**SAMPLE LETTER OF MEDICAL NECESSITY TEMPLATE**

To be considered for prior authorization by physicians

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

1. Please customize the medical necessity letter template based on the medical appropriateness. Text requiring customization is in **RED**.
2. Letters of medical necessity are often key to requesting prior authorization of procedures.
3. After you have customized the letter, ***please make sure to delete this page and any specific 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**  **AVEIR™ VR LEADLESS PACEMAKER**  **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 patients with significant bradycardia and:   * Normal sinus rhythm with rare episodes of A-V block or sinus arrest * Chronic atrial fibrillation * Severe physical disability   Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.  **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. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy to the target patient population.  The Aveir™ Delivery Catheter system 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 atrial 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 Product Materials section in 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 chamber pacemakers with active fixation pacing leads including, but not limited to: Cardiac perforation, Cardiac tamponade, Pericardial effusion, Pericarditis, Valve damage and/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, 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 pacing and/or sensing due to dislodgement or mechanical malfunction of the LP (non-battery related), Loss of capture or sensing due to embolization or fibrotic tissue response at the electrode, Increased capture threshold, Inappropriate sensor response, 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, Helix distortion), 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 hypotension, dyspnea, respiratory failure, syncope, 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 eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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*[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 single chamber leadless pacemaker**

Patient name: *[First and last name]*

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

SS # *[XXX-XX-XXXX]*

Insurance ID # *[XXXXXXXXXXXXXXX]*

Group # *[XXXXXXXXXX]*

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

**CPT Code**: *33274, Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography), and device evaluation (e.g., interrogation or programming) when performed*

*OR*

***CPT Code:*** *33275,**Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) when performed*

I am writing on behalf of my patient, [patient’s name], requesting prior authorization for leadless pacemaker, right ventricular. This procedure is scheduled for an [inpatient/outpatient] setting at [facility name] on [planned procedure date].

**Treatment Rational**

I have examined this patient and have reached a decision that the AVEIR™ VR single chamber leadless pacemaker device is medically necessary for this patient. A leadless pacemaker is a small device inserted into the right ventricle, through a minimally invasive, catheter -based approach, which is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy. The Leadless Pacemaker is indicated for significant bradycardia in the setting of normal sinus rhythm with rare episodes of AV-block or sinus arrest, chronic atrial fibrillation, and/or severe physical disability.

**Patient Clinical History**

*[Or insert if applicable]* Moreover, a traditional 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 that the single 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:**

Patient medical records/chart notes documenting all of 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