BIVENTRICULAR PACEMAKERS FOR THE TREATMENT OF CONGESTIVE HEART FAILURE
MED202.054PS

COVERAGE:

Biventricular Pacemakers are considered medically necessary as a treatment of congestive heart failure in patients who meet all of the following criteria:

- New York Heart Association (NYHA) Class III or IV,
- Left ventricular ejection fraction <35%,
- QRS duration of =>130msec,
- Patients treated with a stable pharmacological medical regime prior to implant, including an ACE inhibitor (or an angiotensin receptor blocker) and a beta-blocker (or angiotensin receptor blocker), digoxin, and diuretics.

DESCRIPTION:

It is estimated that 20%-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 (EKG). 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 the hemodynamic status of the patients. 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 recently received approval by the U.S. Food and Drug Administration (FDA). It has been approved for the treatment of patients with New York Heart Association 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%. Two other major U.S. pacemaker manufacturers (Guidant, and St. Jude Medical) are also developing biventricular pacemakers for similar indications.

RATIONALE:

The FDA approval for the InSync Biventricular Pacing System was based in part on the results of a multi-institutional randomized controlled trial. The results are presented in the FDA Summary of Safety and Effectiveness and are reviewed below.

The following patient selection criteria for the trials are similar to the labeled indication noted above:

- Patients diagnosed (within the previous month) with stable heart failure (NYHA Class III or IV)
QRS duration =>130 ms
Left ventricular end diastolic diameter of =>55 mm
Left ventricular ejection fraction of =<35%
Patients on a stable pharmacological medical regimen prior to implant of the cardiac resynchronization system. This includes an ACE inhibitor or substitute for at least one month and a beta-blocker for at least three months (if tolerated).

The exclusion criteria in the study included the following:

- Prior pacing systems or indications or contraindications for pacing
- Chronic atrial arrhythmias
- Unstable angina, myocardial infarction or prior coronary artery revascularization or coronary angioplasty within the past 3 months
- Existing implantable cardioverter defibrillator (ICD) or indications for an ICD.

A total of 275 patients were enrolled and underwent implantation of the biventricular pacing system. Of these, 171 patients were assigned to the control group in which the device was not activated, and 174 were assigned to the treatment group where the device was activated. The study was a double-blind study and the patients were followed up for 6 months.

The primary outcomes included exercise capacity (measured by a 6-minute hall walk) quality of life (as measured by the Minnesota Living with Heart Failure Questionnaire) and functional status (measured by change in NYHA classification). Secondary outcomes focused on cardiodynamic measures (including oxygen consumption) and a variety of echocardiographic measures, including, among others, left ventricular ejection fraction, mitral regurgitation, and left ventricular end diastolic dimension.

Compared to the control group, the active treatment group reported significant improvements in all outcomes measured. For example, in the treatment group, 68% reported an improvement in NYHA class compared to only 38% in the control group. While an improvement in quality of life was reported by both groups, there was a statistically significant difference in the improvement of the treatment group. Similarly, in the 6-minute hall walk the improvement in the treatment group is statistically significantly greater than that of the control group. The treatment group also reported increases in a variety of cardiodynamic measures, including peak oxygen consumption, LV end-diastolic dimension, and left ventricular ejection fraction. Finally, the InSync Biventricular Pacing system met the primary safety objectives of the study, including implant success rate and freedom from device-related complications. There was no difference in mortality after 6 months. As a condition of FDA approval, the manufacturer will perform a 12-month mortality assessment. The above results are similar to a smaller, single blind crossover trial of similarly selected patients.
PRICING:
None

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member's contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general policies and procedures.

Effective:
3/2003