

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

<b>Effective Date:</b>	<b>1/1/2024</b>
------------------------	-----------------

[POLICY RATIONALE](#)  
[DISCLAIMER](#)  
[POLICY HISTORY](#)

[PRODUCT VARIATIONS](#)  
[DEFINITIONS](#)  
[CODING INFORMATION](#)

[DESCRIPTION/BACKGROUND](#)  
[BENEFIT VARIATIONS](#)  
[REFERENCES](#)

### I. POLICY

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

#### For New York Heart Association Class III or IV

- Left ventricular ejection fraction  $\leq 35\%$ ; **and**
- Sinus rhythm; **and**
- Patients treated with guideline-directed medical therapy (see Policy Guidelines section);

#### AND

- Either left bundle branch block or QRS duration  $\geq 120$  ms

#### For New York Heart Association class II

- Left ventricular ejection fraction  $\leq 30\%$ ; **and**
- Sinus rhythm; **and**
- Patients treated with a guideline-directed medical therapy (see Policy Guidelines section);

#### AND

- Either left bundle branch block or QRS duration  $\geq 150$  ms.

For patients who do not meet the criteria outlined above, but have an indication for a ventricular pacemaker or biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker plus implantable cardiac defibrillator) may be considered **medically necessary** as an alternative to a right ventricular pacemaker in patients who meet all of the following criteria:

- NYHA class I, II, III, or IV heart failure; **and**
- Left ventricular ejection fraction  $\leq 50\%$ ; **and**
- The presence of atrioventricular (AV) block with requirement for a high percentage pacing (see Policy Guidelines section); **and**
- Patients treated with guideline-directed medical therapy (see Policy Guidelines section)

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker plus implantable cardiac defibrillator) is considered **investigational** as a treatment for patients with New York Heart Association class I heart failure who do not meet the above criteria. There is insufficient evidence to support a general 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 plus implantable cardiac defibrillator), are considered **investigational** as a treatment for heart failure in patients with atrial fibrillation who do not meet the above criteria. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

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

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

Cardiac resynchronization therapy with wireless left ventricular endocardial pacing is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

The use of biventricular pacemakers (cardiac resynchronization therapy) for treatment of heart failure in situations other than those described in the policy section are considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

The use of Cardiac Contractility Modulation (CCM) Therapy is considered **experimental and investigational** for treatment of heart failure. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

### Policy Guidelines

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

- Third-degree AV block; **or**
- Second-degree AV block or a PR interval of  $\geq 300$  ms when paced at 100 beats per minute.

Guideline-directed medical therapy for heart failure is outlined in 2022 American Heart Association, American College of Cardiology, and Heart Failure Society of America guidelines for the management of heart failure (Heidenreich et al [2022]).

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

**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

### II. PRODUCT VARIATIONS

[TOP](#)

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

### III. DESCRIPTION/BACKGROUND

[TOP](#)

#### Heart Failure

An estimated six million adults in the United States 20 years of age and older had heart failure between 2015 and 2018. The prevalence continues to increase over time with the aging of the population. Prevalence of disease is higher in women than men 80 years of age and older. Overall prevalence is especially high in Black individuals. A 2008 study demonstrated that Black individuals had the highest risk of developing heart failure, followed by Hispanic, White, and Chinese individuals in the United States. Higher risk reflected differential prevalence of hypertension, diabetes, and lower socioeconomic status. Black individuals also had the highest proportion of incident heart failure not preceded by myocardial infarction (75%). Additionally, Black individuals have a greater 5-year case fatality rate associated with heart failure compared to White individuals. 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.

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

### Regulatory Status

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 ( $\geq 120$  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 FDA approval for updated ICD-D devices (Ilesto/Iforia series). On the basis of the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT) 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 or 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 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 Biventricular versus Right Ventricular Pacing in Heart Failure Patients with Atrioventricular Block (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

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

a fourth lead. Other CRT devices with quadripolar leads have been approved for use outside of the United States (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 2.051 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.

#### IV. RATIONALE

[TOP](#)

##### Summary of Evidence

For individuals who have NYHA class III or IV heart failure with a LVEF 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, symptoms, functional outcomes, quality of life, 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 an improvement in the net health outcome.

For individuals who have NYHA class II heart failure with a LVEF of 30% or less who are in sinus rhythm, treated with guideline-directed medical therapy, and have either LBBB or a QRS

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

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 overall survival, symptoms, functional outcomes, quality of life, 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 (RAFT). 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 (MADIT-CRT) trial reported a mortality benefit for patients with LBBB. Among other outcome measures, hospitalizations for heart failure showed consistent reductions, but quality of life 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. The evidence is sufficient to determine that the technology results in an 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 overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Few patients with NYHA class I heart failure have been included in RCTs. The MADIT-CRT trial included 265 patients with class I heart failure. While the treatment effect on death and hospitalization favored combined implantable cardioverter-defibrillator plus CRT devices versus implantable cardioverter-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 that the technology results in an improvement in the net health outcome.

For individuals who have NYHA class I, II, III or IV heart failure with LVEF of 50% or less and the atrioventricular nodal 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. The relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, 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 right ventricular 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 an 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 six RCTs and registry study. The relevant outcomes

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Results from RCTs have been conflicting, with three reporting improvements for patients with atrial fibrillation, including an all-cause mortality benefit, and others reporting no significant improvements. A registry study reported significant improvements in mortality and hospitalizations for patients with heart failure and atrial fibrillation treated with CRT plus defibrillator compared with implantable cardioverter-defibrillator alone. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure and atrioventricular nodal block who receive CRT, the evidence includes RCTs. The relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, 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 an 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 overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The available RCTs have reported improved outcomes on at least one measure of functional status or quality of life 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 that the technology results in an improvement in the net health outcome.

For individuals who have heart failure who receive CRT combined with remote fluid monitoring, the evidence includes three RCTs. The relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, 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 that the technology results in an improvement in the net health outcome.

### V. DEFINITIONS

[TOP](#)

**ARRHYTHMIA REFERS** to irregularity, or loss of rhythm, of the heart.

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

**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

[TOP](#)

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

### VII. DISCLAIMER

[TOP](#)

*Capital Blue Cross'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. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services.*



## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

### VIII. CODING INFORMATION

[TOP](#)

**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.

**Investigational and not covered for: An Intrathoracic Fluid-Monitoring Sensor with Biventricular pacemakers, Triple-site (Triventricular) CRT, Cardiac Resynchronization Therapy with Wireless Left Ventricular Endocardial Pacing, Cardiac Contractility Modulation (CCM) Therapy and Synchronized Diaphragmatic Stimulation.**

Procedure Codes								
0408T	0409T	0410T	0411T	0412T	0413T	0414T	0415T	0416T
0417T	0418T	0515T	0516T	0517T	0518T	0519T	0520T	0521T
0522T	33999	C1896	C2621	C1824	K1030			

**Covered when medically necessary:**

Procedure Codes								
33202	33203	33207	33208	33213	33214	33217	33221	33224
33225	33228	33229	33230	33231	33240	33249	33263	33264
C1721	C1895	C1899	C1900	C2619	G0448			

ICD-10-CM Diagnosis Code	Description
I11.0	Hypertensive heart disease with heart failure
I50.1	Left ventricular failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure

**IX. REFERENCES**

[TOP](#)

1. Tsao CW, Aday AW, Almarzooq ZI, et al. Heart Disease and Stroke Statistics-2022 Update: A Report From the American Heart Association. *Circulation*. Feb 22, 2022; 145(8): e153-e639. PMID 35078371
2. Bahrami H, Kronmal R, Bluemke DA, et al. Differences in the incidence of congestive heart failure by ethnicity: the multi-ethnic study of atherosclerosis. *Arch Intern Med*. Oct 27, 2008; 168(19): 2138-45. PMID 18955644
3. Loehr LR, Rosamond WD, Chang PP, et al. Heart failure incidence and survival (from the Atherosclerosis Risk in Communities study). *Am J Cardiol*. Apr 01, 2008; 101(7): 1016-22. PMID 18359324
4. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Cardiac Resynchronization Therapy Defibrillator (CRT-D). 2010; 22, 2022
5. Food and Drug Administration. Approval Order: Biotronic PMA P050023. 2013;
6. 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): 401-12. PMID 21320922
7. 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): 251-62. PMID 17709759
8. McAlister FA, Ezekowitz JA, Wiebe N, et al. Systematic review: cardiac resynchronization in patients with symptomatic heart failure. *Ann Intern Med*. Sep 07, 2004; 141(5): 381-90. PMID 15353430

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

9. 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): 935-41. PMID 21851882
10. 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): 860-6. PMID 21962425
11. 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): 1083-7. PMID 21300176
12. 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): 331-40. PMID 21750900
13. 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): 125-35. PMID 21594629
14. Wells G, Parkash R, Healey JS, et al. Cardiac resynchronization therapy: a meta-analysis of randomized controlled trials. *CMAJ.* Mar 08, 2011; 183(4): 421-9. PMID 21282316
15. 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
16. 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): 1800-6. PMID 26269413
17. 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): 447-53. PMID 27043219
18. Ali-Hassan-Al-Saegh 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 2017; 69(1): 112-118. PMID 28228294
19. 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): 1711-2. PMID 11139906
20. 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): 873-80. PMID 11259720
21. 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): 529-34. PMID 12010933

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

22. 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): 1780-7. PMID 12419298
23. Abraham WT, Fisher WG, Smith AL, et al. Cardiac resynchronization in chronic heart failure. *N Engl J Med.* Jun 13, 2002; 346(24): 1845-53. PMID 12063368
24. 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): 2026-33. PMID 12084604
25. 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): 2109-16. PMID 14680736
26. 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): 1454-9. PMID 14563591
27. 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): 2685-94. PMID 12771115
28. 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): 2140-50. PMID 15152059
29. 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 02, 2004; 110(18): 2864-8. PMID 15505095
30. 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): 1539-49. PMID 15753115
31. 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.e1-7. PMID 16824846
32. 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 Homburg Biventricular Pacing Evaluation (HOBIPACE). *J Am Coll Cardiol.* May 16, 2006; 47(10): 1927-37. PMID 16697307
33. 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): 716-22. PMID 16513420

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

34. 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): 2136-44. PMID 17420340
35. 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
36. 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): 2461-71. PMID 17986493
37. 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): 2281-329. PMID 23801822
38. 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 02, 2008; 52(23): 1834-1843. PMID 19038680
39. Moss AJ, Hall WJ, Cannom DS, et al. Cardiac-resynchronization therapy for the prevention of heart-failure events. *N Engl J Med*. Oct 01, 2009; 361(14): 1329-38. PMID 19723701
40. 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): 1509-19. PMID 19765233
41. 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.e1. PMID 20569719
42. 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
43. 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): 2385-95. PMID 21073365
44. 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): 2874-81. PMID 22104549
45. van Geldorp IE, Vernooy K, Delhaas T, et al. Beneficial effects of biventricular pacing in chronically right ventricular paced patients with mild cardiomyopathy. *Europace*. Feb 2010; 12(2): 223-9. PMID 19966323

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

46. 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): 1041-7. PMID 21339317
47. 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): 2021-30. PMID 24610807
48. 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 09, 2011; 58(7): 729-37. PMID 21816309
49. Goldenberg I, Kutiyafa V, Klein HU, et al. Survival with cardiac-resynchronization therapy in mild heart failure. *N Engl J Med*. May 01, 2014; 370(18): 1694-701. PMID 24678999
50. 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
51. 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): 600-5. PMID 15990740
52. Chung ES, Leon AR, Tavazzi L, et al. Results of the Predictors of Response to CRT (PROSPECT) trial. *Circulation*. May 20, 2008; 117(20): 2608-16. PMID 18458170
53. 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): 873-81. PMID 23388213
54. 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): 1454-62. PMID 21670335
55. 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): 147-55. PMID 23394690
56. 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): 163-8. PMID 21815961
57. 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): 260-7.e3. PMID 22305845
58. 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

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

59. Shah RM, Patel D, Molnar J, et al. Cardiac-resynchronization therapy in patients with systolic heart failure and QRS interval 130 ms: insights from a meta-analysis. *Europace*. Feb 2015; 17(2): 267-73. PMID 25164431

60. Peterson PN, Greiner MA, Qualls LG, et al. QRS duration, bundle-branch block morphology, and outcomes among older patients with heart failure receiving cardiac resynchronization therapy. *JAMA*. Aug 14, 2013; 310(6): 617-26. PMID 23942680

61. Kutyifa V, Stockburger M, Daubert JP, et al. PR interval identifies clinical response in patients with non-left bundle branch block: a Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy substudy. *Circ Arrhythm Electrophysiol*. Aug 2014; 7(4): 645-51. PMID 24963007

62. 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

63. Friedman DJ, Bao H, Spatz ES, et al. Association Between a Prolonged PR Interval and Outcomes of Cardiac Resynchronization Therapy: A Report From the National Cardiovascular Data Registry. *Circulation*. Nov 22, 2016; 134(21): 1617-1628. PMID 27760795

64. Hawkins NM, Petrie MC, MacDonald MR, et al. Selecting patients for cardiac resynchronization therapy: electrical or mechanical dyssynchrony? *Eur Heart J*. Jun 2006; 27(11): 1270-81. PMID 16527827

65. Muto C, Solimene F, Gallo P, et al. A randomized study of cardiac resynchronization therapy defibrillator versus dual-chamber implantable cardioverter-defibrillator in ischemic cardiomyopathy with narrow QRS: the NARROW-CRT study. *Circ Arrhythm Electrophysiol*. Jun 2013; 6(3): 538-45. PMID 23592833

66. 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): 1395-405. PMID 23998714

67. Brignole M, Pokushalov E, Pentimalli F, et al. A randomized controlled trial of atrioventricular junction ablation and cardiac resynchronization therapy in patients with permanent atrial fibrillation and narrow QRS. *Eur Heart J*. Dec 01, 2018; 39(45): 3999-4008. PMID 30165479

68. Brignole M, Pentimalli F, Palmisano P, et al. AV junction ablation and cardiac resynchronization for patients with permanent atrial fibrillation and narrow QRS: the APAF-CRT mortality trial. *Eur Heart J*. Dec 07, 2021; 42(46): 4731-4739. PMID 34453840

69. Brignole M, Botto G, Mont L, et al. Cardiac resynchronization therapy in patients undergoing atrioventricular junction ablation for permanent atrial fibrillation: a randomized trial. *Eur Heart J*. Oct 2011; 32(19): 2420-9. PMID 21606084

70. 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

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

71. 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 01, 2012; 5(5): 566-70. PMID 22896584
72. 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
73. 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): 1585-93. PMID 23614585
74. 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
75. 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): 2123-34. PMID 19915220
76. 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): 2533-40. PMID 21875860
77. 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): 1016-25. PMID 25179592
78. 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): 1160-5. PMID 16302897
79. Anselme F, Bordachar P, Pasquie JL, et al. Safety, feasibility, and outcome results of cardiac resynchronization with triple-site ventricular stimulation compared to Hawkins NM, Petrie MC, MacDonald MR, et al. Selecting patients for cardiac conventional cardiac resynchronization. *Heart Rhythm.* Jan 2016; 13(1): 183-9. PMID 26325531
80. 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.* 2016; 80(3): 613-8. PMID 26821688
81. 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): 1228-36. PMID 22651239
82. 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): 1250-8. PMID 25678057
83. 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



**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

84. Gould J, Claridge S, Jackson T, et al. Standard care vs. TRIVentricular pacing in Heart Failure (STRIVE HF): a prospective multicentre randomized controlled trial of triventricular pacing vs. conventional biventricular pacing in patients with heart failure and intermediate QRS left bundle branch block. *Europace*. Nov 22, 2021. PMID 35079787
85. 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
86. 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): 428-35. PMID 26683599
87. 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): 1276-81. PMID 25983310
88. 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
89. Kusumoto FM, Schoenfeld MH, Barrett C, et al. 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*. Aug 20, 2019; 74(7): 932-987. PMID 30412710
90. 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
91. 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 02, 2012; 126(14): 1784-800. PMID 22965336
92. 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): 1810-52. PMID 23741057
93. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. May 03, 2022; 79(17): e263-e421. PMID 35379503

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

- 94. Lindenfeld J, Albert NM, Boehmer JP, et al. HFSA 2010 Comprehensive Heart Failure Practice Guideline. *J Card Fail.* Jun 2010; 16(6): e1-194. PMID 20610207
- 95. National Institute for Health and Care Excellence (NICE). Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure [TA314]. 2014; Accessed September 27, 2022
- 96. New Generation Cardiac Contractility Modulation Device-Filling the Gap in Heart Failure Treatment; PMID 31035648
- 97. Adelstein E, Masoudi F and Dardas T. Cardiac resynchronization therapy in heart failure: Indications. In: *UpToDate Online Journal* [serial online]. Waltham, MA: UpToDate; updated June 9, 2022. Literature review current through August 2022.. Accessed September 27, 2022
- 98. Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.02.10, Cardiac Resynchronization Therapy for the Treatment of Heart Failure. June 2022

**X. POLICY HISTORY**

[TOP](#)

<b>MP 2.007</b>	<b>CAC 12/2/03</b>
	<b>CAC 1/27/04</b>
	<b>CAC 10/26/04</b>
	<b>CAC 6/28/05</b>
	<b>CAC 3/28/06</b>
	<b>CAC 3/27/07</b>
	<b>CAC 5/27/08</b>
	<b>CAC 3/31/09</b> Consensus
	<b>CAC 3/30/10</b> 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.
	<b>CAC 11/22/11</b> 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.
	<b>CAC 10/30/12</b> 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

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

	<p>policy. FEP variation revised for biventricular pacemakers to refer to the FEP policy. Codes reviewed 9/18/12.</p>
	<p><b>CAC 11/26/13</b> 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.</p>
	<p><b>CAC 11/25/14</b> Consensus review. References and rationale updated. No changes to the policy statements. Coding reviewed no changes.</p>
	<p><b>CAC 11/24/15. Minor review.</b> For NYHA Class II, III or IV - changed criteria from "QRS duration of <math>\geq</math> (greater than or equal to) 120-130 msec" to "Either left bundle branch block or QRS duration <math>\geq</math>150 ms" Also changed "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" to "Patients treated with guideline-directed medical therapy. Link added to 2013 American College of Cardiology Foundation/American Heart Association guidelines for the management of heart failure. Policy statement added that CRT in patients with heart failure and AV block may be considered medically necessary with criteria. Rationale and references updated. Coding updated.</p>
	<p><b>5/1/16 Administrative change.</b> Added Medicare variation to reference LCA A54982 Single Chamber and Dual Chamber Permanent Cardiac Pacemakers – Coding and Billing</p>
	<p><b>Admin update 1/1/17:</b> Product variation section reformatted.</p>
	<p><b>CAC 11/29/16</b> Minor review. Removed the following statement. The use of pacemakers or pacemaker monitoring for conditions other than those described in the policy section is considered investigational. Added the following statement. The use of biventricular pacemakers (cardiac resynchronization therapy) for treatment of heart failure in situations other than those described in the policy section are considered <b>investigational</b>. For NYHA Class III or IV changed QRS duration from 150 to 120 ms. Updated rationale and references. Coding reviewed.</p>
	<p><b>10/1/17 Admin update:</b> Added new ICD 10 codes effective from 10/1/17.</p>
	<p><b>CAC 12/19/17</b> Consensus review. No change to policy statements. References and rationale updated. Coding Reviewed. Admin coding review 2/28/18: No changes.</p>
	<p><b>5/25/18</b> Minor revision. The policy title was changed to "Cardiac Resynchronization Therapy for the Treatment of Heart Failure." A new statement was added that cardiac resynchronization therapy with wireless left ventricular endocardial pacing is considered investigational. The policy statement regarding biventricular pacemakers with or without an accompanying implantable defibrillator was changed from "as an alternative to a right ventricular pacemaker" to "as a treatment for patients with New York Heart Association class I heart failure who do</p>

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>CARDIAC INTERVENTION THERAPY FOR THE TREATMENT OF HEART FAILURE</b>
<b>POLICY NUMBER</b>	<b>MP 2.007</b>

	not meet the above criteria.” Rationale revised. Background and references updated. Coding Updated. New codes effective 1/1/19 added.
	<b>3/25/2019. Consensus Review.</b> No changes made to policy statement. References updated.
	<b>3/16/2020 Consensus review.</b> Policy statement unchanged. References updated. Coding reviewed.
	<b>6/14/2021 Minor Review.</b> Policy statement updated to include Cardiac Contractility Modulation (CCM) Therapy. Policy Name Change. Codes added. Reference added.
	<b>12/1/2021 Administrative Review.</b> Added 0674T-0685T. Effective date 1/1/2022.
	<b>3/11/2022 Administrative Review.</b> Added K1030. Effective date 4/1/2022.
	<b>09/22/2020 Consensus Review.</b> No change to policy statement. FEP language revised. Background, Rationale and References updated. New references added. Removed codes 0674T - 0685T. Added 0418T.
	<b>08/03/2023- Consensus review.</b> No change to policy statement or intent.

[Top](#)

*Health care benefit programs issued or administered by Capital Blue Cross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company® and Keystone Health Plan® Central. Independent licensees of the Blue Cross BlueShield Association. Communications issued by Capital Blue Cross in its capacity as administrator of programs and provider relations for all companies.*