Abbott

HEALTH ECONOMICS & REIMBURSEMENT

AVEIR™ AR Atrial Leadless Pacemaker (LP) System Coverage with Evidence Development Study is Approved for Medicare Beneficiaries

On January 18, 2017, the Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD 20.8.4[1]) for coverage of leadless pacemakers. CMS covers leadless pacemaker procedures under a Coverage with Evidence Development Study (CED). The CED study requirement applies to all leadless pacemaker procedures and covers both Traditional Medicare (Medicare fee-for-service) and Medicare Advantage beneficiaries who are enrolled in the study. When submitted claims include a National Clinical Trial (NCT) number, Medicare patients will be automatically enrolled in the study.

On **January 18, 2024**, Abbott received CMS coverage approval of a real-world study for the AVEIR™ AR Atrial leadless pacemaker system. The AVEIR™ AR Atrial LP System Coverage with Evidence Development (CED) Study satisfies CMS' NCD CED requirements (refer to NCD 20.8.4 for further information[1]) for Medicare beneficiaries indicated for, and implanted with, the AVEIR™ AR Atrial LP System. The physician is responsible for determining whether a procedure meets the criteria for coverage, confirming use in accordance with the approved labeling, and confirming coverage, coding and claim submission guidance with the patient's health insurance plan to ensure that claims are accurate, complete, and supported by documentation in the patient's medical record. Please refer to the applicable Medicare policies posted on the CMS website for further information about billing and coding[2].

The National Clinical Trial (NCT) number for the AVEIR™ AR Atrial LP System study is 06100770.

What does this information mean for you?

Coverage, coding and payment for de novo AVEIR™ AR Atrial Leadless Pacemaker implants are available in the inpatient hospital and outpatient hospital setting for Medicare beneficiaries enrolled in the AVEIR™ AR Atrial LP System CED Study.

Additionally, coverage, coding and payment for AVEIR™ VR Ventricular LP, and AVEIR™ DR Dual Chamber Leadless Pacemaker System (including upgrading from a single chamber to a dual chamber) is available for inpatient hospital and outpatient hospital setting for Medicare beneficiaries enrolled in the respective CED Studies. Please note that there are separate CED studies (and separate NCT numbers that must be included on submitted claims) for AVEIR™ VR (NCT 05336877), AR (NCT 06100770) and DR (NCT 05932602).

For general coding and billing questions, contact LeadlessReimbursement@abbott.com.

Important Safety Information

AVEIR™ LEADLESS PACEMAKER SYSTEM

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The Aveir™ Leadless Pacemaker system is indicated for management of one or more of the following permanent conditions: Syncope, Pre-syncope, Fatigue, Disorientation. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-chamber pacing is indicated for patients exhibiting: Sick sinus syndrome, Chronic, symptomatic second- and third-degree AV block , Recurrent Adams-Stokes syndrome, Symptomatic bilateral bundle-branch block when tachyarrhythmia and other causes have been ruled out. Atrial pacing is indicated for patients with: Sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular pacing is indicated for patients with: Significant bradycardia and normal sinus rhythm with only rare episodes of AV block or sinus arrest, Chronic atrial fibrillation, Severe physical disability. MR Conditional: The Aveir Leadless Pacemaker is conditionally safe for use in the MRI environment and according to the instructions in the MRI-Ready Leadless System Manual.

Intended Use: The Aveir™ Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle and/or right atrium. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy within the implanted chamber for the target treatment group. The LP is also intended to operate optionally with another co-implanted LP to provide dual-chamber pacing therapy. The Aveir™ Delivery Catheter is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation includes implanting an LP within the target chamber of the heart.

Contraindications: Use of the Aveir™ Leadless Pacemaker is contraindicated in these cases: Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness. Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor driven rates. Use is contraindicated in patients with an implanted vena cava filter or mechanical tricuspid valve because of interference between these devices and the delivery system during implantation. Persons with known history of allergies to any of the components of this device may suffer an allergic reaction to this device. Prior to use on the patient, the patient should be counseled on the materials (listed in the Product Materials section of the IFU) contained in the device and thorough history of allergies must be discussed.

Adverse Events: Potential complications associated with the use of the Aveir™ Leadless Pacemaker system are the same as with the use of single or dual chamber pacemakers with active fixation pacing leads including, but not limited to: Cardiac perforation, Cardiac tamponade, Pericardial effusion, Pericarditis, Endocarditis, Valve damage or regurgitation, Heart failure, Pneumothorax/hemothorax, Cardiac arrhythmias, Diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation, Palpitations, Hypotension, Syncope, Cerebrovascular accident, Infection, Hypersensitivity reaction to device materials, contrast media, medications, or direct toxic effect of contrast media on kidney function, Pacemaker syndrome, Inability to interrogate or program the LP due to programmer or LP malfunction, Intermittent or complete loss of capture, pacing or sensing (non-battery related), Oversensing, Increased capture threshold, Inappropriate sensor response, Corrupted, intermittent, or loss of i2i communications, Interruption of desired LP function due to electrical interference, either electromyogenic or electromagnetic, Battery malfunction/ premature battery depletion, Device-related complications (Premature deployment, Device dislodgement/embolization of foreign material, Inability to release/re-dock of the LP from the catheter, Helix distortion), Additional surgery or intervention, Death. As with any percutaneous catheterization procedure, potential complications include, but are not limited to: Vascular access complications, such as perforation, dissection, puncture, groin pain, Bleeding or hematoma, Thrombus formation, Thromboembolism, Air embolism, Local and systemic infection, Peripheral nerve damage. General surgery risks and complications from comorbidities, such as, dyspnea, respiratory failure, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at vascular.eifu.abbott or at manuals.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

References
[1] *Centers for Medicare and Medicaid Services: Leadless Pacemakers National Coverage Determination NCD - Leadless Pacemakers (20.8.4). Access: Leadless Pacemakers | CMS*
[2]*CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 3815: R3815CP (cms.gov)*

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