Protocol

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

(20210)

Medical Benefit		**Effective Date**: 07/01/13	**Next Review Date**: 05/15
Preauthorization	Yes	**Review Dates**: 09/09, 01/10, 09/10, 07/11, 07/12, 09/12, 05/13, 05/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

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 which coordinates ventricular pacing to maximize cardiac pumping function and left-ventricular ejection fraction (LVEF).

Background

It is estimated that 20–30% 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 (ECG). This abnormality appears to be associated with increased morbidity and mortality. Biventricular pacemakers using three leads (one in the right atrium and one in each ventricle) have been investigated as a technique to coordinate the contraction of the ventricles, thus improving patients' hemodynamic status. Two strategies are being explored: incorporating biventricular pacing into automatic implantable cardiac defibrillators and the development of stand-alone biventricular pacemakers.

Regulatory Status

There are numerous CRT devices, combined CRT-ICD devices (CRT-D), and combined CRT and fluid monitoring devices. Some of the devices are discussed here. A 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 or longer and a left-ventricular ejection fraction (LVEF) of 35% or less. Biventricular pacemakers have also been combined with automatic implantable cardiac defibrillators (ICDs).

Both Guidant (CONTAK CD® CRT-D System) and Medtronic (InSync® ICD Model 7272) have received U.S. Food and Drug Administration (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 LVEF of 35% or less, QRS duration 130 msec or longer (120 msec or longer for the Guidant device), and remain symptomatic despite a stable, optimal heart failure drug therapy. In 2006, Biotronik Inc. received FDA approval for its combined ICD/CRT device with ventricular pacing leads (Tupos LV/ATx CRT-D/Kronos LV-T CRT-D systems(1)); in 2013, the company received FDA approval for updated ICD/CRT devices (Ilesto/Iforia series) (2)

In September 2010, the FDA expanded the indications for cardiac resynchronization therapy (CRT) to include

patients with class I and II heart failure. In addition to NYHA class I/II heart failure, indications for CRT in mild heart failure include a LVEF of less than 30% and a QRS duration of 130 msec or greater.

Multiple devices manufactured by Medtronic combine a CRT with the OpitVol™ monitoring system. For example, in 2005, the InSync Sentry® system received FDA approval through the supplemental premarket approval (PMA) process. This combined biventricular pacemaker/ICD 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 to provide additional feedback enabling a physician to further tailor medical therapy.

Related Protocol

Implantable Cardioverter Defibrillator (ICD)

Policy (Formerly Corporate Medical Guideline)

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

New York Heart Association class III or IV

- Left ventricular ejection fraction ≤ 35%
- Sinus rhythm
- QRS duration of ≥ 120–130* ms, and
- 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, digoxin, and/or diuretics.

New York Heart Association class II

- Left ventricular ejection fraction ≤ 30%
- Sinus rhythm
- QRS duration of ≥ 120–130* ms, and
- 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, 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 ≥ 130 (e.g., InSync® device) while for others, it is based on QRS duration ≥ 120 ms (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.

Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD) are considered **investigational** as a treatment for patients with NYHA class I heart failure.

Biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD), are considered **investigational** as a treatment for heart failure in patients with atrial fibrillation.

An intrathoracic fluid monitoring sensor is considered **investigational** as a component of a biventricular pacemaker.

Triple-site (triventricular) CRT, using an additional pacing lead, is considered **investigational**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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