Local Coverage Determination (LCD) for Biventricular Pacing/ Cardiac Resynchronization Therapy (L32813)

Contractor Name
First Coast Service Options, Inc.

Document Information

LCD ID Number
L32813

LCD Title
Biventricular Pacing/ Cardiac Resynchronization Therapy

Contractor's Determination Number
A33224

Oversight Region
Region IV

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Original Determination Effective Date
For services performed on or after 10/09/2012

Original Determination Ending Date

Revision Effective Date
For services performed on or after 10/09/2012

Revision Ending Date
American Dental Association.

**CMS National Coverage Policy**
Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

CMS Online Manual System, Pub 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Sections 20.4 (NCD for Implantable Automatic Defibrillator) and 20.8 (NCD for Cardiac Pacemakers).

CMS Online Manual System, Pub 100-04, Medicare Claims Processing Manual, Chapter 4 – Part B Hospital (Including Inpatient Hospital Part B and OPPS), section 10.2.2 – Cardiac Resynchronization Therapy.

CMS Online Manual System, Pub 100-08, Medicare Program Integrity Manual, Chapter 6 – Intermediary MR Guidelines for Specific Services, section 6.5.2.


**Indications and Limitations of Coverage and/or Medical Necessity**
Heart failure is common and rapidly increasing in incidence. It carries a poor prognosis, with an estimated 1-year mortality of 30–50% for patients with advanced disease. It is also associated with a high burden of illness, high resource utilization, and frequent hospitalizations. The current treatment for heart failure involves addressing the underlying cause(s), lifestyle modifications, and pharmacologic interventions. In the majority of cases, treatment is not curative but intended to ameliorate symptoms and improve function. Approximately 20–30% of patients with heart failure exhibit dyssynchronous contractions of the left and right ventricles due to conduction system disease. Dyssynchrony further depresses the already impaired pumping ability of the heart. The New York Heart Association (NYHA) classes for heart failure are defined as follows:

Class I:

Individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion.

Class II:

Individuals with cardiac disease resulting in a slight limitation of physical activity; they are comfortable at rest; ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
Class III:

Individuals with cardiac disease resulting in a marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.

Class IV:

Individuals with cardiac disease resulting in the inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Despite the combination of various therapies for heart failure, some patients remain refractory to full medical treatment. Of the various nonpharmacological approaches, biventricular pacing or Cardiac Resynchronization Therapy (CRT) [also called Cardiac Resynchronization Therapy Pacemaker (CRT-P)] has gained interest since its introduction in the early 1990’s. CRT is the term applied to reestablishing synchronous contraction between the left ventricular free wall and the ventricular septum in an attempt to improve left ventricular efficiency and, subsequently, to improve functional class. Generally, CRT has been used to describe biventricular pacing, but cardiac resynchronization can be achieved by left ventricular pacing only in some patients. Selected patients with moderate to severe heart failure may benefit from CRT or biventricular pacing. CRT, in combination with stable optimal medical therapy, may help the lower chambers of the heart beat together and improve the heart's ability to supply blood and oxygen to the body. CRT is designed to help the right (RV) and left ventricle (LV) beat at the same time in a normal sequence treating ventricular dyssynchrony.

An implantable biventricular pacemaker is an advanced version of a standardized implantable pacemaker. The biventricular pacemaker is implanted in the muscle tissue of the chest, below the collarbone, or in the abdomen. Three leads or wires, one atrial lead [right atrium] and two ventricular leads [right and left ventricles], are transvenously connected from the pacemaker to both sides of the heart. Once the pacemaker is implanted, it is programmed so that both ventricles are stimulated to contract after atrial contraction with the goal of improving left ventricle function, reducing presystolic mitral regurgitation, and improving LV diastolic filling time. The most frequently reported complication of CRT is lead dislodgement, which occurs in approximately 9% of patients.

Some individuals with heart failure are also at high risk for life-threatening heart rhythms. Patients with heart failure who are at high risk for ventricular tachycardia and ventricular fibrillation may require a CRT system that includes implantable cardioverter defibrillator (ICD) therapy. The CRT-P (biventricular pacemaker) plus implantable cardioverter defibrillator (ICD) system [CRT-D] is designed to help the two lower heart chambers, the right and left ventricles, beat at the same time in a normal sequence, treating ventricular dyssynchrony. Additionally, should an individual experience an episode of ventricular tachycardia or ventricular fibrillation, the CRT-D system will detect the life-threatening arrhythmia and automatically correct the heart's rhythm.

Medicare will consider cardiac resynchronization therapy, biventricular pacing (CRT-P), medically necessary when the following criteria are met (1 or 2):

1. 
Medicare will consider cardiac resynchronization therapy with implantable cardioverter defibrillator (ICD) system (CRT-D) medically necessary for patients at high risk for life-threatening ventricular arrhythmia or sudden cardiac arrest when the following criteria are met:

- the aforementioned criteria for CRT-P are met (1 or 2);
- the patient meets a covered indication in CMS’s National Coverage Determination Manual for Implantable automatic defibrillators (NCD 20.4). (Refer to the Medicare Coverage Database at http://www.cms.gov/medicare-coverage-database/); and
- the device is FDA approved for the indication.

Bill Type Codes:
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

011x Hospital Inpatient (Including Medicare Part A)
012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
085x Critical Access Hospital

Revenue Codes:
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject
to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

0360  Operating Room Services - General Classification
0480  Cardiology - General Classification
0960  Professional Fees - General Classification
0975  Professional Fees - Operating Room

CPT/HCPCS Codes
Note: Biventricular pacemaker insertion involves the placement of electrodes into both the right atrium and right ventricle, as well as a third transvenous lead into the external wall of the LV. It is technically more demanding than the insertion of a conventional pacemaker and may require echocardiography or coronary venogram to determine proper placement of the electrodes. Placement of a biventricular pacemaker can be accomplished in an outpatient setting under sedation or general anesthesia. Sometimes, it may not be possible to place the left ventricular lead transvenously (generally performed in an EP lab or cardiac cath lab). In these situations, an epicardial (open) approach by thoracotomy is performed, if the transvenous approach is unsuccessful. A short inpatient stay may be required for epicardial left ventricular lead placement.

For inpatient hospital only, the following ICD-9-CM PROCEDURE CODES should be used:

00.50 Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system (CRT-P)
00.51 Implantation of cardiac resynchronization defibrillator, total system (CRT-D)
00.52 Implantation or replacement of transvenous lead [electrode] into left ventricular coronary venous system
00.53 Implantation or replacement of cardiac resynchronization pacemaker pulse generator only (CRT-P)
00.54 Implantation or replacement of cardiac resynchronization defibrillator pulse generator device only (CRT-D)
37.74 Insertion or replacement of epicardial lead [electrode] into epicardium

Part B of A services

33202  INSERTION OF EPICARDIAL ELECTRODE(S); OPEN INCISION (EG, THORACOTOMY, MEDIAN STERNOTOMY, SUBXIPHOID APPROACH)
33203  INSERTION OF EPICARDIAL ELECTRODE(S); ENDOSCOPIC APPROACH (EG, THORACOSCOPY, PERICARDIOSCOPY)
33206  INSERTION OF NEW OR REPLACEMENT OF PERMANENT PACEMAKER WITH TRANSVENOUS ELECTRODE(S); ATRIAL
33207  INSERTION OF NEW OR REPLACEMENT OF PERMANENT PACEMAKER WITH TRANSVENOUS ELECTRODE(S); VENTRICULAR
33208  INSERTION OF NEW OR REPLACEMENT OF PERMANENT PACEMAKER WITH TRANSVENOUS ELECTRODE(S); ATRIAL
AND VENTRICULAR

33212 INSERTION OF PACEMAKER PULSE GENERATOR ONLY; WITH EXISTING SINGLE LEAD

33213 INSERTION OF PACEMAKER PULSE GENERATOR ONLY; WITH EXISTING DUAL LEADS

UPGRADE OF IMPLANTED PACEMAKER SYSTEM, CONVERSION OF SINGLE CHAMBER SYSTEM TO DUAL CHAMBER SYSTEM (INCLUDES REMOVAL OF PREVIOUSLY PLACED PULSE GENERATOR, TESTING OF EXISTING LEAD, INSERTION OF NEW LEAD, INSERTION OF NEW PULSE GENERATOR)

33214 INSERTION OF 2 TRANSVENOUS ELECTRODES, PERMANENT PACEMAKER OR CARDIOVERTER-DEFIBRILLATOR (INCLUDING REVISION OF POCKET, REMOVAL, INSERTION, AND/OR REPLACEMENT OF EXISTING GENERATOR)

33217 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)

33221 INSERTION OF PACING ELECTRODE, CARDIAC VENOUS SYSTEM, FOR LEFT VENTRICULAR PACING, AT TIME OF INSERTION OF PACING CARDIOVERTER-DEFIBRILLATOR OR PACEMAKER PULSE GENERATOR (EG, FOR UPGRADE TO DUAL CHAMBER SYSTEM) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

33224 REPOSITIONING OF PREVIOUSLY IMPLANTED CARDIAC VENOUS SYSTEM (LEFT VENTRICULAR) ELECTRODE (INCLUDING REMOVAL, INSERTION AND/OR REPLACEMENT OF EXISTING GENERATOR)

33225 INSERTION OF PACING CARDIOVERTER-DEFIBRILLATOR PULSE GENERATOR ONLY; WITH EXISTING DUAL LEADS

33226 INSERTION OF PACING CARDIOVERTER-DEFIBRILLATOR PULSE GENERATOR ONLY; WITH EXISTING MULTIPLE LEADS

33230 INSERTION OF PACING CARDIOVERTER-DEFIBRILLATOR PULSE GENERATOR ONLY; WITH EXISTING SINGLE LEAD

33231 CARDIOVERTER-DEFIBRILLATOR SYSTEM WITH TRANSVENOUS LEAD(S), SINGLE OR DUAL CHAMBER
For CPT codes 33224 and 33225:

398.91  RHEUMATIC HEART FAILURE (CONGESTIVE)
402.01  MALIGNANT HYPERTENSIVE HEART DISEASE WITH HEART FAILURE
402.11  BENIGN HYPERTENSIVE HEART DISEASE WITH HEART FAILURE
402.91  UNSPECIFIED HYPERTENSIVE HEART DISEASE WITH HEART FAILURE

404.01  HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, MALIGNANT, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
404.03  HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.11  HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, BENIGN, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
404.13  HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, BENIGN, WITH HEART FAILURE AND CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.91  HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
404.93  HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH HEART FAILURE AND CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE

428.0  CONGESTIVE HEART FAILURE UNSPECIFIED
428.1  LEFT HEART FAILURE
428.20 - UNSPECIFIED SYSTOLIC HEART FAILURE - ACUTE ON CHRONIC
428.23  SYSTOLIC HEART FAILURE
428.30 - UNSPECIFIED DIASTOLIC HEART FAILURE - ACUTE ON CHRONIC
428.33  DIASTOLIC HEART FAILURE
428.40 - UNSPECIFIED COMBINED SYSTOLIC AND DIASTOLIC HEART FAILURE - ACUTE ON CHRONIC
428.43  COMBINED SYSTOLIC AND DIASTOLIC HEART FAILURE
428.9  HEART FAILURE UNSPECIFIED

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

XX000  Not Applicable

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation
Diagnoses that DO NOT Support Medical Necessity
N/A

Documentations Requirements
The medical record must contain documentation that fully supports the medical necessity and justification of the procedure performed. The documentation must be made available to Medicare upon request. When the documentation does not meet the criteria for the service(s) rendered or the documentation does not establish the medical necessity for the service(s), such service(s) will be denied as not reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act.

A history and physical, discharge summary, physician progress notes and an operative report are typically in the hospital record for the procedures in this local coverage determination (LCD). Other relevant information addressing coverage criteria related to the patient’s episode of care prior to the hospitalization, should be included in the hospital record.

Providers must be able to justify the medical necessity of devices other than single lead devices. This justification should follow standard guidelines for the appropriate use of biventricular pacing and must be available in the patient's medical record.

Medical record documentation maintained by the physician must substantiate the medical need for CRT and must include the following:

- Office notes/hospital record, including history and physical by the attending/treating physician. [Myocardial Infarctions (MIs) must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction (as applicable)]
- Documentation of the history and duration of unsuccessful medical management
- Interpretation and reports for diagnostic studies (as applicable).[Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography]
- Complete operative report outlining operative approach used and all the components of the biventricular pacemaker insertion

Any major procedure has significant benefit and risk (injury or death) that the treating physician discusses with the patient. To meet Medicare’s reasonable and necessary (R&N) threshold for coverage of a procedure, the physician’s documentation for the case should clearly support both the diagnostic criteria for the indication (standard test results and/or clinical findings as applicable) and the medical need (the procedure does not exceed the medical need and is at least as beneficial as existing alternatives, and the procedure is furnished with accepted standards of medical practice in a setting appropriate for the patient’s medical needs and condition). **Lacking compelling arguments for an exception in the supporting documentation, the hospital and physician services can be denied.** If in certain circumstances the patient does not meet all of the required criteria outlined in the LCD for a procedure, but the treating physician feels that the procedure is a covered procedure given the current standards of care, then the documentation must clearly outline the patient’s episode of care that supports the procedure and must clearly address the reason(s) for coverage. For example, if clinical findings (or lack of) for an indication are not consistent with the LCD criteria, it should be directly addressed in the pre-procedure documentation. Also, if certain conservative therapies are not necessary for a given patient, it should be directly noted in the pre-procedure documentation. The clinical judgment of the treating physician is always a
consideration if clearly addressed in the pre-procedure record and if consistent with the episode of care for the patient as documented in patient’s records and claims history.

CMS Online Manual, Pub. 100-08, Chapter 6, Section 6.5.2 states the following regarding the review of claims for procedures with DRG’s:

*Review of the medical record must indicate that inpatient hospital care was medically necessary, reasonable, and appropriate for the diagnosis and condition of the beneficiary at any time during the stay. The beneficiary must demonstrate signs and/or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis.*

**Appendices**

**Utilization Guidelines**

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

**Sources of Information and Basis for Decision**

American Heart Association: Classes of Heart Failure, updated August, 2011. Retrieved from http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article.jsp

Aetna Clinical Policy Bulletin: Biventricular Pacing (Cardiac Resynchronization Therapy)/Combination Resynchronization-Defibrillation Devices for Congestive Heart Failure, number 0610.


Burkhardt JD, MD and Wilkoff BL, MD. Circulation AHA Journals: Interventional Electrophysiology and Cardiac Resynchronization Therapy Delivering Electrical Therapies for Heart Failure, 2007. Retrieved from http://circ.ahajournals.org/content/115/16/2208.full

Cigna Medical Coverage Policy: Biventricular Pacing/Cardiac Resynchronization Therapy (CRT), number 0174.


InterQual® 2012 Procedures Adult Criteria, Pacemaker Insertion, Biventricular +/- ICD Insertion. McKesson Corporation.


Advisory Committee Meeting Notes
This Local Coverage Determination (LCD) does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this LCD was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period
06/07/2012

End Date of Comment Period
07/21/2012

Start Date of Notice Period
08/24/2012

Revision History Number
Original

Revision History Explanation
Revision Number: Original
Start Date of Comment Period: 06/07/2012
Start Date of Notice Period: 08/24/2012
Original Effective Date: 10/09/2012

LCR A2012-053
August 2012 Connection

11/25/2012 - For the following CPT/HCPCS codes either the short description and/or the long description was changed. Depending on which description is used in this LCD, there may not be any change in how the code displays in the document:
33225 descriptor was changed in Group 1
A33224: Medicare Part A local coverage determination (LCD)

**Reason for Change**
This LCD has no Related Documents.

**Related Documents**

**LCD Attachments**
comment summary 06/07/12-07/21/12  (a comment and response document)

Updated on 11/25/2012 with effective dates 10/09/2012 - N/A
Updated on 08/16/2012 with effective dates 10/09/2012 - N/A
Updated on 08/15/2012 with effective dates 10/09/2012 - N/A
Read the [LCD Disclaimer](#)

**A33224: Medicare Part A local coverage determination (LCD)**

**Comment summary**

**LCD Number**
L32813

**Contractor Name**
First Coast Service Options, Inc.

**Contractor Number**
09101 - Florida
09201 - Puerto Rico/Virgin Islands

**Contractor Type**
MAC Part A

**LCD Title**
Biventricular Pacing/ Cardiac Resynchronization Therapy

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**Start Date of Comment Period:**
06/07/2012

**End Date of Comment Period:**
07/21/2012

**Comments received:**

**Comment #1:** A comment was received regarding criteria 1 of the “Indications and Limitations of Coverage and/or Medical Necessity” section to include patients who have “frequent dependence on ventricular pacing” based on the ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities, Class IIa recommendation for CRT with or without implantable cardiac defibrillator (ICD). These guidelines are already referenced in the “Sources of Information and Basis for Decision” section of the draft LCD.

**Contractor response:**

In reference to the 2009 Focused Update Incorporated Into the ACC/AHA 2005 Guidelines, for patients with LVEF less than or equal to 35% with New York Heart Association (NYHA) functional Class III or ambulatory Class IV symptoms who are receiving optimal recommended medical therapy and who have frequent dependence on ventricular pacing, CRT is reasonable. (Class of recommendation IIa, Level of Evidence: C) (Hunt, 2005)

[http://circ.ahajournals.org/content/119/14/e391.full.pdf](http://circ.ahajournals.org/content/119/14/e391.full.pdf)
The final LCD will be revised to include patients who have “frequent dependence on ventricular pacing.”

Rating Scheme for the Strength of the Recommendations:

<table>
<thead>
<tr>
<th>Classes of Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class I:</strong> Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.</td>
</tr>
<tr>
<td><strong>Class II:</strong> Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.</td>
</tr>
<tr>
<td><strong>Class IIa:</strong> Weight of evidence/opinion is in favour of usefulness/efficacy.</td>
</tr>
<tr>
<td><strong>Class IIb:</strong> Usefulness/efficacy is less well established by evidence/opinion.</td>
</tr>
<tr>
<td><strong>Class III:</strong> Evidence or general agreement that the given treatment or procedure is not useful/effective and in some cases may be harmful.</td>
</tr>
</tbody>
</table>

Levels of Evidence-

| Level A: Data derived from multiple randomized clinical trials or meta-analyses. |
| Level B: Data derived from a single randomized clinical trial or large non-randomized studies. |
| Level C: Consensus of opinion of the experts and/or small studies, retrospective studies, registries. |

http://www.guidelines.gov/content.aspx?id=15949&search=cardiac+resynchronization+therapy

Comment #2: A comment was received regarding criteria 2 of the “Indications and Limitations of Coverage and/or Medical Necessity” section to include NYHA Class I ischemic patients to reflect the findings of the 2009 Multicenter Automatic Defibrillator Implantation with Cardiac Resynchronization Therapy (MADIT-CRT) which broadened the patient population that received benefit from CRT to patients with ejection fraction (EF) of ≤ 0.30, QRS ≥ 130ms, and NYHA Class I or II for ischemic patients and NYHA Class II for non-ischemic patients.

Contractor response:

Follow-up of patients in the MADIT-CRT trial averaged 2.4 years. Additional clinical trials with long term outcome data are needed to demonstrate the medical necessity of CRT for patients with NYHA class I heart failure. This recommendation will not be incorporated to the LCD.

Comment #3: A comment was received for the “Indications and Limitations of Coverage and/or Medical Necessity” section, regarding criteria 2 for patients with NYHA classification of heart failure II:

There is disagreement with the exclusion of patients with atrial arrhythmias as CRT is frequently used on patients with atrial fibrillation (AF), especially those in whom atrio-ventricular (AV) node ablation has been or is planning to be performed. It was conceded that data on CRT in patients with AF and heart failure are limited. However, observational studies and a small randomized crossover trial suggest a benefit from CRT in AF patients. A meta-analysis of observational data from five studies (four prospective cohort studies and the MUSTIC randomized trial4) compared responses to CRT in 797 patients in sinus rhythm and 387 patients in AF. The overall use of AV node ablation was 56 percent. The NYHA functional class improved similarly for both groups. In addition, patients may have AF but a plan to later restore sinus rhythm AFTER implantation of a device. These patients would be denied the opportunity to benefit from CRT. It was requested that patients with paroxysmal or persistent atrial fibrillation be covered for CRT based on the studies cited above.

Contractor response:

Based on published literature of a meta-analysis of prospective cohort studies comparing the impact of CRT for patients with NYHA classification of heart failure II in AF and SR, the quality of the studies is limited. Current guidelines regarding the use of CRT in patients with AF have been cautious, suggesting lack of evidence to support
CRT in those with NYHA classification of heart failure II and AF. CRT may have clinical benefit for the LCD covered indication of patients with NYHA classification of heart failure III or IV and chronic atrial fibrillation (AF), but its use in patients with NYHA classification of heart failure II with AF warrants further investigation with randomized controlled trials.

**Comment #4:** A request was made that coverage be expanded to include patients that meet all criteria for indication 1 and 2 in the draft LCD and in whom one “anticipates frequent ventricular pacing”. The ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities lists a Class IIb recommendation that CRT may be considered for patients with LVEF≤35 percent with NYHA functional class I or II symptoms who are receiving optimal recommended medical therapy and who are undergoing implantation of a permanent pacemaker and/or ICD with anticipated frequent ventricular pacing. The Pacing to Avoid Cardiac Enlargement (PACE) study supports forced single ventricular pacing can cause progression of heart failure including a decrease in LVEF. It was requested that all Class I, Class IIa and Class IIb recommendations from the ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities be included in the LCD.

**Contractor response:** This contractor has already incorporated covered indications that concur with the recommendations from the ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities that have a Rating Scheme for the Strength of the Recommendations of Class I and Class IIa. Regarding the Class IIb recommendation that CRT may be considered for patients with LVEF≤35 percent with NYHA functional class I or II symptoms who are receiving optimal recommended medical therapy and who are undergoing implantation of a permanent pacemaker and/or ICD with anticipated frequent ventricular pacing, this recommendation will not be included at this time because long term studies on larger populations of patients are needed to demonstrate the medical necessity of this indication.

**Comment #5:** There are many CPT codes listed in the draft LCD under “Part B of A services” that apply to services other than biventricular pacing/cardiac resynchronization therapy. There are only two codes specific to biventricular pacing/CRT, 33224 [Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previous placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)], and 33225, [Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system and pocket revision) (list separately in addition to code for primary procedure)]. Since the draft LCD applies to patients receiving initial CRT, or patients who are being upgraded to biventricular pacing, CPT codes 33224 and 33225 are the only CPT codes needed in the LCD. There are two additional codes that report generator replacement with existing multiple leads, 33221 and 33231, but it is contended that if the patient has already been receiving CRT, then the LCD does not apply for a generator replacement.

**Contractor response:**

The draft LCD lists some of the possible procedure code or code combinations that could describe the whole episode of care related to CRT but is not an all-inclusive list. The indications and limitations of this LCD are applicable to the entire CRT episode of care, including the generator replacement. The section of the LCD titled “ICD-9 Codes that Support Medical Necessity” lists all the diagnoses that support medical necessity of CPT codes 33224 and 33225, which are procedure codes specific for biventricular pacing/CRT.

**Comment #6:**

With regards to the phrase “Sinus Rhythm or Chronic Atrial Fibrillation (AF)”, would it be possible to further clarify the definition of Chronic Atrial Fibrillation? Is this meant to exclude from coverage patients with other forms of Atrial Fibrillation? Is the definition of Chronic Atrial Fibrillation, any person that has an ICD-9 Diagnosis Code of 427.31 (Atrial Fibrillation) or 427.32 (Atrial Flutter)? Moving forward to ICD-10, will the definition refer to any person with I48.0 (Atrial Fibrillation) or I48.1 (Atrial Flutter)?

a. Please note that in the latest update to the ACC/AHA Guidelines for the treatment of Atrial Fibrillation, the term appears ill-defined, while in the recently published ESC Guidelines it appears to be completely retired.

b. Please also note that specifically for NYHA Class III/IV patients, one randomized study supporting the recommendation for biventricular pacing for heart failure patients with coexistent AF has been published since the 2006 ACC/AHA AF guidelines; we are not aware of other randomized studies in this population. The primary composite endpoint of death from heart failure, hospitalization due to heart failure, or worsening of heart failure occurred in 26% of the right ventricular paced group and was reduced by 63% with biventricular pacing (p =0.005) over a median of 20 months follow-up. The beneficial effects were consistent between the subset of 46 patients who had typical CRT indications (LVEF of 35%, QRS duration of 120 ms, NYHA Class III or IV), and those who did not.
c. Please note that the current HFSA 2010 Chronic Heart Failure Guidelines provide a Class IIa recommendation for CRT for heart failure patients with LVEF of 35%, NYHA functional class III or ambulatory class IV symptoms, and QRS duration of 120 ms.

d. While CRT is not currently indicated as a treatment specifically for AF, it could certainly be playing an important supplementary role to an AF rhythm control strategy in patients receiving CRT for their heart failure. Please note that Hauck and colleagues reported that 17 of 46 heart failure patients with persistent AF and indications for CRT spontaneously converted to sinus rhythm 3 to 31 months after implantation of a CRT system. Similarly, a separate prospective observational study that included 96 CRT indicated patients with chronic AF, 25% of the patients converted to sinus rhythm after 1 year.

e. Finally, the mechanism by which CRT is delivered in patients in Sinus Rhythm (SR) vs. patients in AF is different: in Sinus Rhythm, therapy is achieved through atrial synchronized biventricular pacing, while for those in paroxysmal or persistent AF not controlled pharmacologically, the therapy is often achieved through biventricular pacing.

Contractor response:

Atrial fibrillation is not part of the ICD-9 CM diagnosis codes that supports medical necessity for CRT. Chronic atrial fibrillation, defined as AF that is not of new onset or of initial detection that may be paroxysmal, persistent, longstanding persistent, or permanent, is considered one of the allowable criteria of coverage for patients who have New York Heart Association (NYHA) classification of heart failure III or IV. The primary diagnosis for CRT is heart failure.

Comment #7: In reference to criteria 2 of the “Indications and Limitations of Coverage and/or Medical Necessity” section, would it also be possible to better define the phrase “No Evidence of Atrial Arrhythmia.” The phrase as it stands now creates two separate areas of debate: (1) the temporal nature of the arrhythmia (i.e. is the presence of history of an “Atrial Arrhythmia” and absence of the same arrhythmia at time of implant grounds for non-coverage?) and (2) the actual types of atrial arrhythmias (i.e. atrial fibrillation in its various forms; atrial flutter and/or other atrial tachycardia and arrhythmias). It was requested that specific diagnostic codes be provided. Patients who otherwise fulfill the remainder coverage criteria and with a history of such arrhythmias but who are restored to Sinus Rhythm at time of implant should be covered for CRT under this policy; the same for patients with permanent AF at the time of implant.

a. Note that out of the two randomized controlled trials (MADIT-CRT and RAFT), none specifically excluded NYHA Class II patients who also suffer from all the types of Atrial Fibrillation. MADIT-CRT allowed patients with non-Chronic AF which were in SR at time of enrollment while RAFT was the only large randomized study to allow implants in patients who at that time were in AF.

b. In RAFT, AF patients were required to be rate controlled with a heart rate of ≤60 beats per minute at rest and ≤90 beats per minute during a 6 minute hall walk or a planned AVN ablation after implant to be considered for inclusion (standards articulated in the Fuster 2011 Focused AF Guideline Update). For all patients, CRT-D reduced the risk of all-cause mortality or hospitalization by 25%. Furthermore, the presence of permanent AF at baseline did not influence the favorable treatment effect of CRT (p-interaction = 0.14).

c. It is true that, within the stratum of permanent AF patients, no difference in the primary outcome of death or heart failure hospitalization between those assigned to CRT-D or ICD was demonstrated. Nevertheless, RAFT was not powered to draw conclusions on subsets of the population.

Contractor response:

Regarding ICD-9 CM diagnosis codes, please make reference to answer #6. Regarding the phrase “No Evidence of Atrial Arrhythmia,” it means that patients with NYHA Class II heart failure should not have evidence of any atrial arrhythmia at the time of CRT placement.

Comment #8: With regards to CRT-D coverage, the LCD states: “Medicare will consider cardiac resynchronization therapy with implantable cardioverter defibrillator (ICD) system (CRT-D) medically necessary for patients at high risk for life-threatening ventricular arrhythmia or sudden cardiac arrest when the following criteria are met:

• The aforementioned criteria for CRT-P are met (1 or 2); and
• The patient meets a covered indication in CMS’s National Coverage Determination Manual for implantable automatic defibrillators (NCD 20.4)."

A request was made to confirm that a patient with Atrial Fibrillation is covered for a CRT-D implant as long as they meet all of the stated FSCO criteria as well as NCD 20.4?
Contractor response: Refer to contractor response to comment #6 above.

Comment #9: With regards to CPT® and HCPCS Codes, the guidance states that “For inpatient hospital only, the following ICD-9-CM Procedure codes should be used: 00.50, 00.51, 00.52, 00.53, 00.54.” However, the draft policy stated the following: “Sometimes, it may not be possible to place the left ventricular lead transvenously (generally performed in an EP lab or cardiac cath lab). In these situations, an epicardial (open) approach by thoracotomy is performed, if the transvenous approach is unsuccessful. A short inpatient stay may be required for epicardial left ventricular lead placement.” The ICD-9-CM Procedure codes listed above did not include epicardial lead placement. Should the epicardial lead placement code (37.74: Insertion or replacement of epicardial lead [electrode] into epicardium) be added?

Contractor response: The final LCD will be revised to include ICD-9 procedure code 37.74 for the insertion or replacement of epicardial lead [electrode] into the epicardium by sternotomy or thoracotomy.

Comment #10: In Part B of A Services, 33216 (Insertion of a single transvenous electrode, permanent pacemaker or cardioverter-defibrillator) was not included in the listing of codes. Should it be added? Would you be able to clarify why 33226 (Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator) was included?

Contractor response: Refer to contractor response to comment #5 above.

Comment #11: A suggestion was made to add various cardiomyopathy codes to the covered diagnoses list. Also, for the CRT-D (defibrillator component), a suggestion was made to add cardiac arrest, ventricular fibrillation, and ventricular tachycardia.

Contractor response: The indications section of the LCD has specific criteria that the patient receiving CRT has NYHA classification of heart failure II, III or IV but does not include indications for cardiomyopathy without LV dysfunction. For the CRT-D (defibrillator component), the LCD requires that the criteria for CRT-pacemaker are met along with CMS’s National Coverage Determination for Implantable automatic defibrillators (NCD 20.4). Therefore, the “ICD-9 Codes that Support Medical Necessity” that include the various conditions of heart failure will remain unchanged.