

## Cardiac Resynchronization Therapy (CRT) for Heart Failure (HF) and Cardiac Contractility Modulation (CCM) Devices (Formerly Cardiac Resynchronization Therapy (CRT) for Heart Failure (HF))

Policy Number: **M031113507**  
Effective Date: **11/13/2003**  
Sponsoring Department: **Health Care Services**  
Impacted Department(s): **Health Care Services**

**Type of Policy:**  Internal  External

**Data Classification:**  Confidential  Restricted  Public

### Applies to (Line of Business):

- Corporate (All)
- State Products, if yes which plan(s):  MediSource;  MediSource Connect;  Child Health Plus;  Essential Plan
- Medicare, if yes, which plan(s):  MAPD;  PDP;  ISNP;  CSNP
- Commercial, if yes, which type:  Large Group;  Small Group;  Individual
- Self-Funded Services (*Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.*)

### Excluded Products within the Selected Lines of Business (LOB)

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**Applicable to Vendors?** Yes  No

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### Purpose and Applicability:

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To set forth the medical necessity criteria for cardiac resynchronization therapy (CRT) in patients with heart failure (HF) and Cardiac Contractility Modulation (CCM) Devices.

## **Policy:**

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### **Background:**

Well-designed clinical trials have established the role of cardiac resynchronization therapy (CRT) as a recommended treatment strategy for moderate-to-severe heart failure. A review of the relevant results from the MUSTIC, MIRACLE, CONAK-CD, and MIRACLE ICD trials reveals that in patients with New York Heart Association (NYHA) class III-IV HF, CRT produces consistent improvement in quality of life, functional status, and exercise capacity while also providing strong evidence for reverse remodeling and diminished functional mitral regurgitation, resulting in reductions in both heart failure hospitalizations and all-cause morbidity and mortality. In order to determine the best course of therapy, physicians often assess the stage of heart failure according to the New York Heart Association (NYHA) functional classification system. This system relates symptoms to everyday activities and the patient's quality of life.

Cardiac contractility modulation (CCM) delivers biphasic electrical pulses to the right ventricular septum during the heart's absolute refractory period to induce mild left-ventricular contraction. Its overall benefit remains uncertain. CCM has not been shown to improve long-term heart failure outcomes, may provide only modest improvements in functional capacity, and carries a relatively high risk complication rate of about 10 percent.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined below.

### **Commercial and Self-Funded**

Independent Health covers FDA approved cardiac resynchronization for members who meet the requirements below. Cardiac Contractility Modulation (CCM) Devices are not covered as there is insufficient clinical evidence to support the efficacy and effectiveness of their use.

**Medicare Advantage:** Independent Health covers FDA approved cardiac resynchronization for members who meet the following requirements below. For Cardiac Contractility Modulation, there is currently a National Coverage Determination (NCD). Please refer to the links listed in the Reference section for Medicare Advantage members.

### **MediSource, MediSource Connect, Child Health Plus and Essential Plan:**

MediSource, MediSource Connect, Child Health Plus and Essential Plan cover cardiac resynchronization utilizing the criteria below. MediSource, MediSource Connect, Child Health Plus and Essential Plan do not cover Cardiac Contractility Modulation.

**Clinical Indications:**

FDA approved cardiac resynchronization is considered medically necessary for **1 or more** of the following:

- New York Heart Association (NYHA) functional Class I with Left Bundle Branch Block (LBBB) and **ALL** of the following:
  - Member remains symptomatic despite recommended, optimal medical therapy
  - LVEF  $\leq$  30% and QRS  $\geq$  150 ms
- New York Heart Association (NYHA) functional Class II that remain symptomatic despite recommended, optimal medical therapy and **1 or more** of the following:
  - Member with Left Bundle Branch Block (LBBB), LVEF  $\leq$  35% and QRS  $\geq$  120 ms and  $<$  150 ms
  - Member with non- Left Bundle Branch Block (LBBB), LVEF  $\leq$  35% and QRS  $\geq$  150 ms
- New York Heart Association (NYHA) functional Class III or ambulatory class IV symptoms that remain symptomatic despite recommended optimal medical therapy and **1 or more** of the following:
  - Member with Left Bundle Branch Block (LBBB), LVEF  $\leq$  35% and QRS  $\geq$  120 ms and  $<$  150 ms
  - Member with non- Left Bundle Branch Block (LBBB), LVEF  $\leq$  35% and QRS  $\geq$  150 ms
- Replacement of a cardiac resynchronization therapy (CRT)-ICD implanted when the ejection fraction (EF) was less than or equal to 35% with another CRT-ICD is appropriate regardless of the EF at the time of battery depletion
- In members with a narrow QRS ( $<$ 120 ms), an ejection fraction of less than or equal to 35%, and a clinical indication for an ICD, a CRT-ICD is appropriate when ventricular pacing is anticipated to be greater than or equal to 40%

**NOT COVERED** for **ANY** of the following:

- Biventricular pacemakers CRT or combined biventricular pacemaker-defibrillator devices (CRT/ICD), are considered investigational and not medically necessary for all other indications
- For MediSource, MediSource Connect, Child Health Plus and Essential Plan; Cardiac Contractility Modulation devices are not covered
- For Commercial and Self-Funded products; Cardiac Contractility Modulation devices are considered experimental and investigational

**Pre-Authorization Required?** Yes  No

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Pre-authorization is required at the present time.

## Definitions

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**Cardiac contractility modulation (CCM) therapy** delivers electrical stimulation to the heart muscle to enhance ventricular contractions, aiming to boost cardiac output and gradually improve the strength and structure of the heart in patients with systolic heart failure (HF), who have not achieved sufficient benefit from optimal medical therapy.

**Heart failure (HF)** is a prevalent chronic cardiac condition associated with substantial morbidity and mortality developing over time as the heart's pumping action grows weaker. CHF may affect the right side of the heart only, occurring if the heart cannot pump enough blood to the lungs to pick up oxygen. Right-side heart failure may cause fluid to build up in the feet, ankles, legs, liver, abdomen, and the veins in the neck. Left-side heart failure occurs if the heart cannot pump enough oxygen-rich blood to the rest of the body. Right-side and left-side heart failure also may cause shortness of breath and fatigue (tiredness). Most cases involve both sides of the heart.

**Left Ventricular Ejection Fraction (LVEF)** refers to the percentage of blood that is pumped out of a filled ventricle with each heartbeat. A normal ejection fraction is  $\geq 50$ .

**Left Bundle Branch Block (LBBB)** results when normal electrical activity in the His-Purkinje system is interrupted, altering the normal sequence of activation with a resultant characteristic appearance on an EKG. LBBB complicates the diagnosis of myocardial ischemia/infarction and interferes with the interpretation of exercise testing. In patients with significant LV dysfunction, LBBB results in left ventricular dyssynchrony and may contribute to heart failure.

**New York Heart Association (NYHA) functional classification system** relates symptoms to everyday activities and the patient's quality of life. The functional classifications are as follows:

- Class I (Mild): No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath);
- Class II (Mild): Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea;
- Class III (Moderate): Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.
- Class IV (Severe): Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

**QRS complex** is the term for the deflections in an electrocardiogram (EKG) tracing that represent the ventricular activity of the heart. The entire QRS duration normally lasts for 0.06 to 0.10 sec (1.5 to 2.5 small boxes) and is not influenced by heart rate.

**Resynchronization therapy** is a technique to improve coordination of contraction of the ventricles, thus improving the hemodynamic status of the patient. In addition to the 2 leads (right atrium and right ventricle) used by a common pacemaker, CRT pacemakers have a third lead that is positioned in a vein on the outer surface of the left ventricle allowing the CRT pacemaker to simultaneously stimulate the left and right ventricles and restore a coordinated, or synchronous, pumping action.

## References

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### Related Policies, Processes and Other Documents

N/A

### Non-Regulatory references

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### Regulatory References

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***This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.***

## Version Control

Signature / Approval on File? Yes  No

Revision Date	Owner	Notes
3/1/2026	Health Care Services	Revised
12/1/2024	Health Care Services	Revised
12/1/2023	Health Care Services	Revised
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2/1/2019	Medical Management	Revised
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