BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Bi-Ventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure

Policy #: 055
Category: Surgery

Latest Review Date: June 2020
Policy Grade: A

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Proprietary Information of Blue Cross and Blue Shield of Alabama
An Independent Licensee of the Blue Cross and Blue Shield Association

POLICY:

Effective for dates of service on or after June 8, 2018:

Blue Advantage will treat **Biventricular Pacemakers, with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD)** as a **covered** benefit **for the treatment of heart failure (HF)** when **ALL** of the following criteria are met:

New York Heart Association (NYHA) Class III or IV

- Left ventricular ejection fraction ≤ 35%.
- Sinus rhythm
- Patients treated with guideline-directed medical therapy*

AND

- Either QRS duration of ≥ 120 msec**-or left bundle branch block

New York Heart Association (NYHA) Class II

- Left ventricular ejection fraction ≤30%
- Sinus rhythm
- Patients treated with guideline-directed medical therapy*

AND

- Either QRS duration of ≥120msec** or left bundle branch block

Blue Advantage patients who do not meet the criteria outlined above, but have an indication for a ventricular pacemaker, biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD) will **meet** Blue Advantage's medical criteria for coverage **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
- Left ventricular ejection fraction ≤50%
- The presence of atrioventricular block with requirement for a high percentage of ventricular pacing***
- Patients treated with guideline directed medical therapy**

*Guideline-directed medical therapy for heart failure is outlined in 2013 American College of Cardiology Foundation/American Heart Association guidelines for the management of heart failure.

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

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

- 3rd degree atrioventricular block; OR

- 2nd degree atrioventricular block or a PR interval of 300ms or more when paced at 100 beats per minute.

Blue Advantage will treat **combination automatic implantable cardiac defibrillators (AICD) and biventricular pacemakers** as a covered benefit for patients who meet criteria for **BOTH** a biventricular pacemaker and an AICD. **Please see CMS National Coverage Determination (NCD) 20.4 for criteria for the ICD**.

Blue Advantage will treat **biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator,** as a **non-covered** benefit and as **investigational.**

- Treatment for patients with NYHA class I heart failure who do not meet the above criteria
- Including but not limited to the following:
  - atrial Fibrillation
  - unstable angina
  - myocardial infarction
  - prior coronary artery revascularization or angioplasty within the past 3 months

Blue Advantage will treat **intrathoracic fluid monitoring sensor as a component of a biventricular pacemaker** as a **non-covered benefit** and as **investigational.**

Blue Advantage will treat **triple-site** (triventricular) **CRT**, using an **additional pacing lead** as a **non-covered benefit** and as **investigational.**

Blue Advantage will treat **cardiac resynchronization therapy with wireless left ventricular endocardial pacing** as a **non-covered benefit** and as **investigational.**

Effective for dates of service on or after June 1, 2015 and prior to June 8, 2018:
Blue Advantage will treat **Biventricular Pacemakers** as a **covered** benefit for the treatment of heart failure (HF) when **all** of the following criteria are met:

New York Heart Association (NYHA) Class III or IV

- Left ventricular ejection fraction ≤ 35%.
- Sinus rhythm
- Patients treated with guideline-directed medical therapy*

AND

- Either QRS duration of ≥ 120 msec**-or left bundle branch block

New York Heart Association (NYHA) Class II

- Left ventricular ejection fraction ≤30%
- Sinus rhythm
- Patients treated with guideline-directed medical therapy*

AND

- Either QRS duration of ≥120msec** or left bundle branch block

Blue Advantage patients who do not meet the criteria outlined above, but have an indication for a ventricular pacemaker, biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD) will **meet** Blue Advantage's medical criteria for coverage **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
- Left ventricular ejection fraction ≤50%
- The presence of atrioventricular block with requirement for a high percentage of ventricular pacing***
- Patients treated with guideline directed medical therapy**

*Guideline-directed medical therapy for heart failure is outlined in 2013 American College of Cardiology Foundation/American Heart Association guidelines for the management of heart failure.

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

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

- 3rd degree atrioventricular block; OR
- 2nd degree atrioventricular block or a PR interval of 300ms or more when paced at 100 beats per minute.

Blue Advantage will treat **triple-site** (triventricular) **CRT**, using an **additional pacing lead** as a **non-covered benefit** and as **investigational.**

Blue Advantage will treat **combination automatic implantable cardiac defibrillators (AICD) and biventricular pacemakers** as a covered benefit for patients who meet criteria for BOTH a biventricular pacemaker and an AICD. **Please see CMS National Coverage Determination (NCD) 20.4 for criteria for the ICD**.

Blue Advantage will treat **biventricular pacemakers with or without an accompanying implantable cardiac defibrillator** as a **non-covered** benefit and as **investigational** for the following indications:

- Treatment for patients with NYHA class I heart failure who do not meet the above criteria
- Including but not limited to the following:
  - atrial Fibrillation
  - unstable angina
  - myocardial infarction

- prior coronary artery revascularization or angioplasty within the past 3 months

Blue Advantage will treat **intrathoracic fluid monitoring sensor as a component of a biventricular pacemaker** as a **non-covered benefit** and as **investigational.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

Heart Failure

It is estimated that 20%-30% of patients with heart failure (HF) have intraventricular conduction disorders resulting in a contraction pattern that is not coordinated and a wide QRS interval on the electrocardiogram (ECG). This abnormality appears to be associated with increased morbidity and mortality.

Treatment

Biventricular pacemakers using 3 leads (1 in the right atrium, 1 endocardial in the right ventricle, 1 epicardial for the left ventricle), also known as 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 1 of 2 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.

KEY POINTS:

The most recent literature review was updated through March 31, 2020.

Summary of Evidence
For individuals who have heart failure (New York Heart Association [NYHA] class III/IV) with left ventricular ejection fraction ≤ 35% who are in sinus rhythm, treated with guideline-directed medical therapy, and have either LBBB or QRS duration ≥120ms, who receive cardiac resynchronization therapy (CRT), the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. 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 use of CRT in patients with NYHA class III or IV heart failure. The RCTs have consistently reported that CRT treatment reduces mortality, improves functional status, and improves quality of life for patients with NYHA class III or IV heart failure. The evidence is sufficient to determine quantitatively 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 120 ms or more who receive CRT with or without defibrillator, the evidence includes RCTs and systematic reviews of RCTs. 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 4 RCTs assessing CRT have been published. A mortality benefit was reported in 1 of the 4 trials, the Resynchronization-Defibrillation for Ambulatory Heart Failure Trial. None of the other 3 RCTs reported a mortality difference, but a subgroup analysis of the 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 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. 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. 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. Relevant outcomes are OS, 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

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 with atrial fibrillation and heart failure who receive CRT, the evidence consists of RCTs and observational studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Data from RCTs have reported conflicting results, with 1 reporting improvements for patients with atrial fibrillation (AF) and others reporting no significant improvements. Results from observational studies are also conflicting. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure and atrioventricular (AV) nodal block who receive CRT, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. One large RCT demonstrated that CRT led to improvements in heart failure-related hospitalizations and urgent care visits among patients with heart failure and AV 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 1 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 who receive triple-site CRT, the evidence includes small RCTs and a meta-analysis that included nonrandomized studies. 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 1 measure of functional status or quality of life with triple-site CRT compared to conventional CRT. However, the trials are small and have methodologic limitations. In addition, outcomes reported differed across studies. Triple-site CRT was also associated with higher radiation exposure and a greater number of additional procedures postimplantation. Larger, high-quality RCTs are needed to better define the benefit-risk ratio for triple-site CRT compared to 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 3 RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Three small 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.

Practice Guidelines and Position Statements

American College of Cardiology, American Heart Association, and Heart Rhythm Society
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:

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 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)."	IIa	B-R

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

In 2013, the American College of Cardiology (ACC) Foundation and American Heart Association (AHA) Task Force on Practice Guidelines published guidelines for the management of heart failure. These guidelines make recommendations regarding cardiac resynchronization therapy (CRT) for heart failure (HF) that are in line with those made by the ACC/AHA and Heart Rhythm Society related to CRT for HF outlined below.

A focused update to 2008 guidelines for device-based treatment of cardiac rhythm abnormalities were published jointly by ACC/AHA/HRS in 2012. These guidelines included the following recommendations on CRT for heart failure:

Class I recommendations:

- 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 (GDMT). (Level of Evidence: A for NYHA Class III/IV; Level of Evidence: B for NYHA Class II)

Class IIa recommendations:

- 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. (Level of Evidence: 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. (Level of Evidence: 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. (Level of Evidence: B)
- 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 anticipated requirement for significant (>40%) ventricular pacing. (Level of Evidence: C)

Class IIb recommendations:

- 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. (Level of Evidence: 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. (Level of Evidence: 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. (Level of Evidence: B)

Class III recommendations (no benefit)

- CRT is not recommended for patients with NYHA Class I or II symptoms and non-LBBB pattern with QRS duration less than 150 ms. (Level of Evidence: B)
- CRT is not indicated for patients whose comorbidities and/or frailty limit survival with good functional capacity to less than one year. (Level of Evidence: C)

Heart Failure Society of America

The Heart Failure Society of America released comprehensive guidelines on the management of heart failure in 2010. The guidelines include the following recommendations related to the use of CRT:

- Biventricular pacing therapy is recommended for patients in sinus rhythm with a widened QRS interval (≥120 ms) and severe LV systolic dysfunction (LVEF ≤ 35%) who have persistent, moderate to severe HF (NYHA III) despite optimal medical therapy. (Level of Evidence: 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 ≤35% who have persistent, moderate to severe HF (NYHA III) despite optimal medical therapy. (Level of Evidence: B).
- Selected ambulatory NYHA IV patients in sinus rhythm with QRS ≥120 ms and LV systolic dysfunction may be considered for biventricular pacing therapy. (Level of Evidence: B).

- Biventricular pacing therapy may be considered in patients with reduced LVEF and QRS ≥ 150 ms who have NYHA I or II HF symptoms. (Level of Evidence: B).
- In patients with reduced LVEF who require chronic pacing and in whom frequent ventricular pacing is expected, biventricular pacing may be considered. (Level of Evidence: C).

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence's 2014 guidance provided recommendations on cardiac resynchronization therapy for heart failure. The recommendations for patients with LVEF≤35% are as follows:

- 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

U.S. Preventive Services Task Force Recommendations
Not applicable

KEY WORDS:
InSync®, Biventricular Pacemaker, biventricular pacing, congestive heart failure (CHF), pacemaker, cardiac resynchronization, CRT, cardiac resynchronization therapy, Viva™ Quad XT, Viva Quad S, Attain Performa®, Dynagen, Inogen, OptiVol™, Triple site CRT, Triventricular Pacemaker, intrathoracic fluid monitoring sensor; WiSE-CRT, EBR Systems

APPROVED BY GOVERNING BODIES:
There are numerous CRT devices, combined implantable cardiac defibrillator (ICD) plus CRT devices (CRT-D), and combined CRT plus fluid monitoring devices. Some of the devices are discussed here. For example, in 2001, a stand-alone biventricular pacemaker (InSync® Biventricular Pacing System, Medtronic) received approval by U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) 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. Both Guidant (CONTAK CD® CRT-D System) and Medtronic (InSync® ICD Model 7272) have received FDA approval through the PMA process for combined cardiac resynchronization therapy defibrillators for patients at high risk of sudden

cardiac death due to ventricular arrhythmias and who have NYHA Class III or IV heart failure with LVEF of 35% or less, QRS duration 130 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 through the FDA for its combined ICD/CRT 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/CRT devices (Ilesto/Iforia series).

In September 2010, FDA expanded the indications for some CRT devices to include patients with Class I and II heart failure. Based on data from the MADIT-CRT study, indications for three Guidant (Boston Scientific) CRT-defibrillator devices (Cognis®, Livian®, and Contak Renewal devices) were expanded to include patients with heart failure who receive stable optimal pharmacologic therapy for heart failure and who meet any one of the following classifications:

- Moderate-to-severe heart failure (NYHA class III-IV) with ejection fraction less than 35% and QRS duration greater than 120ms.
- Left bundle branch block with QRS greater than or equal to 130ms, 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, FDA further expanded the indications for multiple Medtronic CRT devices to include patients with NYHA functional class I, II, or III heart failure, who have LVEF of 50% or less on stable, optimal heart failure medical therapy, if indicated, and have AV 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 BLOCK-HF study, a Medtronic-sponsored RCT to evaluate the use of CRT in patients with NYHA class I, II, or III heart failure, LVF ≤50%, and AV block.

Several CRT devices incorporate a fourth lead, providing quadripolar pacing. The Medtronic VIVA™ Quad XT and the Viva Quad S incorporate a fourth lead, the Medtroinc Attain Performa® left ventricular lead, which received clearance for marketing from FDA in August 2014. The Dynagen™ X4 and Inogen™ X4 devices incorporate a fourth lead. Other CRT devices with quadripolar leads have been approved for use outside of the United States (e.g. St. Jude Quartet™ left ventricular lead.

Multiple devices manufactured by Medtronic combine a CRT with the OpitVol™ monitoring system. For example, in 2005, the InSync Sentry® system received FDA approval through the supplemental premarket approval (PMA) process. This combined biventricular pacemaker/ICD is also equipped to monitor intrathoracic fluid levels using bioimpedance technology, referred to as OptiVol™ Fluid Status Monitoring. Bioimpedance measures, defined as the electrical resistance of tissue to flow of current, are performed many times per day using a vector from the right ventricular coil on the lead in the right side of the heart to the implanted pacemaker devices; changes in bioimpedance reflect intrathoracic fluid status and are evaluated based on a computer algorithm. For example, changes in a patient's daily average of intrathoracic bioimpedance can be monitored; differences in the daily average compared with a baseline are reported as the OptiVol Fluid Index. It has been proposed that these data may be used as an early warning system of cardiac decompensation or to provide additional feedback enabling a

physician to further tailor medical therapy. (See medical policy #441 – *Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting* for stand alone devices)

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.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

0515T	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]) **(Effective 01/01/2019)**
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only **(Effective 01/01/2019)**
0517T	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 **(Effective 01/01/2019)**
0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing **(Effective 01/01/2019)**
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter) **(Effective 01/01/2019)**
0520T	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 **(Effective 01/01/2019)**
0521T	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 **(Effective 01/01/2019)**
0522T	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 **(Effective 01/01/2019)**
33207	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular
33208	Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
33213	Insertion of pacemaker pulse generator only; with existing dual leads
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
33221	Insertion of pacemaker pulse generator only; with existing multiple leads
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-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 (i.e., 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)
33228	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system
33229	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; multiple lead system
33233	Removal of permanent pacemaker pulse generator only

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005
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Medical Policy Group, August 2006
Medical Policy Group, August 2009
Available for comment July 17-August 31, 2009
Medical Policy Group, October 2009
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Medical Policy Group, April 2011
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Medical Policy Group, November 2011
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Medical Policy Group, April 2013
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Medical Policy Group, April 2014
Medical Policy Group, December 2014
Medical Policy Group, June 2015
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Medical Policy Group, June 2016
Medical Policy Group, December 2016
Medical Policy Group, June 2017
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Medical Policy Group, December 2018, 2019 CPT Coding Update
Medical Policy Group, June 2019
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This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.