Biventricular Pacing/ Cardiac Resynchronization Therapy

FIRST COAST SERVICE OPTIONS
MAC - PART A/B
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L33271

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 – Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A and B

LCD Title
Biventricular Pacing/ Cardiac Resynchronization Therapy

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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 quotations 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).
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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.


Primary Geographic Jurisdiction

Florida
Puerto Rico/Virgin Islands

Oversight Region

Region I

Original Determination Effective Date

10/01/2015

Original Determination Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

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. 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.
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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 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 (pacing) 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. • New York Heart Association (NYHA) classification of heart failure III or IV; and
   • Sinus rhythm, or chronic atrial fibrillation (AF), or frequent dependence on ventricular pacing; and
   • left ventricular ejection fraction (LVEF) less than or equal to 35%; and
   • QRS duration greater than or equal to 120 msec; and
   • beneficiary is on a stable pharmacologic regimen before implantation, which may include any of the following, unless contraindicated: angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, beta blocker, digoxin, or diuretics; and
   • the device is approved by the Food and Drug Administration (FDA) for this indication.

2. • NYHA classification of heart failure II; and
   • sinus rhythm; and
   • no evidence of atrial arrhythmia; and
   • left ventricular ejection fraction (LVEF) less than or equal to 30%; and
   • left bundle branch block with QRS duration greater than or equal to 130 msec; and
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- beneficiary is on a stable pharmacologic regimen before implantation, which may include any of the following, unless contraindicated: angiotensin-converting enzyme inhibitor, angiotensin receptor blocker; beta blocker; digoxin, or diuretics, and
- the device is FDA approved for this indication.

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 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.

Type of Bill Code

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

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)
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
33214 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 pulse generator)
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 implantable defibrillator] pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)
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33225  Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, 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)

33230  Insertion of implantable defibrillator pulse generator only; with existing dual leads

33231  Insertion of implantable defibrillator pulse generator only; with existing multiple leads

33240  Insertion of implantable defibrillator pulse generator only; with existing single lead

33249  Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber

For inpatient hospital only, the following ICD-10-CM PROCEDURE CODES should be used:

<table>
<thead>
<tr>
<th>Code</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>02H43JZ</td>
<td>Insertion of Pacemaker Lead into Coronary Vein, Percutaneous Approach</td>
</tr>
<tr>
<td>02H43KZ</td>
<td>Insertion of Defibrillator Lead into Coronary Vein, Percutaneous Approach</td>
</tr>
<tr>
<td>02H43MZ</td>
<td>Insertion of Cardiac Lead into Coronary Vein, Percutaneous Approach</td>
</tr>
<tr>
<td>02H44JZ</td>
<td>Insertion of Pacemaker Lead into Coronary Vein, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>02HL01Z</td>
<td>Insertion of Pacemaker Lead into Left Ventricle, Open Approach</td>
</tr>
<tr>
<td>02HL0KZ</td>
<td>Insertion of Defibrillator Lead into Left Ventricle, Open Approach</td>
</tr>
<tr>
<td>02HL3JZ</td>
<td>Insertion of Pacemaker Lead into Left Ventricle, Percutaneous</td>
</tr>
<tr>
<td>02HL3KZ</td>
<td>Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Approach</td>
</tr>
<tr>
<td>02HN01Z</td>
<td>Insertion of Pacemaker Lead into Pericardium, Open Approach</td>
</tr>
<tr>
<td>02HN0MZ</td>
<td>Insertion of Cardiac Lead into Pericardium, Open Approach</td>
</tr>
<tr>
<td>02HN3JZ</td>
<td>Insertion of Pacemaker Lead into Pericardium, Percutaneous Approach</td>
</tr>
<tr>
<td>02HN3MZ</td>
<td>Insertion of Cardiac Lead into Pericardium, Percutaneous Approach</td>
</tr>
<tr>
<td>02HN4JZ</td>
<td>Insertion of Pacemaker Lead into Pericardium, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>02HN4MZ</td>
<td>Insertion of Cardiac Lead into Pericardium, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0JH607Z</td>
<td>Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Chest Subcutaneous Tissue and Fascia, Open Approach</td>
</tr>
<tr>
<td>0JH609Z</td>
<td>Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Chest Subcutaneous Tissue and Fascia, Open Approach</td>
</tr>
<tr>
<td>0JH637Z</td>
<td>Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach</td>
</tr>
<tr>
<td>0JH639Z</td>
<td>Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach</td>
</tr>
<tr>
<td>0JH807Z</td>
<td>Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach</td>
</tr>
<tr>
<td>0JH809Z</td>
<td>Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach</td>
</tr>
<tr>
<td>0JH837Z</td>
<td>Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach</td>
</tr>
<tr>
<td>0JH839Z</td>
<td>Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach</td>
</tr>
</tbody>
</table>

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.
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ICD-10 Codes that Support Medical Necessity

For CPT codes 33224 and 33225:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I09.81</td>
<td>Rheumatic heart failure</td>
</tr>
<tr>
<td>I11.0</td>
<td>Hypertensive heart disease with heart failure</td>
</tr>
<tr>
<td>I13.0</td>
<td>Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease</td>
</tr>
<tr>
<td>I13.2</td>
<td>Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease</td>
</tr>
<tr>
<td>I50.20-I50.9</td>
<td>Congestive Heart Failure</td>
</tr>
</tbody>
</table>

Diagnoses that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Associated Information

Documentation 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 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 local coverage determination (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.

**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**

FCSO reference LCD number(s) L32811

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](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](http://circ.ahajournals.org/content/115/16/2208.full)

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


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


Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

04/01/2014

Revision Number: Original

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

Related Documents

N/A

LCD Attachments

N/A

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Document formatted: 04/24/2014 (DA/et)