**SAMPLE APPEAL LETTER FOR DENIED CLAIMS TEMPLATE**

AVEIR™ DR Dual Chamber Leadless Pacemaker Systems

**Instructions for completing the sample appeal letter for denied claims:**

1. Please customize the appeal letter template based on the medical appropriateness. Text requiring customization is in **RED**.
2. 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.
3. 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-2310462 v1.0

*[Physician Letterhead] [Date]*

Attention: Appeals Department

Reference Number: *[ ] [Payer contact name]*

*[Payer contact title]*

*[Payer]*

*[Street address]*

*[City, State, zip code]*

**Re: Reconsideration of Claims Denial *(enter number)* for the AVEIR™ Dual Chamber Leadless Pacemaker, requesting review by a Same Specialty Provider (Cardiologist)**

Patient name: *[First and last name]*

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

Insurance ID # *[XXXXXXXXXXXXXXX]*

Group # *[XXXXXXXXXX]*

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

***CPT Code****: (chose one of the two options)*

* ***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)*

Dear *[Payer contact name]*:

I am writing to request *reconsideration of the denied claim, [claim #],* for the above-referenced service. The service was a medically necessary implant of the AVEIR Dual Chamber Leadless Pacemaker System, provided to *[patient’s name]* on *[procedure date]*.

The request for prior authorization was submitted prior to the procedure [date of submission], and approved on [date of approval], [enter reference #/prior authorization approval letter #]. The claim, however, is now denied due to enter denial reason. *If claim was denied due to procedure falling outside of allowable timeline given on original prior authorization approval, explain in detail why procedure took place prior or after.*

I urge you to reconsider your denial of the claim in light of the patient’s specific clinical need, as well as the evidence for this technology. Leadless pacemakers are delivered via catheter to the heart, and function similarly to other transvenous single-chamber ventricular pacemakers.

FDA approved 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 for continuous, 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.

[If applicable] Documentation by the referring physician, as well as my examination, supports the determination of this patient’s need for the dual chamber leadless pacemaker.

*[Insert paragraph explaining, in your own words, why AVEIR DR is medically necessary for this patient. Where accurate, consider documenting how the patient’s condition reflects the on-label use of the product; why more extensive interventions are inadequate in light of the patient’s condition; your expectations of the patient’s outcomes without the LP procedure; how patient’s way of life and/or medical condition has benefited already from the procedure itself]*

I am attaching the patient’s medical record information and letter of medical necessity from my initial and approved request.

*[Include the following statement if additional information is to be attached]*

I have attached *relevant excerpts from the patient’s ongoing medical record, a summary of clinical evidence with references from peer-reviewed medical journals, etc.*

As explained above, I believe in this case that the Aveir DR Dual Chamber leadless pacemaker implant is and was medically necessary for this patient and as such this service should be granted coverage and reimbursed by *(insert name of insurance company)* accordingly.

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

Sincerely,

*[Physician’s name and credentials]*

*[Title]*

*[Name of practice]*

*[Street address]*

*[City, State, zip code] [Phone number]*

Enclosures:

*[Copy of original Prior Authorization approval letter]*

*[Patient medical records/chart notes]*

*[FDA Approval letter – AVEIR™ DR Dual Chamber Leadless Pacemaker]*

*[Evidence summary and select literature]*