

Evidence Based Guideline

Biventricular Pacemakers for CHF

File Name: biventricular_pacemakers_for_chf
Origination: 10/2000
Last CAP Review: 6/2011
Next CAP Review: 6/2012
Last Review: 6/2011

Description of Procedure or Service

It is estimated that 20 to 30% of patients with congestive heart failure (CHF) have intraventricular conduction disorders resulting in a discoordinated contraction pattern and a wide QRS interval on the electrocardiogram (ECG). This abnormality appears to be associated with increased morbidity and mortality. Biventricular pacemakers using 3 leads (1 in the right atrium and 1 in each ventricle) have been investigated as a technique to coordinate the contraction of the ventricles, thus improving the patient's hemodynamic status. Two strategies are being explored: incorporating biventricular pacing into automatic implantable cardiac defibrillators and the development of stand-alone biventricular pacemakers.

One stand-alone biventricular pacemaker (InSync® Biventricular Pacing System, Medtronic) has received approval by the U.S. Food and Drug Administration (FDA) for the treatment of patients with New York Heart Association (NYHA) Class III or IV heart failure, on a stable pharmacologic regimen, who also have a QRS duration of > 130 msec and a left ventricular ejection fraction of < 35%. Biventricular pacemakers have also been combined with automatic implantable cardiac defibrillators (AICDs). Both Guidant (CONTAK CD® CRT-D System) and Medtronic (InSync® ICD Model 7272) have received FDA approval for combined cardiac resynchronization therapy defibrillators for patients at high risk of sudden cardiac death due to ventricular arrhythmias and who have NYHA Class III or IV heart failure with left ventricular ejection fraction of 35% or less, QRS duration > 130 msec (>120 msec for the Guidant device) and remain symptomatic despite a stable, optimal heart failure drug therapy. For further information on AICDs, see the BCBSNC Medical Policy titled, "External Defibrillators".

In 2005, the InSync Sentry System received FDA approval through the supplemental premarket approval (PMA) process. This combined biventricular pacemaker/AICD is also equipped to monitor intrathoracic fluid levels using bioimpedance technology, referred to as OptiVol Fluid Status monitoring. Bioimpedance measures, defined as the electrical resistance of tissue to flow of current, are performed many times per day using a vector from the right ventricular coil on the lead in the right side of the heart to the implanted pacemaker devices. Changes in bioimpedance reflect intrathoracic fluid status and are evaluated based on a computer algorithm. For example, changes in a patient's daily average of intrathoracic bioimpedance can be monitored; differences in the daily average compared to a baseline are reported as the OptiVol Fluid Index. It has been proposed that these data may be used as an early warning system of cardiac decompensation, or provide additional feedback enabling a physician to further tailor medical therapy.

*****Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Evidence Based Guideline for Biventricular Pacemakers for CHF

Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD) may be appropriate as a treatment of congestive heart failure in patients who meet all of the following criteria:

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New York Heart Association class III or IV:

- Left ventricular ejection fraction less than or equal to 35%
- Sinus rhythm
- QRS duration of greater than or equal to 120-130* msec
- Patients treated with a stable pharmacological medical regimen prior to implant, such as an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker (or angiotensin receptor blocker), digoxin, and/or diuretics

New York Heart Association class II

- Left ventricular ejection fraction less than or equal to 30%
- Sinus rhythm
- QRS duration of greater than or equal to 120–130* msec
- Patients treated with a stable pharmacological medical regimen prior to implant, such as an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker (or angiotensin receptor blocker), digoxin, and/or diuretics

* The FDA-labeled indications for QRS duration vary by device. For some devices, FDA approval is based on QRS duration of greater than or equal to 130msec (e.g., InSync® device) while for others it is based on QRS duration of greater than or equal to 120msec (e.g., CONTAK CD® CRT-D System). These differences in QRS duration arise from differences in the eligibility criteria in the trials on which the FDA approval is based.

Medical Evidence regarding Biventricular Pacemakers for CHF indicates it is not recommended in the following situations

Biventricular pacemakers are not recommended as a treatment of CHF in patients who do not meet the criteria noted above.

An intrathoracic fluid monitoring sensor as a component of a biventricular pacemaker is not recommended.

Benefits Application

This evidence based guideline relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this guideline.

Billing/Coding/Physician Documentation Information

This guideline may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 33211, 33213, 33224, 33225, 33226, 33230, 33231, 33262, 33263, 33264, G0448

Scientific Background and Reference Sources

BCBSNA Medical Policy Reference Manual, 2.02.10, 7/16/99

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Specialty Matched Consultant Advisory Panel - 9/00

Medical Policy Advisory Group - 10/00

BCBSA Medical Policy Reference Manual, 2.02.10, 11/20/01

Specialty Matched Consultant Advisory Panel - 8/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.10, 12/17/03

Dixon J, Horn E, Neglia J, Medina N, Garan H. (2004 February). Loss of left bundle branch block following biventricular pacing therapy for heart failure: evidence for electrical remodeling? *J Interv Card Electrophysiol*, 10(1), 47-50. Retrieved April 16, 2004 from http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=14739749

Conaway DG, Sullivan R, McCulloch Pa. (2004 Winter). Improved symptoms, physical limitation, and self-efficacy after resynchronization in a patient with heart failure and a prolonged QRS duration. *Rev Cardiovasc Med*, 5(1), 53-57. Retrieved April 16, 2004 from http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15029112

Specialty Matched Consultant Advisory Panel - 6/2004

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Agency for Healthcare Research and Quality (AHRQ) Evidence Report/Technology Assessment Number 106. (2004, November) Cardiac resynchronization therapy for congestive heart failure. Retrieved November 15, 2005 from <http://www.ahrq.gov/downloads/pub/evidence/pdf/resynch/resynchf.pdf>

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Centers for Medicare and Medicaid Services. Local Coverage Determination for Resynchronization Therapy for Congestive Heart Failure (Bi-Ventricular Pacing) (L11585). Retrieved 10/12/07 from http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=11585&lcd_version=14&show=all

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.10, 10/10/06

U.S. Food and Drug Administration. Approval letter for InSync® Biventricular Pacing System, Medtronic. Retrieved on 08/24/01 from http://www.accessdata.fda.gov/cdrh_docs/pdf/p010015a.pdf

U.S. Food and Drug Administration. Approval letter for CONTAK CD® CRT-D System. Retrieved on 09/14/04 from http://www.accessdata.fda.gov/cdrh_docs/pdf/P010012S026a.pdf

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U.S. Food and Drug Administration PMA for InSync Sentry System. Retrieved on 07/18/05 from <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm110720.htm>

BCBSA TEC Assessment [Electronic Version], Cardiac Resynchronization Therapy for Mild Congestive Heart Failure. 2009

BCBSA Medical Policy Reference Manual [Electronic Version] 2.02.10, 10/06/09

Specialty Matched Consultant Advisory Panel - 6/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.10, 4/14/11

Al-Majed NS, McAlister FA, Bakal JA et al. Meta-analysis: cardiac resynchronization therapy for patients with less symptomatic heart failure. *Ann Intern Med* 2011. Retrieved on May 18, 2011 from <http://www.annals.org/content/early/2011/02/11/0003-4819-154-6-201103150-00314.full>

Specialty Matched Consultant Advisory Panel review 6/2011

Policy Implementation/Update Information

9/00 Specialty Matched Consultant Advisory Panel.

10/00 Original policy issued. Medical Policy Advisory Group - Approved.

3/02 Policy statement changed from investigational to include eligible indications for coverage.

9/02 Specialty Matched Consultant Advisory Panel review. Clarified the "When Biventricular Pacemakers for CHF are covered" section.

1/03 Statement added to Billing/Coding Section indicating that Medical Records may be ordered.

8/03 Added codes 33224 and 33225 to policy.

1/04 Benefits Application and Billing/Coding sections updated for consistency.

7/29/04 Specialty Matched Consultant Advisory Panel review 06/08/2004 with no changes made to criteria. References added.

3/16/06 Specialty Matched Consultant Advisory Panel review 2/27/06. No change to policy coverage criteria. Expanded Description of Procedure for clarification. Rationale added to Policy Guidelines. Policy number added to Key Words. References and codes updated.

8/21/06 Medical Policy changed to Evidence Based Guideline. (adn)

4/21/08 Routine biennial review. Definition of New York Heart Association Functional Classification moved from Guidelines section to Medical Term Definitions section. In the guidelines section for When Biventricular Pacemakers are appropriate: revised Item 2 to read "Left ventricular ejection fraction of less than or equal to 35%" and revised Item 3 to read "QRS duration of greater than or equal to 120 msec." Added Item B to read, "NYHA Class II Class II patients with a pacemaker and who meet criteria 2 through 4 above may be appropriate for biventricular pacemakers rather than standard pacemakers if they require a routine pacemaker replacement." References updated. Specialty Matched Consultant Advisory Panel review 3/12/08. No change to policy statement. (adn)

8/3/2010 Specialty Matched Consultant Advisory Panel review 6/2010. Removed Evidenced Based Policy Guideline number. Description section extensively revised. Added "An intrathoracic fluid monitoring sensor as a component of a biventricular pacemaker is not recommended" to the Not Recommended Indications section. References updated.(mco)

7/19/11 Re-formatted the "When Appropriate" section and included new guidelines for NYHA Class II

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patients as follows: “Left ventricular ejection fraction less than or equal to 30%, Sinus rhythm, QRS duration of greater than or equal to 120–130* msec, Patients treated with a stable pharmacological medical regimen prior to implant, such as an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker (or angiotensin receptor blocker), digoxin, and/or diuretics” References updated. Specialty Matched Consultant Advisory Panel review 6/2011. (mco)

12/30/11 New codes added to “Billing/Coding” section: 33230, 33231, 33262, 33263, 33264, G0448. Effective date 1/1/2012. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.