulation post AV nodal ablation evaluation (the PAVE study). *J Cardiovasc Electrophysiol*. Nov 2005;16(11):1160-1165. PMID 16302897.
74. Anselme F, Bordachar P, Pasquie JL, et al. Safety, feasibility, and outcome results of cardiac resynchronization with triple-site ventricular stimulation compared to conventional cardiac resynchronization. *Heart Rhythm*. Jan 2016;13(1):183-189. PMID 26325531.
75. Bencardino G, Di Monaco A, Russo E, et al. Outcome of patients treated by cardiac resynchronization therapy using a quadripolar left ventricular lead. *Circ J*. Feb 25 2016;80(3):613-618. PMID 26821688.
76. Lenarczyk R, Kowalski O, Sredniawa B, et al. Implantation feasibility, procedure-related adverse events and lead performance during 1-year follow-up in patients undergoing triple-site cardiac resynchronization therapy: a substudy of TRUST CRT randomized trial. *J Cardiovasc Electrophysiol*. Nov 2012;23(11):1228-1236. PMID 22651239.
77. Pappone C, Calovic Z, Vicedomini G, et al. Improving cardiac resynchronization therapy response with multipoint left ventricular pacing: Twelve-month follow-up study. *Heart Rhythm*. Jun 2015;12(6):1250-1258. PMID 25678057.
78. Rogers DP, Lambiase PD, Lowe MD, et al. A randomized double-blind crossover trial of triventricular versus biventricular pacing in heart failure. *Eur J Heart Fail*. May 2012;14(5):495-505. PMID 22312038.
79. Zhang B, Guo J, Zhang G. Comparison of triple-site ventricular pacing versus conventional cardiac resynchronization therapy in patients with systolic heart failure: A meta-analysis of randomized and observational studies. *J Arrhythmia*. 2018;34:55-64. PMID 29721114.
80. Domenichini G, Rahneva T, Diab IG, et al. The lung impedance monitoring in treatment of chronic heart failure (the LIMIT-CHF study). *Europace*. Mar 2016;18(3):428-435. PMID 26683599.

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Louisiana

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

Policy # 00009

Original Effective Date: 06/05/2002

Current Effective Date: 04/13/2020

81. Luthje L, Vollmann D, Seegers J, et al. A randomized study of remote monitoring and fluid monitoring for the management of patients with implanted cardiac arrhythmia devices. *Europace*. Aug 2015;17(8):1276-1281. PMID 25983310.
82. Bohm M, Drexler H, Oswald H, et al. Fluid status telemedicine alerts for heart failure: a randomized controlled trial. *Eur Heart J*. Nov 01 2016;37(41):3154-3163. PMID 26984864.
83. Kusumoto, FF, Schoenfeld, MM, Barrett, CC, Edgerton, JJ, Ellenbogen, KK, Gold, MM, Goldschlager, NN, Hamilton, RR, Joglar, JJ, Kim, RR, Lee, RR, Marine, JJ, McLeod, CC, Oken, KK, Patton, KK, Pellegrini, CC, Selzman, KK, Thompson, AA, Varosy, PP. 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, and the Heart Rhythm Society. *J. Am. Coll. Cardiol.*, 2018 Nov 10. PMID 30412710.
84. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. *Circulation*. Oct 15 2013;128(16):1810-1852. PMID 23741057.
85. Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. *Circulation*. May 27 2008;117(21):e350-408. PMID 18483207.
86. Tracy CM, Epstein AE, Darbar D, et al. 2012 ACCF/AHA/HRS focused update of the 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. [corrected]. *Circulation*. Oct 2 2012;126(14):1784-1800. PMID 22965336.
87. Heart Failure Society of America, Lindenfeld J, Albert NM, et al. HFSA 2010 Comprehensive Heart Failure Practice Guideline. *J Card Fail*. Jun 2010;16(6):e1-194. PMID 20610207.
88. National Institute for Health and Care Excellence (NICE). Implantable cardioverter defibrillators and cardiac resynchronization therapy for arrhythmias and heart failure [TA314]. 2014; <https://www.nice.org.uk/guidance/ta314>.

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Louisiana

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

Policy # 00009

Original Effective Date: 06/05/2002

Current Effective Date: 04/13/2020

Policy History

Original Effective Date: 06/05/2002

Current Effective Date: 04/13/2020

04/18/2002 Medical Policy Committee review

06/05/2002 Managed Care Advisory Council approval

06/24/2002 Format revision. No substance change to policy.

06/01/2004 Medical Director review. Format revision. Clinical criteria revision.

06/15/2004 Medical Policy Committee review

06/28/2004 Managed Care Advisory Council approval

11/02/2004 Medical Director review. Clinical criteria revision

11/16/2004 Medical Policy Committee review

11/29/2004 Managed Care Advisory Council approval

04/05/2005 Medical Director review

04/18/2005 Medical Director review

04/22/2005 Medical Director review

04/27/2005 Medical Policy Committee review. Clinical criteria revision. Combination automatic implantable cardiac defibrillators (AICD) and biventricular pacemakers criteria further defined; “patients with New York Heart Association (NYHA) Class III or IV CHF, with a QRS duration of >120-130 msec”. FDA labeled indication for the InSync device and CONTAK CD® CRT-D System added. Investigational statement added to address cases not meeting clinical criteria.

04/04/2007 Medical Director review

04/18/2007 Medical Policy Committee approval. Policy statements revised indicating that intrathoracic bioimpedance is considered investigational as a component of a biventricular pacemaker; patient selection criteria for combined biventricular pacemaker/ACID revised to indicate that a combined device would be considered medically necessary in patients who meet the criteria for a biventricular pacemaker alone. Rationale /Source and Background/Overview updated.

04/02/2008 Medical Director review

04/16/2008 Medical Policy Committee approval. No changes to policy statement.

04/02/2009 Medical Director review

04/15/2009 Medical Policy Committee approval. No changes to policy statement.

04/08/2010 Medical Policy Committee approval

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- 04/21/2010 Medical Policy Implementation Committee approval. Added statement “Based on review of available data, the Company considers biventricular pacemakers with or without an accompanying implantable cardiac defibrillator as a treatment of NYHA class I or II heart failure to be investigational to the policy.
- 04/07/2011 Medical Policy Committee approval
- 04/13/2011 Medical Policy Implementation Committee approval. Sinus rhythm added to the list of patient selection criteria.
- 04/12/2012 Medical Policy Committee review
- 04/25/2012 Medical Policy Implementation Committee approval. Cardiac resynchronization therapy use in patients with NYHA class II heart failure meeting specific criteria now may be considered eligible for coverage; all other uses in mild heart failure (e.g., class I) considered investigational. The term “congestive” was removed from the title and text.
- 02/04/2013 Coding revised
- 04/03/2014 Medical Policy Committee review
- 04/23/2014 Medical Policy Implementation Committee approval. Additional investigational statement added for triple-site (triventricular) CRT.
- 04/02/2015 Medical Policy Committee review
- 04/20/2015 Medical Policy Implementation Committee approval. Updated rationale/source and references. Coverage eligibility unchanged.
- 08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
- 04/07/2016 Medical Policy Committee review
- 04/20/2016 Medical Policy Implementation Committee approval. Coverage statement with criteria added for CRT in patients with heart failure and AV block. Existing coverage criteria changed to include presence of LBBB (and QRS >120-130 ms) OR QRS >150 ms.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
- 04/06/2017 Medical Policy Committee review
- 04/19/2017 Medical Policy Committee approval. Coverage eligibility unchanged.
- 05/03/2018 Medical Policy Committee review
- 05/16/2018 Medical Policy Implementation Committee approval. Changed “a combined biventricular pacemaker/implantable cardiac defibrillator” to “a combined biventricular pacemaker plus implantable cardiac defibrillator” where it appears in

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the coverage section. Replaced “a stable pharmacologic medical regimen” with “guideline-directed medical therapy” for patients treated before implant in the Patient Selection Criteria. Coverage eligibility unchanged.

07/05/2018 Medical Policy Committee review

07/11/2018 Medical Policy Implementation Committee approval. Policy statement added that cardiac resynchronization therapy with wireless left ventricular endocardial pacing is considered investigational.

07/03/2019 Medical Policy Committee review

07/18/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/05/2020 Medical Policy Committee review

03/11/2020 Medical Policy Implementation Committee approval. Added New York Heart Association (NYHA) class II to coverage with criteria to Classes III and IV coverage for biventricular pacemakers with or without an accompanying ICD as a treatment of heart failure. Removed previous coverage with criteria for New York Heart Association (NYHA) class II. Added the NYHA Functional Classification table to the Policy Guidelines section.

10/12/2020 Coding update

Next Scheduled Review Date: 03/2021

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0515T, 0516T, 0517T, 0518T, 0519T, 0520T, 0521T, 0522T, 33211, 33213, 33217, 33224, 33225, 33226, 33228, 33229, 33230, 33231, 33249
HCPCS	C1721, C1785, C2619, C2621
ICD-10 Diagnosis	I50.0-I50.9

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);

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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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