CARDIAC RESYNCHRONIZATION THERAPY
Medicare Local Coverage Determination (LCD) - L33271 Checklist
Medicare National Coverage Determination (NCD) - 20.4

LCD-L33271 Billing Article A57634 NCD 20.4	**Patient Name:**	**MR:**

Effective Date: For services performed on or after 10/01/2017

Cardiac Resynchronization Therapy (CRT), biventricular pacing [also called Cardiac Resynchronization Therapy Pacemaker (CRT-P)]. 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. It is designed to help the right (RV) and left ventricle (LV) beat at the same time in a normal sequence treating ventricular dyssynchrony. Selected patients with moderate to severe heart failure may benefit from CRT.
A *biventricular pacemaker* is implanted in the muscle tissue of the chest, below the collarbone, or in the abdomen with three leads or wires, one atrial lead [right atrium] and two ventricular leads [right and left ventricles], transvenously connected from the pacemaker to both sides of the heart. The pacemaker resynchronize the heart by detecting heart rate irregularities and emitting tiny pulses of electricity to correct them.
CRT with implantable cardioverter defibrillator (ICD) system (CRT-D) is indicated for some individuals with heart failure who are at high risk for life-threatening heart rhythms. The CRT-P (pacing) plus implantable cardioverter defibrillator system [CRT-D] are designed to treat ventricular dyssynchrony along with detecting and correct life threatening arrhythmia automatically correcting the heart's rhythm.

COVERAGE INDICATIONS

CRT-P and CRT-D IS considered medically reasonable and necessary when the applicable criteria below is met:

	CRT-P **The following criteria are met (1 OR 2):**	**CRT-D** **The following criteria are met (1 or 2 AND 3):**
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.	• 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.
	OR	**OR**
2 ☐	• New York Heart Association (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 • 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.	• New York Heart Association (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 • 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.
		AND
3 ☐	N/A	• Patient meets covered indication for Implantable Cardioverter Defibrillator (ICD) as specified in the NCD 20.4; and • The device is FDA approved for this indication.

DOCUMENTATION REQUIREMENTS

Justification of medical necessity for a device other than single lead device; must substantiate the medical need for CRT and include the following:

☐	Documentation to clearly support both the diagnostic criteria for the indication and the medical need
☐	Myocardial infarctions documented and defined, per the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction
☐	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
☐	Operative report outlining operative approach used and all the components of the biventricular pacemaker insertion

Note: If LCD criteria is not met, documentation must clearly outline the patient's episode of care that supports the procedure and must clearly address the reason(s) for coverage.

CODING INFORMATION

View LCD for coding information and for the list of Inpatient-Only Procedures. Additional coding guidelines for Biventricular Pacing/Cardiac Resynchronization Therapyare provided below:

Coding Guidelines

Local Coverage Article:
Implantable Automatic Defibrillators – Coding and Billing (A56341)

Note:
Outpatient Procedures: 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 echochardiography 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.

Inpatient Only Procedures: 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. These procedures must be performed in an inpatient only hospital setting ordered by the treating physician. View LCD for the list of Inpatient only Procedures.

Checklist completed by: **Date:**