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
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 2013 American College of Cardiology Foundation and American Heart Association guidelines for the management of heart failure (Yancy et al
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 atrioventricular 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 2013 American College of Cardiology Foundation and American Heart Association guidelines for the management of heart failure (Yancy et al 2013).

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 (i.e., 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.

<table>
<thead>
<tr>
<th>Insurance Type</th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>Prior authorization is <strong>required</strong>.</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is <strong>required</strong>.</td>
</tr>
<tr>
<td>Medicare HMO Blue™</td>
<td>Prior authorization is <strong>required</strong>.</td>
</tr>
</tbody>
</table>
Medicare PPO Blue℠ | Prior authorization is not required.

**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>
<tr>
<td>02HL3JZ</td>
<td>Insertion of Pacemaker Lead into Left Ventricle, Percutaneous Approach</td>
</tr>
<tr>
<td>02HL3KZ</td>
<td>Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Approach</td>
</tr>
</tbody>
</table>
02HL4JZ  Insertion of Pacemaker Lead into Left Ventricle, Percutaneous Endoscopic Approach
02HL4KZ  Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Endoscopic Approach
02PA0MZ  Removal of Cardiac Lead from Heart, Open Approach
02PA3MZ  Removal of Cardiac Lead from Heart, Percutaneous Approach
02PA4MZ  Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Endoscopic Approach
0JH607Z  Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
0JH609Z  Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
0JH637Z  Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
0JH639Z  Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
0JH807Z  Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach
0JH809Z  Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach
0JH837Z  Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach
0JH839Z  Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach
0JPT0PZ  Removal of Cardiac Rhythm Related Device from Trunk Subcutaneous Tissue and Fascia, Open Approach
0JPT3PZ  Removal of Cardiac Rhythm Related Device from Trunk Subcutaneous Tissue and Fascia, Percutaneous Approach

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:

**ICD-10 Diagnosis Codes**

<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>
<tr>
<td>I50.89</td>
<td>Other heart failure</td>
</tr>
<tr>
<td>I50.9</td>
<td>Heart failure, unspecified</td>
</tr>
</tbody>
</table>
**Description**

**Heart Failure**

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 three leads (one in the right atrium, one endocardial in the right ventricle, one 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 two 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 one of two 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**

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.

For individuals who have New York Heart Association (NYHA) class III or IV heart failure with a left ventricular ejection fraction 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 CRT with or without defibrillator, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. The relevant outcomes are overall survival (OS), symptoms, functional outcomes, quality of life (QOL), 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 QOL 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 a meaningful improvement in the net health outcome.

For individuals who have NYHA class II heart failure with a left ventricular ejection fraction 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. The relevant outcomes are OS, symptoms, functional outcomes, QOL, hospitalizations, and treatment-related morbidity. For patients with NYHA class II heart failure, at least four RCTs assessing CRT have been published. A mortality benefit was reported in one of the four trials, the Resynchronization-Defibrillation for Ambulatory Heart Failure Trial. None of the other three RCTs reported a mortality difference, but a subgroup analysis of the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy trial reported a mortality benefit for patients with LBBB. Among other outcome measures, hospitalizations for heart failure showed consistent reductions, but QOL 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 a meaningful 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. The relevant outcomes are OS, symptoms,
functional outcomes, QOL, hospitalizations, and treatment-related morbidity. Few patients with NYHA class I heart failure have been included in RCTs. The Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy trial included 265 patients with class I. While the treatment effect on death and hospitalization favored combined implantable cardiac defibrillator plus CRT devices vs implantable cardiac defibrillator 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 the effects of the technology on health outcomes.

For individuals who have NYHA class I, II, III or IV heart failure with left ventricular ejection fraction of 50% or less and the presence of atrioventricular 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 and systematic reviews of RCTs. The relevant outcomes are OS, symptoms, functional outcomes, QOL, hospitalizations, and treatment-related morbidity. For patients who have atrioventricular nodal block, some degree of left ventricular 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 RV pacing alone. For patients who require ventricular pacing but have no left ventricular 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 a meaningful 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 four RCTs and observational studies. The relevant outcomes are OS, symptoms, functional outcomes, QOL, hospitalizations, and treatment-related morbidity. Results from RCTs have been conflicting, with one reporting improvements for patients with atrial fibrillation and others reporting no significant improvements. Results from observational studies are also conflicting. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure and atrioventricular nodal block who receive CRT, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are OS, symptoms, functional outcomes, QOL, 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 atrioventricular block but who would not necessarily meet conventional criteria for CRT. For patients who require ventricular pacing but have no left ventricular 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 a meaningful 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. The relevant outcomes are OS, symptoms, functional outcomes, QOL, hospitalizations, and treatment-related morbidity. The available RCTs have reported improved outcomes on at least one measure of functional status or QOL 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 define better the benefit-risk ratio for triple-site CRT compared with conventional CRT. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure who receive CRT combined with remote fluid monitoring, the evidence includes three RCTs. The relevant outcomes are OS, symptoms, functional outcomes, QOL, 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 the effects of the technology on health outcomes.
Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/2018</td>
<td>BCBSA National medical 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>6/2017</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>7/2016</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>9/2015</td>
<td>BCBSA National medical 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>
</tr>
<tr>
<td>5/2015</td>
<td>Clarified coding information</td>
</tr>
<tr>
<td>7/2014</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<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>
</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
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


