Clinical Policy Bulletin: Leadless Cardiac Pacemaker

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Policy

Aetna considers leadless cardiac pacemakers experimental and investigational for arrhythmias and all other indications because of insufficient evidence of its safety and effectiveness.

Background

A leadless cardiac pacemaker system is a pulse generator with built-in battery and electrode for implantation in a cardiac chamber via a transfemoral catheter approach.

Leadless pacemakers are designed to achieve the same pacing results as a standard pacemaker, but the process for implanting the leadless pacemaker is different from standard pacemakers. The leadless pacemaker is placed via a catheter into the right ventricle. Unlike a standard pacemaker, a leadless pacemaker does not require creation of a surgical pocket for the pacemaker, and it requires no leads. The pacemaker battery life is equivalent to that of similar standard single chamber pacemakers.

Advantages of a leadless pacemaker over a standard pacemaker is avoidance of a surgical scar or lump under the skin where the pacemaker sits. Additional potential advantages include avoidance of problems with lead placement and reduction in risk of infections. A number of leadless cardiac pacemakers are currently in development, including the Nanostim Leadless Pacemaker (St. Jude Medical) and the Micra Transcatheter Pacing System (Medtronic).

Reddy, et al. (2014) reported on a prospective, nonrandomized study of the safety and clinical performance of a leadless cardiac pacemaker. The primary safety end point was freedom from complications at 90 days. Secondary performance end points included implant success rate, implant time, and measures of device performance (pacing/sensing thresholds and rate-responsive performance). The
mean age of the patient cohort (n=33) was 77±8 years, and 67% of the patients were male (n=22/33). The most common indication for cardiac pacing was permanent atrial fibrillation with atrioventricular block (n=22, 67%). The implant success rate was 97% (n=32). Five patients (15%) required the use of >1 leadless cardiac pacemaker during the procedure. One patient developed right ventricular perforation and cardiac tamponade during the implant procedure, and eventually died as the result of a stroke. The overall complication-free rate was 94% (31/33). After 3 months of follow-up, the measures of pacing performance (sensing, impedance, and pacing threshold) either improved or were stable within the accepted range.

Additional studies are necessary to evaluate the safety, efficacy and stability of leadless pacemakers.

The above policy is based on the following references:

