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, non-randomized study of the safety and clinical performance of a leadless cardiac pacemaker (LCP). 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 atrio-ventricular block (n = 22, 67 %). The implant success rate was 97 % (n = 32). Five patients (15 %) required the use of more than 1 LCP 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.

Reddy and associates (2015) studied a miniaturized, fully self-contained LCP that is non-surgically implanted in the right ventricle with the use of a catheter. In this multicenter study, these researchers...
implanted an active-fixation LCP in patients who required permanent single-chamber ventricular pacing. The primary efficacy end-point was both an acceptable pacing threshold (less than or equal to 2.0 V at 0.4 msec) and an acceptable sensing amplitude (R wave greater than or equal to 5.0 mV, or a value equal to or greater than the value at implantation) through 6 months. The primary safety end-point was freedom from device-related serious adverse events through 6 months. In this ongoing study, the pre-specified analysis of the primary end-points was performed on data from the first 300 patients who completed 6 months of follow-up (primary cohort). The rates of the efficacy end-point and safety end-point were compared with performance goals (based on historical data) of 85 % and 86 %, respectively. Additional outcomes were assessed in all 526 patients who were enrolled as of June 2015 (the total cohort). The LCP was successfully implanted in 504 of the 526 patients in the total cohort (95.8 %). The intention-to-treat primary efficacy end-point was met in 270 of the 300 patients in the primary cohort (90.0 %; 95 % confidence interval [CI]: 86.0 to 93.2, p = 0.007), and the primary safety end-point was met in 280 of the 300 patients (93.3 %; 95 % CI: 89.9 to 95.9; p < 0.001). At 6 months, device-related serious adverse events were observed in 6.7 % of the patients; events included device dislodgement with percutaneous retrieval (in 1.7 %), cardiac perforation (in 1.3 %), and pacing-threshold elevation requiring percutaneous retrieval and device replacement (in 1.3 %). The authors concluded that the LCP met pre-specified pacing and sensing requirements in the large majority of patients; device-related serious adverse events occurred in approximately 1 in 15 patients. The main drawback of this study was its short-term follow-up.

Miller et al (2015) stated that despite significant advances in battery longevity, lead performance, and programming features since the first implanted permanent pacemaker was developed, the basic design of cardiac pacemakers has remained relatively unchanged over the past 50 years. Because of inherent limitations in their design, conventional (transvenous) pacemakers are prone to multiple potential short- and long-term complications. Accordingly, there has been intense interest in a system that is capable of providing the symptomatic and potentially life-saving therapies of cardiac pacemakers while mitigating many of the risks associated with their weakest link -- the transvenous lead. The authors concluded that a LCP system represents the future of cardiac pacing systems, similar to the transition that occurred from the use of epicardial pacing systems to the familiar transvenous systems of today. These researchers summarized the current evidence and potential benefits of LCP systems, which are either commercially available (in Europe) or under clinical investigation.

Knops and colleagues (2015) noted that a LCP system was recently introduced to overcome lead-related complications of conventional pacing systems. To date, long-term results of an LCP system are unknown. These investigators evaluated the complication incidence, electrical performance, and rate response characteristics within the first year of follow-up of patients implanted with an LCP. They retrospectively assessed intermediate-term follow-up data for 31 of 33 patients from the LEADLESS trial cohort who had an indication for single-chamber pacing and received an LCP between December 2012 and April 2013. The mean age of the cohort was 76 ± 8 years, and 65 % were male. Between 3 and 12 months of follow-up, there were no pacemaker-related adverse events reported. The pacing performance results at 6- and 12-month follow-up were, respectively, as follows: mean pacing threshold (at a 0.4-ms pulse width), 0.40 ± 0.26 V and 0.43 ± 0.30 V; R-wave amplitude 10.6 ± 2.6 mV and 10.3 ± 2.2 mV; and impedance 625 ± 205 ohms and 627 ± 209 ohms. At the 12-month follow-up in 61 % of the patients (n = 19 of 31), the rate response sensor was activated, and an adequate rate response was observed in all patients. The authors concluded that the LCP demonstrated very stable performance and reassuring safety results during intermediate-term follow-up. They stated that these results support the use of the LCP as a promising alternative to conventional pacemaker systems; continued evaluation is warranted to further characterize this system.

Ritter et al (2015) described the early performance of a novel self-contained miniaturized pacemaker. Patients having Class I or II indication for ventricular demand (VVI) pacing underwent implantation of a Micra transcatheter pacing system, from the femoral vein and fixated in the right ventricle using 4 retractable nitinol tines. Pre-specified objectives were greater than 85 % freedom from unanticipated serious adverse device events (safety) and less than 2 V 3-month mean pacing capture threshold at
0.24 ms pulse width (efficacy). Patients were implanted (n = 140) from 23 centers in 11 countries (61 % male, mean age of 77.0 ± 10.2 years) for atrio-ventricular block (66 %) or sinus node dysfunction (29 %) indications. During mean follow-up of 1.9 ± 1.8 months, the safety end-point was met with no unanticipated serious adverse device events. Thirty adverse events related to the system or procedure occurred, mostly due to transient dysrhythmias or femoral access complications. One peri-cardial effusion without tamponade occurred after 18 device deployments. In 60 patients followed to 3 months, mean pacing threshold was 0.51 ± 0.22 V, and no threshold was ≥2 V, meeting the efficacy endpoint (p < 0.001). Average R-wave was 16.1 ± 5.2 mV and impedance was 650.7 ± 130 ohms. The authors concluded that early assessment showed that the transcatheter pacemaker can safely and effectively be applied. Moreover, they stated that long-term safety and benefit of the pacemaker will further be evaluated in the trial.

Sperzel et al (2015) stated that despite undisputable benefits, conventional pacemaker therapy is associated with specific complications related to the subcutaneous device and the transvenous leads. Recently, 2 miniaturized LCP, Nanostim™ (St. Jude Medical) and Micra™ (Medtronic), which can be completely implanted inside the right ventricle using steerable delivery systems, entered clinical application. The WiCS™-cardiac resynchronization therapy (CRT) system (wireless cardiac stimulation for CRT, EBR Systems) delivers leadless left ventricular endocardial stimulation for cardiac resynchronization. The authors concluded that in addition to obvious cosmetic benefits, leadless pacing systems may have the potential to overcome some complications of conventional pacing. However, they noted that acute and long-term complications still remains to be determined, as well as the feasibility of device explantation years after device placement.

Neuzil and Reddy (2015) stated that traditional trans-venous approach for permanent cardiac pacing can be associated with significant acute and chronic complications related partly to either the insertion of trans-venous lead or subcutaneous placement of pacemaker device. These researchers summarized the current status of a novel self-contained leadless cardiac pacemaker in the first-in-human and subsequent series of feasibility studies in patients indicated for ventricular rate-responsive pacing (VVI). Using a femoral venous approach, the device is implanted at the right ventricular apical septum region. They described the technical and clinical characterization of this innovative technology – 2 different systems of leadless pacemakers are currently implanted to the patients. Up to now, the electrical parameters, such as pacing thresholds, sensing parameters, and pacing impedances, either improved or remained stable within the accepted range. The authors discussed the potential benefit of leadless cardiac pacing, and concluded that all available data demonstrated the feasibility of this approach.

Kypta and co-workers (2016) stated that conventional pacemaker therapy is limited by short- and long-term complications, most notably device infection. Leadless transcatheter pacing systems (TPS) may be beneficial in this type of patients as they eliminate the need for a device pocket and leads and thus may reduce the risk of re-infection. These researchers evaluated a novel procedure in 6 patients with severe device infection who were pacemaker-dependent. After lead extraction a single chamber TPS was implanted into the right ventricle. Of the 6 patients who underwent lead extraction due to severe device infection at the authors’ institution, 3 were diagnosed with a pocket infection only, whereas the other 3 showed symptoms of both pocket and lead infection. Successful lead extraction and TPS implantation was accomplished in all patients. Four patients were bridged with a temporary pacemaker between 2 hours and 2 days after lead extraction, whereas 2 patients had the TPS implanted during the same procedure just before traditional pacemaker system removal. All patients stayed free of infection during the follow-up period of 12 weeks. An additional positron emission tomography (PET) scan was performed in each patient and indicated no signs of an infection around the TPS. The authors concluded that transcatheter pacemaker implantation was safe and feasible in 6 patients and did not result in re-infection even if implanted before removal of the infected pacemaker system within the same procedure. Therefore, implantation of a TPS may be an option for patients with severe device infection, especially in those with blocked venous access or who are pacemaker- dependent.

Seriwala and associates (2016) noted that cardiac pacemakers are a critical management option for
patients with rhythm disorders. Current efforts to develop leadless pacemakers have 2 primary goals: (i) to reduce lead-associated post-procedural morbidity, and (ii) to avoid the surgical scar associated with placement. After extensive studies on animal models and technological advancements, these devices are currently under investigation for human use. These investigators reviewed the evidence from animal studies and the technological advancements that have ushered in the era of use in humans. They also discussed different leadless pacemakers currently under investigation, along with limitations and future developments of this innovative concept.

Arkles and Cooper (2016) noted that the role of leadless devices to treat cardiac rhythm disorders and heart failure (HF) is emerging. Subcutaneous defibrillator (S-ICD) and leadless pacemakers were developed to ameliorate the risks associated with chronic transvenous leads. Potential benefits of leadless pacemakers and S-ICD include more favorable infection profile, less risk of venous stenosis or occlusion, and less risk of tricuspid valve insufficiency. The authors concluded that novel implantable leadless monitors for HF represent a novel diagnostic tool that can guide therapy for congestive HF.

Meyer and colleagues (2016) stated that electrical cardiac pacing today is the standard therapy for symptomatic bradycardia. Importantly, despite technical advantages, complications associated with conventional trans-venous pacing leads and pockets are still challenging in a relevant number of patients. Beyond cosmetic benefits, miniaturized leadless pacemaker may partly overcome these limitations and beneficially influence implantation-related physical restrictions. Initial findings with single-chamber pacemakers for right ventricular pacing, which are completely implanted via a femoral venous vascular access, are promising. The authors concluded that leadless pacing offers novel perspectives regarding cardiac implantable electronic devices although acute safety and the long-term performance of these systems needs to be determined in more detail.

An assessment by the Canadian Agency for Drugs and Technologies in Health (CADTH, 2015) concluded: "Differences in safety and pacing performance because of design differences between the two leadless pacemakers are currently unknown. Further evaluation of leadless pacemakers for long-term pacing performance, complication rates, and cost-effectiveness compared with traditional pacemakers is required."

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

**CPT Codes / HCPCS Codes / ICD-10 Codes**

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+".*

*ICD-10 codes will become effective as of October 1, 2015*:

**CPT codes not covered for indications listed in the CPB**:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0387T</td>
<td>Transcatheter insertion or replacement of permanent leadless pacemaker, ventricular</td>
</tr>
<tr>
<td>0389T</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report, leadless pacemaker system</td>
</tr>
<tr>
<td>0390T</td>
<td>Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure or test with analysis, review and report, leadless pacemaker system</td>
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0391T Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, leadless pacemaker system

Other CPT codes related to the CPB:

0388T Transcatheter removal of permanent leadless pacemaker, ventricular

ICD-10 codes not covered for indications listed in the CPB (not all inclusive):

I47.0 - I49.9 Cardiac dysrhythmias

The above policy is based on the following references:

Amendment to
Aetna Clinical Policy Bulletin Number: 0893 Leadless Cardiac Pacemaker

There are no amendments for Medicaid.