**SAMPLE LETTER OF MEDICAL NECESSITY TEMPLATE**

AVEIR™ DR Dual Chamber Leadless Pacemaker Systems

**Instructions for completing the sample letter of medical necessity:**

1. Letters of medical necessity are often key to requesting **prior authorization** of procedures.
2. Please customize the medical necessity letter template based on the medical appropriateness. Text requiring customization is in **RED**.
3. After you have customized the letter, ***please make sure to delete this Instructions page and any RED text instructions*** for completion, disclaimers, Abbott logos, caution statement, trademarks and document number that are seen throughout the letter.
4. For independent consideration and review, please make all changes that 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. Please see the FDA-approved label for information relevant to any prescribing decisions.

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| **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 include 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/> for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.



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MAT-23119491 v1.0

*[Physician Letterhead]*

*[Date]*

Attention: Prior Authorization Department

*[Payer contact name]*

*[Payer contact title]*

*[Payer]*

*[Street address]*

*[City, State, zip code]*

**Re: Request for Prior Authorization of AVEIR™ DR Dual Chamber Leadless Pacemaker by a Same Specialty Provider (Cardiologist)**

Patient name: *[First and last name]*

Patient date of birth: *[XX/XX/XXXX]*

Insurance ID # *[XXXXXXXXXXXXXXX]*

Group # *[XXXXXXXXXX]*

Planned Date of Service: *[XX/XX/XXXX]*

***Diagnosis:*** *(list ICD 10 Dx code and diagnosis code descriptor)*

***CPT Code****: (two options shown below)*

* ***0795T****, Transcatheter insertion of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)*
* ***0796T,*** *Transcatheter**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)*

I am writing on behalf of my patient, [patient’s name], requesting prior authorization for the dual chamber leadless pacemaker. This procedure is scheduled for an [inpatient/outpatient] setting at [facility name] on [planned procedure date]. I have examined this patient and have reached a decision that the AVEIR DR Dual Chamber Leadless Pacemaker device is medically necessary for this patient.

**About Dual Chamber Leadless Pacing**

FDA approved on June 29, 2023, the AVEIR DR Leadless Pacemaker System is capable of pacing and sensing in both chambers of the heart through the combination of an atrial leadless pacemaker and a ventricular leadless pacemaker. Dual chamber, leadless synchronous pacing between the atrium and the ventricle is made possible with implant-to-implant communication technology, capable of providing pacing in both chambers to support atrioventricular synchrony.

The AVEIR DR Leadless Pacemaker system is indicated for management of one or more of the following permanent conditions: Syncope, Pre-syncope, Fatigue, and 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, or Symptomatic bilateral bundle-branch block when tachyarrhythmia and other causes have been ruled out.

**Patient Clinical History**

*[Or insert if applicable]* Moreover, a traditional dual chamber transvenous pacemaker is not sufficient for this patient for the following reason(s): *[insert clinical reasons why the leadless pacemaker is more clinically appropriate, or why traditional transvenous pacemaker is a minor or absolute contraindication].*

*Are you requesting an* ***urgent*** *review? Definition of* ***urgent****: When the physician believes that 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.

**In closing**

I believe the dual chamber leadless pacemaker is medically reasonable and necessary and warrants prior authorization of coverage and payment for this service. I have attached relevant excerpts from the patient’s medical record, including relevant history and physical to include symptoms and pertinent findings, signs and symptoms, treatments tried and failed, and results of diagnostic testing.

Please let me know if I can provide any additional information. Thank you for your attention.

Sincerely,

*[Physician’s name and credentials]*

*[Title]*

*[Name of practice]*

*[Street address]*

*[City, State, zip code]*

*[Phone number]*

**Enclosures:**

*Attach any relevant information, such as*

* *FDA approval letter*
* *Relevant clinical studies / publications*
* *Patient medical records/chart notes documenting all the following required clinical information:*
* *ICD Diagnosis and indication for procedure*
* *Relevant history and physical to include patient’s symptoms and pertinent findings*
* *Treatments tried, failed and/or contraindicated, including pharmacologic therapy, if applicable*