

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)

Applicable to Vendors? Yes No

Purpose and Applicability:

To set forth the medical necessity criteria for cardiac resynchronization therapy (CRT) in patients with heart failure (HF).

Policy:

Commercial, Self-Funded and Medicare Advantage:

Independent Health covers FDA approved cardiac resynchronization for members who meet the following requirements:

1. New York Heart Association (NYHA) **functional Class I** with **Left Bundle Branch Block (LBBB)** that remains symptomatic despite recommended, optimal medical therapy, and the following:
 - **LVEF** \leq 30% and **QRS** \geq 150 ms
2. New York Heart Association (NYHA) **functional Class II** that remain symptomatic despite recommended, optimal medical therapy, and the following:
 - With LBBB, LVEF \leq 35% and QRS \geq 120 ms
 - With non-LBBB, LVEF \leq 35% and QRS \geq 150 ms
3. New York Heart Association (NYHA) **functional Class III** or **ambulatory class IV** symptoms that remain symptomatic despite recommended optimal medical therapy and either of the following:
 - With LBBB, LVEF \leq 35% and QRS \geq 120 ms
 - With non-LBBB, LVEF \leq 35% and QRS \geq 150 ms
4. 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; and
5. In patients 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%.

Biventricular pacemakers CRT or combined biventricular pacemaker-defibrillator devices (CRT/ICD), are considered investigational and not medically necessary for all other indications.

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

MediSource, MediSource Connect, Child Health Plus and Essential Plan cover cardiac resynchronization utilizing the criteria above.

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.

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 above.

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.

Pre-Authorization Required? Yes No

Pre-authorization is not required at the present time. Criteria above will be utilized upon retro-review.

Definitions

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 ≥ 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

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
12/1/2023	Health Care Services	Revised
12/1/2022	Health Care Services	Reviewed
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