HEALTH ECONOMICS & REIMBURSEMENT

AVEIR™ DR Dual Chamber Leadless Pacemaker (LP) Systems
Prior Authorization Suggestions for Implanting Physician(s)

Please consider the suggestions below when pursuing a Prior Authorization for AVEIR DR LP Dual chamber procedure, including upgrades. This is directional awareness in creating a case for your patient's coverage. This list is not all-inclusive, and nothing in this document should be construed as a guarantee by Abbott regarding reimbursement or payment amounts, or that reimbursement or other payment will be received. For independent consideration and review, please make all changes you believe appropriate, or disregard these suggestions in their entirety. The healthcare provider is ultimately responsible for the accuracy and completeness of all claims submitted to third-party payers. In addition, the provider should note that laws, regulations, and coverage policies are complex and updated frequently, and, therefore, the customer should check with its local carriers or intermediaries often and should consult with legal counsel or a financial or reimbursement specialist for any questions related to billing, reimbursement, or any related issue. Please see the FDA-approved label for information relevant to any prescribing decisions.

CAT III CPT‡ CODES	DESCRIPTION	INCLUDED
0795T	Transcatheter insertion of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	☐
0798T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	☐
0796T	Insertion of a permanent dual chamber leadless pacemaker, right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual chamber leadless pacemaker system)	☐
0797T	Insertion of a permanent dual chamber leadless pacemaker, right ventricular pacemaker component (when part of a dual chamber leadless pacemaker system)	☐

Please include proper CATEGORY III CPT‡ Code dependent upon dual chamber procedure.

The following clinical information may be required when submitting a prior authorization request for the aforementioned CATEGORY III CPT‡ codes. It is the sole responsibility of the prescribing healthcare provider to diagnose and treat the patient. Nothing in this document is intended to interfere with the independent clinical judgment of the prescribing healthcare provider. This information is subject to change. Please check your patient's benefit administrator's prior authorization requirements before submitting a prior authorization request.

SUGGESTED INFORMATION TO INCLUDE WITH PRIOR AUTHORIZATION	INCLUDED
ICD-10 CM Diagnosis code and medical necessity for procedure	☐
Absolute contraindication to conventional dual chamber transvenous pacemaker	☐
Relative contraindication to conventional dual chamber transvenous pacemaker	☐
Clinical reasoning as to why leadless pacemaker procedure is appropriate for patient	☐
Are you requesting an urgent review? Definition of **urgent**: When the physician believes waiting for a decision under the standard time frame could place the patient's life, health, or ability to regain maximum function in serious jeopardy. Examples of urgent situations include complete heart block, profound bradycardia with syncope/near syncope, existing pacemaker system malfunction with profound bradycardia/pacemaker dependence, etc.	☐

AVEIR™ DR Dual Chamber Leadless Pacemaker (LP) System

Important Safety Information

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 a 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 https://vascular.eifu.abbott/en/index.html or at https://manuals.sjm.com/ or more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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