Medical Policy

Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure

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- Policy: Commercial
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Policy Number: 101

BCBSA Reference Number: 2.02.10 (For Plan internal use only)
NCD/LCD: N/A

Related Policies
- Implantable Cardioverter Defibrillator (ICD), #070
- Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting, #287

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (ie, a combined biventricular pacemaker plus implantable cardiac defibrillator) may be considered MEDICALLY NECESSARY as a treatment of heart failure in patients who meet all the following criteria:

- New York Heart Association (NYHA) Class III or IV,
  - Left ventricular ejection fraction ≤35%
  - Sinus rhythm
  - Patients treated with guideline-directed medical therapy*
    - AND
  - Either left bundle branch block OR QRS duration of ≥150 ms.

- New York Heart Association (NYHA) Class II,
  - Left ventricular ejection fraction ≤30%, AND
  - Sinus rhythm
  - Patients treated with a guideline-directed medical therapy*
    - AND
  - Either left bundle branch block OR QRS duration of ≥150 ms.
Guideline-directed medical therapy for heart failure is outlined in the 2022 American Heart Association, American College of Cardiology, and Heart Failure Society of America guidelines for the management of heart failure (Heidenreich et al [2022]).

For patients who do not meet the criteria outlined above, but have an indication for a ventricular pacemaker or biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (ie, a combined biventricular pacemaker/implantable cardiac defibrillator) may be considered **MEDICALLY NECESSARY** as an alternative to a right ventricular pacemaker in patients who meet all of the following criteria:

- New York Heart Association class I, II, III, or IV heart failure;
- Left ventricular ejection fraction ≤50%;
- The presence of atroventricular block with requirement for a high percentage of ventricular pacing*; **AND**
- Patients treated with guideline-directed medical therapy.*

*Atrioventricular block with a requirement for a high percentage of ventricular pacing is considered to be present when there is either:
  - Third-degree atrioventricular block; or
  - Second-degree atrioventricular block or a PR interval of ≥300 ms when paced at 100 beats per minute.

Guideline-directed medical therapy for heart failure is outlined in the 2022 American Heart Association, American College of Cardiology, and Heart Failure Society of America guidelines for the management of heart failure (Heidenreich et al [2022]).

Biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator (ie, a combined biventricular pacemaker plus implantable cardiac defibrillator), are considered **INVESTIGATIONAL** as a treatment for patients with NYHA class I heart failure who do not meet the above criteria.

Biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator (ie., a combined biventricular pacemaker plus implantable cardiac defibrillator), are considered **INVESTIGATIONAL** as a treatment for heart failure in patients with atrial fibrillation who do not meet the above criteria.

Triple-site (triventricular) cardiac resynchronization therapy, using an additional pacing lead, is considered **INVESTIGATIONAL**.

Intrathoracic fluid monitoring sensor is considered **INVESTIGATIONAL** as a component of a biventricular pacemaker.

Cardiac resynchronization therapy with wireless left ventricular endocardial pacing is considered **INVESTIGATIONAL**.

**Prior Authorization Information**

**Inpatient**
- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

**Outpatient**
- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

| Commercial Managed Care (HMO and POS) | Prior authorization is **not required**. |
Prior authorization is **not required**.

<table>
<thead>
<tr>
<th><strong>Commercial PPO and Indemnity</strong></th>
<th>Prior authorization is <strong>not required</strong>.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medicare HMO Blue℠</strong></td>
<td><strong>not required</strong>.</td>
</tr>
<tr>
<td><strong>Medicare PPO Blue℠</strong></td>
<td><strong>not required</strong>.</td>
</tr>
</tbody>
</table>

**CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria **MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

**CPT Codes**

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33224</td>
<td>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)</td>
</tr>
<tr>
<td>33225</td>
<td>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)</td>
</tr>
</tbody>
</table>

**ICD-10 Procedure Codes**

<table>
<thead>
<tr>
<th>ICD-10-PCS procedure codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>02H40JZ</td>
<td>Insertion of Pacemaker Lead into Coronary Vein, Open Approach</td>
</tr>
<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>02H60JZ</td>
<td>Insertion of Pacemaker Lead into Right Atrium, Open Approach</td>
</tr>
<tr>
<td>02H63JZ</td>
<td>Insertion of Pacemaker Lead into Right Atrium, Percutaneous Approach</td>
</tr>
<tr>
<td>02H64JZ</td>
<td>Insertion of Pacemaker Lead into Right Atrium, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>02HK0JZ</td>
<td>Insertion of Pacemaker Lead into Right Ventricle, Open Approach</td>
</tr>
<tr>
<td>02HK0KZ</td>
<td>Insertion of Defibrillator Lead into Right Ventricle, Open Approach</td>
</tr>
<tr>
<td>02HK3JZ</td>
<td>Insertion of Pacemaker Lead into Right Ventricle, Percutaneous Approach</td>
</tr>
<tr>
<td>02HK3KZ</td>
<td>Insertion of Defibrillator Lead into Right Ventricle, Percutaneous Approach</td>
</tr>
<tr>
<td>02HK4JZ</td>
<td>Insertion of Pacemaker Lead into Right Ventricle, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>02HK4KZ</td>
<td>Insertion of Defibrillator Lead into Right Ventricle, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>02HL0JZ</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>
</tbody>
</table>
The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and ICD Procedure codes above if medical necessity criteria are met:

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I50.20</td>
<td>Unspecified systolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.1</td>
<td>Left ventricular failure, unspecified</td>
</tr>
<tr>
<td>I50.21</td>
<td>Acute systolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.22</td>
<td>Chronic systolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.23</td>
<td>Acute on chronic systolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.33</td>
<td>Acute on chronic diastolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.40</td>
<td>Unspecified combined systolic (congestive) and diastolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.41</td>
<td>Acute combined systolic (congestive) and diastolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.42</td>
<td>Chronic combined systolic (congestive) and diastolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.43</td>
<td>Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.810</td>
<td>Right heart failure, unspecified</td>
</tr>
<tr>
<td>I50.811</td>
<td>Acute right heart failure</td>
</tr>
<tr>
<td>I50.812</td>
<td>Chronic right heart failure</td>
</tr>
<tr>
<td>I50.813</td>
<td>Acute on chronic right heart failure</td>
</tr>
<tr>
<td>I50.814</td>
<td>Right heart failure due to left heart failure</td>
</tr>
<tr>
<td>I50.82</td>
<td>Biventricular heart failure</td>
</tr>
<tr>
<td>I50.83</td>
<td>High output heart failure</td>
</tr>
<tr>
<td>I50.84</td>
<td>End stage heart failure</td>
</tr>
</tbody>
</table>
Description
Heart Failure
An estimated 6.7 million adults in the United States 20 years of age and older had heart failure between 2017 to 2020. The prevalence continues to increase over time with the aging of the population. Prevalence of disease is higher in women than men 80 years of age and older. Overall prevalence is especially high in Black individuals. A 2008 study demonstrated that Black individuals had the highest risk of developing heart failure, followed by Hispanic, White, and Chinese individuals in the United States. Higher risk reflected differential prevalence of hypertension, diabetes, and lower socioeconomic status. Black individuals also had the highest proportion of incident heart failure not preceded by myocardial infarction (75%). Additionally, Black individuals have a greater 5-year case fatality rate associated with heart failure compared to White individuals. It is estimated that 20% to 30% of patients with heart failure have intraventricular conduction disorders resulting in a contraction pattern that is not coordinated and a wide QRS interval on the electrocardiogram. This abnormality appears to be associated with increased morbidity and mortality.

Treatment
Biventricular pacemakers using 3 leads (1 in the right atrium, 1 endocardial in the right ventricle, 1 epicardial for the left ventricle), also known as cardiac resynchronization therapy (CRT), have been investigated as a technique to coordinate the contraction of the ventricles, thus improving patients’ hemodynamic status. Originally developed CRT devices typically used 2 ventricular leads for biventricular pacing. Devices and implantation techniques have been developed to allow for multisite pacing, with the goal of improving CRT response. This may be accomplished in 1 of 2 ways: through the use of multiple leads within the coronary sinus (triventricular pacing) or through the use of multipolar left ventricular pacing leads, which can deliver pacing stimuli at multiple sites. Wireless left ventricular endocardial pacing is also being evaluated for patients who are not candidates for or do not respond to standard epicardial pacing leads.

Summary
Description
Cardiac resynchronization therapy (CRT), which consists of synchronized pacing of the left and right ventricles, is intended to treat patients with heart failure and dyssynchronous ventricular contractions. Treatment involves placement of a device that paces both ventricles and coordinates ventricular pacing to maximize cardiac pumping function and left ventricular ejection fraction (LVEF).

Summary of Evidence
For individuals who have New York Heart Association (NYHA) class III or IV heart failure with a left ventricular ejection fraction (LVEF) of 35% or less who are in sinus rhythm, treated with guideline-directed medical therapy, and have either left bundle branch block (LBBB) or a QRS interval of 150 ms or more who receive cardiac resynchronization therapy (CRT) with or without defibrillator, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are overall survival (OS), symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. There is a large body of clinical trial evidence supporting the use of CRT in patients with NYHA class III or IV heart failure. The RCTs have consistently reported that CRT reduces mortality, improves functional status, and improves quality of life for patients with NYHA class III or IV heart failure. Multiple subgroup analyses of RCTs have demonstrated that the benefit of CRT is mainly restricted to patients with LBBB or QRS interval greater than 150 ms. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have NYHA class II heart failure with an LVEF of 30% or less who are in sinus rhythm, treated with guideline-directed medical therapy, and have either LBBB or a QRS interval of 150 ms or more who receive CRT with or without defibrillator, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are OS, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. For patients with NYHA class II heart failure, at least 4 RCTs assessing CRT have been
published. A mortality benefit was reported in 1 of the 4 trials, the Resynchronization-Defibrillation for Ambulatory Heart Failure Trial (RAFT). None of the other 3 RCTs reported a mortality difference, but a subgroup analysis of the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT) trial reported a mortality benefit for patients with LBBB. Among other outcome measures, hospitalizations for heart failure showed consistent reductions, but quality of life and functional status did not improve. Multiple subgroup analyses of RCTs have demonstrated that the benefit of CRT is mainly restricted to patients with LBBB or a QRS interval greater than 150 ms. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have NYHA class I heart failure who receive CRT with or without defibrillator, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are OS, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Few patients with NYHA class I heart failure have been included in RCTs. The MADIT-CRT trial included 265 patients with class I heart failure. While the treatment effect on death and hospitalization favored combined implantable cardioverter-defibrillator (ICD) plus CRT devices versus ICD alone for class I patients, the confidence interval was large and included a 25% to 30% increase in events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have NYHA class I, II, III or IV heart failure with LVEF of 50% or less and atrioventricular (AV) nodal block with requirement for a high percentage of ventricular pacing, treated with guideline-directed medical therapy, who receive CRT with or without defibrillator, the evidence includes RCTs. Relevant outcomes are OS, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. For patients who have AV nodal block, some degree of left ventricular (LV) dysfunction, and who would not necessarily meet conventional criteria for CRT but would require ventricular pacing, a large RCT has demonstrated improvements in heart failure-related hospitalizations and urgent care visits among patients treated with CRT instead of right ventricular (RV) pacing alone. For patients who require ventricular pacing but have no LV dysfunction, results of a small RCT have suggested that biventricular pacing is associated with improved measures of cardiac function, but the trial was small and underpowered to detect differences in clinical outcomes. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure and atrial fibrillation who receive CRT with or without defibrillator, the evidence includes 6 RCTs and a registry study. Relevant outcomes are OS, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Results from RCTs have been conflicting, with 3 reporting improvements for patients with atrial fibrillation, including an all-cause mortality benefit, and others reporting no significant improvements. A registry study reported significant improvements in mortality and hospitalizations for patients with heart failure and atrial fibrillation treated with CRT plus defibrillator compared with implantable cardioverter-defibrillator alone. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure and AV nodal block who receive CRT, the evidence includes RCTs. Relevant outcomes are OS, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. One large RCT demonstrated that CRT led to reductions in heart failure-related hospitalizations and urgent care visits among patients with heart failure and AV block who would not necessarily meet conventional criteria for CRT. For patients who require ventricular pacing but have no LV dysfunction, results of a small RCT have suggested that biventricular pacing is associated with improvement in cardiac function, but the trial was small and underpowered to detect differences in clinical outcomes. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure who receive triple-site CRT, the evidence includes small RCTs and a meta-analysis that included nonrandomized studies. Relevant outcomes are OS, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The available RCTs have reported improved outcomes on at least 1 measure of functional status or quality of life with triple-site CRT compared with conventional CRT. However, the trials were small and had methodologic limitations. Also, outcomes reported differed across studies. Triple-site CRT was also associated with higher radiation
exposure and a greater number of additional procedures postimplantation. Larger, high-quality RCTs are needed to better define the benefit-risk ratio for triple-site CRT compared with conventional CRT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure who receive CRT combined with remote fluid monitoring, the evidence includes 3 RCTs. Relevant outcomes are OS, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Three RCTs have reported no improvement in outcomes associated with remote fluid monitoring for patients with heart failure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/2023</td>
<td>Annual policy review. 2 references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>6/2022</td>
<td>Annual policy review. Description, summary, and references updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>6/2021</td>
<td>Annual policy review. Description, summary, and references updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>7/2020</td>
<td>Annual policy review. Description, summary, and references updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>10/2018</td>
<td>Annual policy review. Policy statement added that cardiac resynchronization therapy with wireless left ventricular endocardial pacing is considered investigational. Effective 10/1/2018.</td>
</tr>
<tr>
<td>1/2018</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>10/2017</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>7/2017</td>
<td>Annual policy review. Medically necessary criteria clarified. 7/1/2017.</td>
</tr>
<tr>
<td>6/2017</td>
<td>Clarified coding information.</td>
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<tr>
<td>7/2016</td>
<td>New references added from Annual policy review.</td>
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<tr>
<td>9/2015</td>
<td>Annual policy review. Policy statements for CRT in class II and II/IV heart failure changed to include presence of LBBB (and QRS &gt;120-130 ms) OR QRS &gt;150 ms as medically necessary criteria. New medically necessary indications described. Clarified coding information. Effective 9/1/2015.</td>
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<td>5/2015</td>
<td>Clarified coding information</td>
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<tr>
<td>7/2014</td>
<td>New references added from Annual policy review.</td>
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<tr>
<td>5/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>4/2014</td>
<td>Coding information clarified</td>
</tr>
<tr>
<td>3/2013</td>
<td>Annual policy review. New investigational indications described. Cardiac Resynchronization Therapy” added to policy title. Effective 3/1/2013</td>
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<tr>
<td>12/1/2011</td>
<td>Annual policy review. Changes to policy statements.</td>
</tr>
</tbody>
</table>

**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)
References

34. Rao RK, Kumar UN, Schafer J, et al. Reduced ventricular volumes and improved systolic function with cardiac resynchronization therapy: a randomized trial comparing simultaneous biventricular pacing, sequential biventricular pacing, and left ventricular pacing. Circulation. Apr 24 2007; 115(16): 2136-44. PMID 17420340


Khazanie P, Greiner MA, Al-Khatib SM, et al. Comparative Effectiveness of Cardiac Resynchronization Therapy Among Patients With Heart Failure and Atrial Fibrillation: Findings From the National Cardiovascular Data Registry's Implantable Cardioverter-Defibrillator Registry. Circ Heart Fail. Jun 2016; 9(6). PMID 27296396


