

**Policy: MP141**

**Section: Medical Benefit Policy**

**Subject: Biventricular Pacemaker/Cardiac Resynchronization Therapy**

**I. Policy:** Biventricular Pacemaker/Cardiac Resynchronization Therapy

**II. Purpose/Objective:**

To provide a policy of coverage regarding Biventricular Pacemaker/Cardiac Resynchronization Therapy

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**Medicaid Business Segment**

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

**DESCRIPTION:** Biventricular pacing (aka: cardiac resynchronization therapy – CRT) is a pacemaker that utilizes three leads (one in the right atrium, and one in each ventricle) to electrically pace and coordinate the synchronous contraction of both ventricles of the heart, thereby improving hemodynamic status

**INDICATIONS:**

Member must be under the care of, and the device be recommended by a cardiologist sub-specializing in electrophysiology.

Biventricular pacing/CRT is considered medically necessary for members who meet **all** of the following criteria:

- Moderate to severe congestive heart failure (New York Heart Assn. Functional Class I, III or IV)\*; **and**
- Sinus rhythm, or chronic atrial fibrillation (AF), or frequent dependence on ventricular pacing; **and**
- Member remains symptomatic in spite of optimized pharmacotherapy; **and**
- Left ventricular ejection fraction of 35% or less; **and**
- QRS duration of 120 ms or greater

If a patient is at high risk of sudden cardiac death due to ventricular arrhythmias in addition to the indications listed above, a cardiac resynchronization therapy defibrillator (CRT-D) system may be considered. Refer to **MP140 [Automatic Implantable Cardioverter-Defibrillator (AICD)/ CRT-D]** for appropriate clinical criteria.

\*The NYHA classification of heart failure is a 4-tier system that categorizes patients based on subjective impression of the degree of functional compromise. The four NYHA functional classes are as follows:

**NYHA Classification System for Heart Failure**

Class I. No limitation of physical activity. No shortness of breath, fatigue, or heart palpitations with ordinary physical activity.

Class II. Slight limitation of physical activity. Shortness of breath, fatigue, or heart palpitations with ordinary physical activity, but patients are comfortable at rest.

Class III. Marked limitation of activity. Shortness of breath, fatigue, or heart palpitations with less than ordinary physical activity, but patients are comfortable at rest.

Class IV. Severe to complete limitation of activity. Shortness of breath, fatigue, or heart palpitations with *any* physical exertion and symptoms appear even at rest.

**LIMITATIONS:**

Biventricular pacing devices must be:

- Approved by the FDA; or
- Part of a Medicare –qualified clinical trial; or
- Part of an FDA Category B clinical trial with IDE number

**EXCLUSIONS:**

Biventricular pacing/CRT is considered investigational when used to treat the following conditions:

- Unstable angina
- Myocardial infarction or prior coronary artery revascularization or angioplasty within the previous three months.
- Restrictive cardiomyopathy or treatment-resistant hypertension
- Prophylactic pacemaker use
- Chronic atrial arrhythmias or ineffective atrial contractions (unless utilized in conjunction with, or post, AV nodal ablation)

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

**CODING ASSOCIATED WITH:** Biventricular Pacemaker/Cardiac Resynchronization Therapy

**The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.**

- 33202 Insertion of epicardial electrode(s); open incision (e.g., thoracotomy, median sternotomy, subxiphoid approach)
- 33203 Insertion of epicardial electrode(s); endoscopic approach (e.g., thoracoscopy, pericardioscopy)
- 33206 Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial
- 33207 ventricular
- 33208 ventricular and atrial
- 33211 Insertion or replacement of temporary transvenous dual chamber pacing electrodes
- 33213 Insertion or replacement of pacemaker pulse generator only; dual chamber
- 33214 Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)
- 33216 Insertion of a single transvenous electrode, permanent pacemaker or cardioverter-defibrillator
- 33217 Insertion of 2 transvenous electrodes, permanent pacemaker or cardioverter-defibrillator
- 33221 Insertion of pacemaker pulse generator only, with existing multiple leads
- 33224 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)
- 33225 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)
- 33226 Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)
- 33230 Insertion of pacing cardioverter-defibrillator pulse generator only; with existing dual leads
- 33231 Insertion of pacing cardioverter-defibrillator pulse generator only; with existing multiple leads
- 33240 Insertion of pacing cardioverter-defibrillator pulse generator only, with existing single leads
- 33249 Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s) single or dual chamber
- 33262 Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; single lead system
- 33263 Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system
- 33264 Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; multiple lead system
- 93641 Electrophysiologic test of single- or dual- chamber pacing ICD leads and pulse generator including defibrillation threshold test, at time of implantation
- C1721 Cardioverter-defibrillator; dual chamber
- C1722 Cardioverter-defibrillator; single chamber
- C1777 Lead, cardioverter-defibrillator (AICD), endocardial single coil
- C1779 Lead, pacemaker, transvenous VDD single pass
- C1785 Pacemaker, dual chamber, rate-responsive (implantable)
- C1882 Cardioverter-defibrillator, other than single or dual chamber
- C1895 Lead, AICD, endocardial dual coil
- C1896 Lead, AICD, other than endocardial single or dual coil
- C1898 Lead, pacemaker, other than transvenous VDD single pass
- C1899 Lead, AICD, combination
- C1900 Lead, left ventricular coronary venous system
- C2619 Pacemaker, dual chamber, nonrate-responsive (implantable)
- C2620 Pacemaker, single chamber, non-rate responsive (implantable)
- C2621 Pacemaker, other than single or dual chamber
- G0448 Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

**LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

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Centers for Medicare and Medicaid Services, Code of Federal Regulations 42 CFR § 405.201

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This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 6/04

**Revised:** 7/05 (Updated CMS coverage); 5/06 (remove prior auth); 6/15 (Removed GOLD from Limitations); 5/19 (expand qualifying HF categories)

**Reviewed:** 5/07, 5/08, 5/09, 6/10, 6/11, 6/12, 6/13, 6/14, 6/16, 5/17, 5/18