MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Cardiac Resynchronization Therapy (Biventricular Pacemakers) for the Treatment of Heart Failure**
Policy Number	**7.01.58**
Category	**Technology Assessment**
Original Effective Date	**11/21/02**
Committee Approval Date	**10/15/03, 08/19/04, 04/21/05, 01/19/06, 11/16/06, 09/20/07, 10/23/08, 09/17/09, 04/22/10, 06/16/11, 06/21/12, 06/20/13, 08/21/14, 07/16/15, 07/21/16, 07/20/17, 08/16/18, 08/15/19, 07/16/20, 08/19/21, 08/18/22, 08/17/23**
Current Effective Date	**08/17/23**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature and the position of the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and the Heart Rhythm Society (HRS), biventricular pacing, with or without an implantable cardiac defibrillator, for the treatment of heart failure has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option in the management of patients with **chronic heart failure AND WITH left bundle branch block pattern (LBBB)** who have **EITHER**:
   A. New York Heart Association (NYHA) Functional Class of II, III or Ambulatory Class IV; and
   B. Sinus rhythm; and
   C. Left ventricular ejection fraction less than or equal to 35%; **AND**
   D. QRS duration of equal to or greater than 0.12 s; **AND**
   E. Ongoing symptoms despite stable optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents, including, but not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and/or diuretics.

   OR:
   F. New York Heart Association Functional Class of I; **AND**
   G. Sinus rhythm; **AND**

H. Left ventricular ejection fraction less than or equal to 30%; **AND**
I. QRS duration of equal to or greater than 0.15 s; **AND**
J. Ongoing symptoms despite stable optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents, including, but not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and/or diuretics.

II. Based upon our criteria and assessment of the peer-reviewed literature, biventricular pacing with or without an implantable cardiac defibrillator for the treatment of heart failure has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option in the management of patients with **chronic heart failure and non-left bundle branch block pattern (non-LBBB)** who have **EITHER**:
A. New York Heart Association Functional Class of III or Ambulatory Class IV; **AND**
B. Sinus rhythm; and left ventricular ejection fraction less than or equal to 35%; **AND**
C. QRS duration of equal to or greater than 0.12 s; AND
D. Ongoing symptoms despite stable optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents, including, but not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and/or diuretics.

OR:
A. New York Heart Association Functional Class of II; AND
B. Sinus rhythm; and
C. Left ventricular ejection fraction less than or equal to 35%; AND
D. QRS duration of equal to or greater than 0.15 s; AND
E. Ongoing symptoms despite stable optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents, including, but not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and/or diuretics.

III. Based upon our criteria and assessment of the peer-reviewed literature, biventricular pacing, with or without an implantable cardiac defibrillator, for the treatment of heart failure has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option in the management of patients with **chronic heart failure (NYHA Class I, II, or III) and atrial fibrillation** who meet criteria for cardiac resynchronization therapy (CRT) and have **ALL** of the following:
A. Left ventricular ejection fraction less than or equal to 35% on stable optimal medical therapy; **AND**
B. AV nodal ablation or pharmacologic rate control that allows nearly 100% ventricular pacing with CRT; **AND**
C. Ongoing symptoms despite stable optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents, including, but not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and/or diuretics.

IV. Based upon our criteria and assessment of the peer-reviewed literature, biventricular pacing, with or without an implantable cardiac defibrillator, for the treatment of heart failure has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option in the management of persons with **chronic heart failure** who are undergoing **new device placement or replacement** and have **ALL** of the following:
A. Left ventricular ejection fraction less than or equal to 35%; **AND**
B. Anticipated requirement of greater than 40% ventricular pacing; **AND**
C. Ongoing symptoms despite stable optimal medical regimen with maximally tolerated doses of appropriate pharmacologic agents, including, but not limited to, ACE inhibitors (or angiotensin receptor blockers), beta blockers, and/or diuretics.

V. Based upon our criteria and assessment of the peer-reviewed literature, biventricular pacing for the treatment of **heart failure** has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option in the management of persons who have **ALL** of the following:
A. Left ventricular ejection fraction less than 50%; **AND**
B. NYHA Class I, II, or III heart failure; **AND**
C. High grade atrioventricular (AV) block, including AV nodal ablation, requiring more than 40% pacing (CRT).

VI. Based upon our criteria and assessment of the peer-reviewed literature, biventricular pacing is considered **investigational** for patients who do not meet any of the indications identified above.

VII. Based upon our criteria and assessment of the peer-reviewed literature, an **intrathoracic fluid monitoring sensor** is considered **investigational** as a component of a biventricular pacemaker.

VIII. Based upon our criteria and assessment of the peer-reviewed literature, cardiac resynchronization therapy for the treatment of heart failure with **wireless left ventricular endocardial pacing** is considered **investigational**.

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

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services

POLICY GUIDELINE

The New York Heart Association (NYHA) Heart Failure Classification (NYHA, 1994) are defined as follows:

Functional Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.

Functional Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.

Functional Class III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.

Functional Class IV: Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Ambulatory Functional Class IV: Class IV heart failure with no active acute coronary syndrome; no inotropes; and on guideline-directed medical therapy (GDMT) defined as initial medical therapy with angiotensin-converting enzyme inhibitors (ACEi) or angiotensin-receptor blockers (ARB), beta-blockers (BB), and mineralocorticoid receptor antagonists (MRA) titrating to maximally tolerated doses for patients with heart failure with reduced ejection fraction (HFrEF).

DESCRIPTION

Approximately 30 percent of persons with chronic heart failure have intraventricular conduction disorders resulting in a discoordinated contraction pattern and a wide QRS interval on the electrocardiogram (EKG). Studies suggest that this intraventricular conduction delay is associated with increased morbidity and mortality. Prolonged QRS duration in these patients contributes to abnormal septal wall motion, reduced cardiac contractility, decreased diastolic filling time and extended mitral valve regurgitation. Biventricular pacing, or cardiac resynchronization therapy (CRT), along with optimal medical therapy, has demonstrated improved hemodynamic status in some persons with chronic heart failure.

The biventricular pacemaker provides specially timed electrical impulses to simultaneously stimulate right and left ventricles of the heart to contract. The system consists of a pulse generator that is implanted in the chest and connected to three leads that deliver the electrical impulses. One lead is placed in the right atrium, and the other two are placed in the right and left ventricles. A biventricular pacemaker may also include an automatic implantable cardioverter defibrillator (ICD), which is a device designed to monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias, to reduce the risk of sudden death.

Biventricular pacing via a wireless left ventricular (LV) endocardial pacing electrode is being evaluated for patients with congestive heart failure eligible for cardiac resynchronization therapy (CRT) who either do not respond to conventional CRT or remain untreated due to an inability or impediment to coronary sinus (CS) lead implantation.

The WiSE-CRT system (EBR Systems, Sunnyvale, California) was developed to address this at-risk patient population and provides biventricular pacing by sensing right ventricular pacing output from a previously placed conventional device

(i.e., pacemaker or defibrillator using uni- or biventricular leads) that subsequently transmits an ultrasound pulse to the wireless electrode inserted onto the left ventricle endocardium resulting in a left ventricular pacing pulse emission. The WiSE-CRT system has European CE approval and continues to be studied in clinical trials to assess its safety and efficacy in support of U.S. Food and Drug Administration (FDA) approval.

RATIONALE

AHA/ACC/HFSA 2022 Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines; They give guidelines to support the use of Cardiac Resynchronization Therapy (CRT) in patients with heart failure. The guidelines address patients with heart failure, with or without LBBB.

ACC/AHA/HRS 2018 Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay: Executive Summary. Permanent Pacing Techniques and Methods for Chronic Therapy/Management of Bradycardia Attributable to AV-Block: In patients with AV-block who have an indication for permanent pacing with LVEF between 36-50% 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 (Class IIA recommendation).

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

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

A subanalysis of the MADIT-CRT trial data (Zareba, 2011) of patients with NYHA class I/II CHF demonstrated that, compared with non-LBBB patients (those with RBBB or nonspecific intraventricular conduction disturbances), patients with LBBB QRS morphology showed significant clinical benefit from CRT-D therapy, as measured by reduced risk of heart failure event or death and risk of ventricular tachycardia/fibrillation or death. Non-LBBB patients did not benefit clinically, despite a significant reduction in left ventricular volumes. These findings formed the basis for recent FDA approval of new broadened indications for CRT in mild or asymptomatic heart failure patients with LBBB. There is still a question as to whether CRT therapy should be used in non-LBBB patients, even when advanced heart failure is present, and which non-LBBB patients might still benefit clinically from CRT. Further research investigating the rationale, mechanisms, and clinical benefit is needed to determine whether CRT therapy should be pursued in non-LBBB patients.

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

The MIRACLE ICD study was the smallest of the three studies, enrolling 186 patients with class II CHF and an indication for an ICD in an unblinded fashion. Patients were randomized to ICD/CRT-ON versus ICD/CRT-OFF and followed for

six months. There was no difference in the primary outcome of peak oxygen uptake between groups. There were also no differences reported between groups on the secondary outcomes of functional status as measured by the six-minute walk, QOL as measured by the Minnesota Living with Heart Failure Questionnaire, and New York Heart Association CHF class.

All three randomized, controlled trials reported significant improvements in echocardiographic measures of left-ventricular (LV) pump function. LV ejection fraction improved more in the CRT group in each trial, with a range of improvement of 3.0–11.0%, compared with the control group. There were also substantial improvements in LV end-systolic and end-diastolic volumes (LVESV, LVEDV) in all three trials. All reported relatively large improvements in the LVESV and the LVEDV in favor of the CRT group. Complications in these trials were not uniformly reported; however, each trial contained some information on short- and long-term complications. Short-term complication rates ranged from 4–22%, with lead dislodgement and hematoma at the access site most common. Long-term complications were reported by two of the trials, with rates of 16% and 35%. The majority of these long-term complications were lead dislodgement.

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

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

In 2019, the U.S. FDA granted Breakthrough Device Designation for the WiSE (Wireless Stimulation Endocardially) CRT System (EBR Systems, Inc) for the treatment of heart failure. The WiSE CRT System is designed to improve the heart's pumping ability by synchronizing the left and right ventricles to distribute blood to the lungs and body more effectively. The WiSE-CRT provides biventricular pacing by sensing right ventricular pacing output from a previously placed conventional device (i.e., pacemaker or defibrillator using uni- or biventricular leads) that subsequently transmits an ultrasound pulse to the wireless electrode inserted onto the left ventricle endocardium resulting in a left ventricular pacing pulse emission. The WiSE-CRT has European CE approval and continues to be studied in clinical trials to assess its safety and efficacy in support of U.S. FDA approval.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
0515T **(E/I)**	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])
0516T **(E/I)**	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only
0517T **(E/I)**	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; pulse generator component(s) (battery and/or transmitter) only
0518T **(E/I)**	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing
0519T **(E/I)**	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)
0520T **(E/I)**	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter), including placement of a new electrode
0521T **(E/I)**	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording, and disconnection per patient encounter, wireless cardiac stimulator for left ventricular pacing
0522T **(E/I)**	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, wireless cardiac stimulator for left ventricular pacing
0695T **(E/I)**	Body surface–activation mapping of pacemaker or pacing cardioverter-defibrillator lead(s) to optimize electrical synchrony, cardiac resynchronization therapy device, including connection, recording, disconnection, review, and report; at time of implant or replacement (Use 0695T in conjunction with 33224, 33225, 33226)
0696T **(E/I)**	at time of follow-up interrogation or programming device evaluation (Use 0696T in conjunction with 93281, 93284, 93286, 93287, 93288, 93289)
33202	Insertion of epicardial electrode(s); open incision (e.g., thoracotomy, median sternotomy, subxiphoid approach)
33203	Insertion of epicardial electrode(s); endoscopic approach (e.g., thoracoscopy, pericardioscopy)
33207	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular

Code	Description
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
33211	Insertion or replacement of temporary transvenous dual chamber pacing electrodes (separate procedure)
33213	Insertion of pacemaker pulse generator only; with existing dual leads
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)
93281	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead pacemaker system
93286	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system, or leadless pacemaker system
93288	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system, or leadless pacemaker system

HCPCS Codes

Code	Description
C7537	Insertion of new or replacement of permanent pacemaker with atrial transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)
C7538	Insertion of new or replacement of permanent pacemaker with ventricular transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)

Code	Description
C7539	Insertion of new or replacement of permanent pacemaker with atrial and ventricular transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)
C7540	Insertion of new or replacement of permanent pacemaker with atrial and ventricular transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)

ICD10 Codes

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

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*Key Article

KEY WORDS

Bioimpedance, Cardiac Resynchronization Therapy, Heart failure, Resynchronization

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, cardiac resynchronization therapy for heart failure is not addressed in National or Regional Medicare coverage determinations or policies.

There is currently a Local Coverage Article (LCA) and Billing and Coding: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers (A54909) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers. Please refer to the following LCA website for Medicare members: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=54909&ver=21&keyword=cardiac%20resynchronization&keywordType=all&areaId=s41&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1 accessed 07/06/23.