

### Cardiac Rhythm Management

# AVEIR™ LEADLESS PACEMAKERS (LP) Medicare Reimbursement Guide

Effective January 1st, 2024

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### **TERMS AND CONDITIONS**

All content herein may be based upon several sources, included but not limited to primary sources, scientific literature, commercially available data sets, customer supplied information, and external sources.

Estimates shown are for illustrative purposes only. This content is not intended for any other purpose.

It should be noted that there are usually differences between economic modelling actual results. Abbott does not take responsibility for any such discrepancies. There is no guarantee of any potential economic outcome, including payment, cost savings, or procedure volume. Economic outcomes are dependent on many factors and will vary.

Certain Maryland hospitals paid under Maryland Waiver provisions using All Patient Refined Diagnosis Related Group (APR-DRG) are excluded from payment under the Medicare Inpatient Prospective Payment System (IPPS).

Reimbursement Calculators should not be provided at no charge to actively licensed Healthcare Professionals (HCPs) who regularly practice in Vermont.

This information is not to be distributed to third parties.

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MEDICARE COVERAGE **INTRO** 

MEDICARE REIMBURSEMENT

#### INTRODUCTION

# NATIONAL AVEIR<sup>TM</sup> LEADLESS PACEMAKERS MEDICARE REIMBURSEMENT GUIDE

### AVEIR<sup>TM</sup> VR Ventricular Leadless Pacemaker **System Introduction**

The AVEIR<sup>™</sup> VR Ventricular Leadless Pacemaker (LP) System is a single-chamber pacing system implanted in a patient's right ventricular chamber of the heart. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy for patients indicated for the therapy. As a leadless pacemaker, the AVEIR<sup>TM</sup> VR LP does not need a connector, pacing lead, or pulse generator pocket. The LP is delivered percutaneously via the femoral vein through an AVEIR<sup>TM</sup> Introducer and Delivery Catheter.

### **AVEIR™ DR Dual Chamber Leadless Pacemaker System Introduction**

The AVEIR<sup>™</sup> DR Dual Chamber Leadless Pacemaker (LP) System is a dual-chamber pacing system implanted in a patient's right ventricular and right atrial chambers of the heart. The LP system is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy in both chambers for patients indicated for the therapy. As a leadless pacemaker system, the AVEIR<sup>™</sup> DR Dual Chamber LPs do not need a connector, pacing lead, or pulse generator pocket. Each LP is delivered percutaneously via the femoral vein through an AVEIR<sup>TM</sup> Introducer and Delivery Catheter.

### **Reimbursement Hotline**

Abbott offers a reimbursement hotline, which provides live coding and reimbursement information from dedicated reimbursement specialists. Coding and reimbursement support is available from 8 a.m. to 5 p.m. Central Time, Monday through Friday at 855-569-6430 or HCE@abbott.com. Coding and reimbursement assistance is provided subject to the disclaimers set forth in this content.

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#### LEADLESS PACEMAKER THERAPY

The leadless pacemaker procedure using AVEIR<sup>TM</sup> VR Ventricular Leadless Pacemaker System is approved by CMS under a claims analysis study that will passively collect and analyze real world data to demonstrate the role of the therapy in patients that need a pacemaker. View the NCD: Leadless Pacemakers (20.8.4). Leadless Pacemaker must be used in accordance with FDA approved label for the device. It is the responsibility of the physician to determine whether the procedure meets the criteria for coverage and for confirming use in accordance with approved labeling. It is the responsibility of the physician to diagnose and treat the patient and to confirm coverage, coding and claim submission guidance with the patient's health insurance plan to ensure claims are accurate, complete and supported by documentation in the patient's medical record.

### MEDICARE CLAIM FORM INSTRUCTIONS

Physician is responsible for determining whether the procedure meets the criteria for coverage and confirming use in accordance with approved labeling. It is the responsibility of the physician to diagnose and treat the patient and to confirm coverage, coding and claim submission guidance with the patient's health insurance plan to ensure claims are accurate, complete, and supported by documentation in the patient's medical record.

CLAIMS IDENTIFYING INFORMATION TO SIGNIFY PATIENT IS PARTICIPATING IN A STUDY	PROFESSIONAL CLAIM FORM (CMS 1500-837P)	INSTITUTIONAL CLAIM FORM (UB-04-837i)
National Clinical Trial (NCT) Number	05336877 (For paper claims, Report: CT05336877)	05336877
Condition Code 30	Not reported on Physician Claim	30
Secondary Diagnosis Code	Z00.6 (Encounter for examination for normal comparison and control in clinical research program)	Z00.6 (Encounter for examination for normal comparison and control in clinical research program)
Q0 Modifier	Q0 (Investigational clinical service provided in a clinical research study that is an approval clinical research study)	Q0 (Investigational clinical service provided in a clinical research study that is an approved clinical research study)
Value codes	Not applicable	D4 ("code") and NCT number ("amount")



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## COVERAGE WITH EVIDENCE DEVELOPMENT FREQUENTLY ASKED QUESTIONS (FAQs)

These FAQs are intended for general informational purposes only to help provide information that may assist in understanding of Medicare's Coverage with Evidence Development (CED) Study policy relating to the AVEIR<sup>TM</sup> VR Ventricular Leadless Pacemaker System when used in accordance with its FDA approved labeling. Physician is responsible for determining whether the procedure meets the criteria for coverage and confirming use in accordance with approved labeling. It is the responsibility of the physician to diagnose and treat the patient and to confirm coverage, coding and claim submission guidance with the patient's health insurance plan to ensure claims are accurate, complete and supported by documentation in the patient's medical record.

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
Is AVEIR <sup>™</sup> VR Ventricular LP covered by CMS? The Centers for Medicare and Medicaid has a National Coverage Determination for leadless pacemakers, Policy 20.8.4. This is a CED policy that is applicable to all leadless pacemaker procedures for all Medicare beneficiaries, including Medicare fee-for- service and Medicare Advantage. As part of the coverage criteria, CMS requires all patients to be included in a CMS approved study. Abbott has a real-world study for AVEIR <sup>™</sup> VR Ventricular LP, AVEIR <sup>™</sup> VR Ventricular LP CED study to meet these coverage requirements and has obtained approval. The AVEIR <sup>™</sup> VR Ventricular LP CED study has a clinical trial number to be utilized only for patients indicated for AVEIR <sup>™</sup> VR Ventricular LP.	Medicare coverage is now available for AVEIR™ VR Leadless Pacemaker implant procedures for any Medicare beneficiaries indicated for a leadless pacemaker and included in the AVEIR™ VR Ventricular LP CED study.
How do I report that the AVEIR <sup>™</sup> VR Ventricular LP patient is part of a CMS approved study? Under the CMS CED policy, CMS requires that you report a National Clinical Trial number on the applicable claim. The NCT number for the AVEIR <sup>™</sup> VR Ventricular LP CED study is NCT05336877.	The inclusion of the AVEIR™ VR Ventricular LP CED study NCT number (NCT 05336877) is required for CMS coverage purposes.
<b>Is the AVEIRTM VR Ventricular LP CED study study the same as AVEIRTM VR's Leadless</b> <b>Pacemaker FDA post-approval study (PAS)?</b> No. They are two separate studies with two different NCT numbers. The AVEIRTM VR Ventricular LP CED study study is a CMS approved CED Study that is required for CMS coverage. The PAS is a predetermined group of sites participating in a registry that was established to meet post approval FDA requirements, independent from the CED study.	The NCT number (NCT 05336877) assigned to the AVEIR™ VR Ventricular LP CED study is unique to the AVEIR™ VR Leadless Pacemaker. The inclusion of the unique AVEIR™ VR Ventricular LP CED study NCT number (NCT 05336877) is a requirement for CMS coverage for AVEIR™ VR LP procedures.

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### COVERAGE WITH EVIDENCE DEVELOPMENT FAQs (continued)

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
Does my hospital's Institutional Review Board (IRB) need to approve the AVEIR <sup>™</sup> VR Ventricular LP CED study? The AVEIR <sup>™</sup> VR Ventricular LP CED study involves CMS claims or clinical data that are collected in the context of healthcare delivery, and the data collection involves no direct patient contact and will not influence the care a patient receives during routine interactions with the healthcare system. Therefore, IRB approvals are unlikely to be required by the hospital. Abbott, being the main entity in the AVEIR <sup>™</sup> VR Ventricular LP CED study study, has requested and been granted a waiver of informed consent and a HIPAA waiver from Western IRB. The Council for International Organizations of Medical Sciences (CIOMS), in a publication issued jointly with the World Health Organization (WHO), has stated that a waiver of the informed consent requirement may be granted by an IRB, "when the research design involves no more than minimal risk and a requirement of individual informed consent would make the conduct of the research impracticable (for example, where the research involves only excerpting data from subjects' records)". (Data on file at Abbott)	It is unlikely an IRB approval would be required by the hospital. We recommend that you review the hospital's policies and procedures along with this information.
Is the AVEIR <sup>™</sup> VR Ventricular LP CED study NCT number (NCT 05336877) required to be reported on private payer or Medicaid patient claims for coverage? The NCT number (NCT 05336877) does not apply to private payers or Medicaid. The AVEIR <sup>™</sup> VR Ventricular LP CED study NCT number (NCT 05336877) is required for Medicare beneficiaries' coverage only, including Fee-For-Service and Medicare Advantage.	AVEIR™ VR Ventricular LP CED study NCT number (NCT 05336877) is only required in connection with claims for coverage for Medicare beneficiaries.
Who can I contact if I have more questions? Contact the Health Economics team at Abbott: LeadlessReimbursement@abbott.com or you can contact the reimbursement hotline, which provides live coding and reimbursement information from dedicated reimbursement specialists. Coding and reimbursement support is available from 8 a.m. to 5 p.m. Central Time, Monday through Friday at (855) 569-6430	AVEIR™ VR Ventricular LP CED study NCT number (NCT 05336877) is only required in connection with claims for coverage for Medicare beneficiaries.

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### **MEDICARE COVERAGE**

#### LEADLESS PACEMAKER THERAPY

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CLAIMS IDENTIFYING INFORMATION TO SIGNIFY PATIENT IS PARTICIPATING IN A STUDY	PROFESSIONAL CLAIM FORM (CMS 1500-837P)	INSTITUTIONAL CLAIM FORM (UB-04-837i)
National Clinical Trial (NCT) Number	05932602 (For paper claims, Report: CT05932602)	05932602
Condition Code 30	Not reported on Physician Claim	30
Secondary Diagnosis Code	Z00.6 (Encounter for examination for normal comparison and control in clinical research program)	Z00.6 (Encounter for examination for normal comparison and control in clinical research program)
Q0 Modifier	Q0 (Investigational clinical service provided in a clinical research study that is an approval clinical research study)	Q0 (Investigational clinical service provided in a clinical research study that is an approved clinical research study)
Value codes	Not applicable	D4 ("code") and NCT number ("amount")

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These FAQs are intended for general informational purposes only to help provide information that may assist in understanding of Medicare's Coverage with Evidence Development (CED) Study policy relating to the AVEIR<sup>™</sup> DR Dual Chamber LP when used in accordance with its FDA approved labeling. Physician is responsible for determining whether the procedure meets the criteria for coverage and confirming use in accordance with approved labeling. It is the responsibility of the physician to diagnose and treat the patient and to confirm coverage, coding and claim submission guidance with the patient's health insurance plan to ensure claims are accurate, complete and supported by documentation in the patient's medical record.

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
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How do I report that the AVEIR <sup>™</sup> DR Dual Chamber LP patient is part of a CMS approved study? Under the CMS CED policy, CMS requires that you report a National Clinical Trial number on the applicable claim. The NCT number for the AVEIR <sup>™</sup> DR Dual Chamber LP CED study is NCT05932602.	The inclusion of the AVEIR™ DR Dual Chamber LP CED study NCT number (NCT 05932602) is required for CMS coverage purposes.
Is the AVEIR <sup>™</sup> DR Dual Chamber LP CED study the same as AVEIR <sup>™</sup> DR Dual Chamber Leadless Pacemaker's FDA post-approval study (PAS)? No. They are two separate studies with two different NCT numbers. The AVEIR <sup>™</sup> DR Dual Chamber LP CED study is a CMS approved CED Study that is required for CMS coverage. The PAS is a predetermined group of sites participating in a registry that was established to meet post approval FDA requirements, independent from the CED study.	The NCT number (NCT 05932602) assigned to the AVEIR™ DR Dual Chamber LP CED study is unique to the AVEIR™ DR Dual Chamber LP. The inclusion of the unique ACED study NCT number (NCT 05932602) is a requirement for CMS coverage for AVEIR™ DR Dual Chamber LP procedures.

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## COVERAGE WITH EVIDENCE DEVELOPMENT FAQs (continued)

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
Does my hospital's Institutional Review Board (IRB) need to approve the AVEIR <sup>™</sup> DR Dual Chamber LP CED study? The AVEIR <sup>™</sup> DR Dual Chamber LP CED study involves CMS claims or clinical data that are collected in the context of healthcare delivery, and the data collection involves no direct patient contact and will not influence the care a patient receives during routine interactions with the healthcare system. Therefore, IRB approvals are unlikely to be required by the hospital. Abbott, being the main entity in the AVEIR <sup>™</sup> DR Dual Chamber LP CED study, has requested and been granted a waiver of informed consent and a HIPAA waiver from Western IRB. The Council for International Organizations of Medical Sciences (CIOMS), in a publication issued jointly with the World Health Organization (WHO), has stated that a waiver of the informed consent requirement may be granted by an IRB, "when the research design involves no more than minimal risk and a requirement of individual informed consent would make the conduct of the research impracticable (for example, where the research involves only excerpting data from subjects' records)". (Data on file at Abbott)	It is unlikely an IRB approval would be required by the hospital. We recommend that you review the hospital's policies and procedures along with this information.
Is the AVEIR <sup>™</sup> DR Dual Chamber LP CED NCT number (NCT 05932602) required to be reported on private payer or Medicaid patient claims for coverage? The NCT number (NCT 05932602) does not apply to private payers or Medicaid. The AVEIR <sup>™</sup> DR Dual Chamber LP CED NCT number (NCT 05932602) is required for Medicare beneficiaries' coverage only, including Fee-For-Service and Medicare Advantage.	AVEIR™ DR Dual Chamber LP CED study NCT number (NCT 05932602) is only required in connection with claims for coverage for Medicare beneficiaries.
Who can I contact if I have more questions? Contact the Health Economics team at Abbott: LeadlessReimbursement@abbott.com or you can contact the reimbursement hotline, which provides live coding and reimbursement information from dedicated reimbursement specialists. Coding and reimbursement support is available from 8 a.m. to 5 p.m. Central Time, Monday through Friday at (855) 569-6430	Please contact the Abbott team using these channels when needed.

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## COVERAGE WITH EVIDENCE DEVELOPMENT FAQs (continued)

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
If a patient with an existing AVEIR <sup>TM</sup> VR ventricular leadless pacemaker is being upgraded to a dual chamber leadless pacemaker with an AVEIR <sup>TM</sup> AR atrial component, what NCT number would apply? NCT 05932602 for the AVEIR <sup>TM</sup> DR Dual Chamber LP CED Study, as these patients are now receiving dual chamber leadless pacing therapy post procedure.	AVEIR™ DR Dual Chamber LP CED study NCT number (NCT 05932602) is applicable to patients receiving AVEIR™ Dual Chamber leadless pacing capabilities.
If a patient with an existing AVEIR <sup>™</sup> AR atrial leadless pacemaker is being upgraded to a dual chamber leadless pacemaker with an AVEIR <sup>™</sup> VR ventricular component, what NCT number would apply? NCT 05932602 for the AVEIR <sup>™</sup> DR Dual Chamber LP CED Study, as these patients are now receiving dual chamber leadless pacing therapy post procedure.	AVEIR™ DR Dual Chamber LP CED study NCT number (NCT 05932602) is applicable to patients receiving AVEIR™ Dual Chamber leadless pacing capabilities.

C Abbott	INTRO MEDICARE COVERAG	GE MEDICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING   REFERENCES   CLOSING
AVEIRTM	VR Ventricular Leadless Pacemake	r System	AVEIR™ DR Dual Chamber	Leadless Pacemaker System
PHYSICIAN	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

CPT‡	DESCRIPTION		MEDICARE NATIONAL RATE	
CODE	DESCRIPTION	RVU	FACILITY	NON-FACILITY
	IMPLANT			
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.	7.80	\$461	NA
	REMOVAL			
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral ventriculography), when performed.	8.59	\$487	NA
	IN-PERSON DEVICE FOLLOW-UP			
93279	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system or leadless pacemaker system in one cardiac chamber.	0.65	\$30*	\$66
93288	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system, or leadless pacemaker system	0.43	\$20*	\$55
	PERI-PROCEDURE DEVICE PROGRAMMING; PACEMAKER			
93286	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system, or leadless pacemaker system	0.3	\$14*	\$44

\* Facility rates shown with an \* reflect payment when modifier 26 is used (i.e. payment only for the professional component).

Effective Dates: January 1, 2024 - December 31, 2024

NA: Medicare has not established a payment amount for this code. Check with your local Medicare Administrative Contractor (MAC) to verify the payment amount.

It is incumbent upon the physician to determine which, if any, modifiers should be used first.

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PHYSICIAN	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE NATIONAL RATE
	IMPLANT/REPLACEMENT			
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.	J1	5224	\$18,585
	REMOVAL WITHOUT LEADLESS REPLACEMENT			
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral ventriculography), when performed.	J1	5183	\$3,040
	PACEMAKER DEVICE PROGRAMMING- IN PERSON			
93279	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system or leadless pacemaker system in one cardiac chamber	Q1	5741	\$36
	PACEMAKER DEVICE INTERROGATION- IN PERSON			
93288	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system, or leadless pacemaker system	Q1	5741	\$36
	PERI-PROCEDURE DEVICE PROGRAMMING; PACEMAKER			
93286	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system, or leadless pacemaker system	Ν	NA	NA

J1: Hospital Part B services paid through a comprehensive APC

N: Items and Services Packaged into APC Rates

Q1: STV-Packaged Codes

NA: Medicare has not established a payment amount for this code. Check with your local Medicare Administrative Contractor (MAC) to verify the payment amount.

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ICD-10 PCS CODE	ICD-10 CS CODE DESCRIPTION		MEDICARE NATIONAL RATE
	LEADLESS PACEMAKERS		
02HK3NZ	Insertion of Intracardiac Pacemaker into Right Ventricle, Percutaneous approach	228 with MCC	\$35,279
02PA3NZ	Removal of Intracardiac Pacemaker from Heart, Percutaneous Approach		
02WA3NZ	Revision of Intracardiac Pacemaker from Heart, Percutaneous Approach	229 without MCC	\$22,262

Effective Dates: October 1, 2023 - September 30, 2024

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AVEIR™ VR Ventricular Leadless Pacemaker System			AVEIR™ DR Dual Chamber	r Leadless Pacemaker System
PHYSICIAN	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

### HCPCS Device Category C-Codes

C-CODE	DESCRIPTION
	LEADLESS PACEMAKERS
C1786	Pacemaker, single-chamber rate responsive (implantable)
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser

### ICD-10-CM (International Classification of Diseases, Tenth Revision, Clinical Modification) Diagnosis Codes

Diagnosis codes are used by both hospitals and physicians to document the indication for the procedure. For Cardiac Pacemaker, Implantable Cardioverter Defibrillator (ICD) and Implantable/Insertable Cardiac Monitors (ICM) patients, there are many possible diagnosis code scenarios and a wide variety of possible combinations. The possible scenarios and combinations are too numerous to capture in this document. The customer should check with their local carriers or intermediaries and should consult with legal counsel or a financial, coding or reimbursement specialist for coding, reimbursement or billing questions related to ICD-10-CM diagnosis codes. Diagnosis is the sole responsibility of the physician and reimbursement support provided is not intended to affect the physician's independent clinical judgment.

### **Commercial (Private) Payers**

Coverage for leadless pacemakers varies by payer policy.

We encourage providers to contact non-Medicare payers to confirm coverage prior to performing the procedure.

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AVEIR™ \	/R Ventricular Leadless Pacemake	r System	AVEIR™ DR Dual Chambe	r Leadless Pacemaker System
PHYSICIAN	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

#### 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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 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<sup>TM</sup> 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, Helk distortion), Deatter

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).

	RO MEDICARE COVERAGE MI	EDICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING REFERENCES CLOSING
AVEIR <sup>™</sup> VR Ventr	icular Leadless Pacemaker System		AVEIR™ DR Dual Chambe	er Leadless Pacemaker System
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

FDA approved June 29, 2023, the AVEIR<sup>TM</sup> DR Leadless Pacemaker (LP) 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. On July 1, 2023, the American Medical Association (AMA) approved a series of Category III CPT‡ Codes to report dual chamber leadless pacemaker procedures. Category III CPT‡ codes are a set of temporary codes to report emerging technology, services, and procedures. These codes are intended to be used to track the usage of these services, and the data collected may be used to substantiate widespread usage by the AMA. However, Category III codes are not valued and assigned a federal physician fee schedule by CMS. This document provides reference material related to general considerations for physician crosswalk payment for dual chamber leadless pacemaker system procedures when performed consistent with the product's labeling.

Reporting a Category III CPT code for Physician services require special considerations, in that Category III CPT codes for Dual Chamber Leadless Pacemaker Procedures do not have an assigned payment rate (established RVU (Relative Value Unit)) in Medicare's physician fee schedule, and private insurers do not have assignment of RVUs to use as a basis for setting physician payment. Since Category III codes do not have established RVUs, prior authorization requests (please note that traditional Medicare does not require prior authorization) and claims must generally be submitted with supporting documentation and may be subject to review. Comparable Category I CPT‡ codes that are similar to the Category III code may be identified to provide accurate information to payers for consideration when they are processing claims. By providing a comparable Category I CPT‡ code, along with additional documentation, payers can better understand what took place during the procedure, and value it accordingly.

Payers will review each claim with a CPT<sup>‡</sup> code for dual chamber leadless pacemaker procedures individually, and payment determinations will be made on a case-by-case basis. Therefore, it is strongly recommended that the provider contact payers to ensure the new Category III codes are included in contracts and to inquire about any guidelines for submission and documentation of these claims.

Recommended Supporting Documentation for Claim Submission (List is not comprehensive; check with your applicable payer)

- 1. A cover letter describing the services rendered and why the service was needed
- 2. Copy of operative report that details the procedure including provider's time and effort during procedure
  - Time, effort and equipment necessary to perform procedure
  - Include the relevant crosswalk Category I CPT<sup>‡</sup> code for a comparable procedure while also noting any and all differences with the services provided for the dual chamber leadless pacemaker procedure with an increase or decreased percentage of the work/time associated with the referenced comparable procedure
- 3. Customized Letter of Medical Necessity for the patient receiving the procedure
- 4. Copy of FDA Approval Letter
- 5. Copy of published clinical data

	RO MEDICARE COVERAGE ME	DICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING FORMS REFERENCES CLOSING
AVEIR™ VR Vent	ricular Leadless Pacemaker System		AVEIR™ DR Dual Chamber I	Leadless Pacemaker System
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

Physicians are encouraged to identify comparable crosswalk Category I CPT<sup>+</sup> codes to reference in supporting documentation provided with the claim submission when billing for Dual Chamber Leadless Pacemaker procedures. Since the Category III CPT<sup>+</sup> code does not have established RVUs, payers do not have a pre-defined reference for establishing payment. Physicians will need to document in detail the work involved with specificity of time, the complexity of the procedure, and practice expense relative to comparable procedures with established RVUs and payment amounts.

Physicians should enter the appropriate Category III CPT<sup>‡</sup> code for the procedure and bill an amount comparable to the crosswalk code. If a comparable crosswalk includes multiple units, then the explanation line should include all activity combined into one explanation (do not enter multiple lines of crosswalk codes). Applicable Category III codes for dual chamber leadless pacemaker procedures and an example of Crosswalk comparisons are included on the following pages in this section.

	RO MEDICARE COVERAGE MEL	DICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING REFERENCES CLOSING
AVEIR™ VR Ventricular Leadless Pacemaker System			AVEIR™ DR Dual Chamber	Leadless Pacemaker System
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

# AVEIR™ DR Dual Chamber LP System Physician Coding

Category III Codes

INSERTION

CPT‡ CODE	DESCRIPTION	WORK RVU
0795T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, (right atrial and right ventricular components)	N/A

#### REMOVAL

CPT‡ CODE	DESCRIPTION	WORK RVU
0798T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	N/A
0799T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial component)	N/A
0800T	Transcatheter removal of permanent dual chamber leadless pacemaker (right ventricular component)	N/A

#### **REMOVAL & REPLACEMENT**

CPT‡ CODE	DESCRIPTION	WORK RVU
0801T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	N/A
0802T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial component)	N/A
0803T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right ventricular component)	N/A

#### UPGRADE TO DUAL CHAMBER

CPT‡ CO	DESCRIPTION	WORK RVU
07961	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)	N/A
07971	Transcatheter insertion of a permanent dual chamber leadless pacemaker, right ventricular pacemaker component (when part of a dual chamber leadless pacemaker system)	N/A

AVEIR<sup>TM</sup> Leadless Pacemakers Medicare Reimbursement Guide

	RO MEDICARE COVERAGE ME	EDICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING   REFERENCES   CLOSING FORMS
AVEIR <sup>TM</sup> VR Ventricular Leadless Pacemaker System AVEIR <sup>TM</sup> DR Dual Chamber Leadless Pacemaker System				
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

# AVEIR<sup>™</sup> DR Dual Chamber LP System Physician Coding

#### PROGRAMMING DEVICE EVALUATION

CPT‡ CODE	DESCRIPTION	WORK RVU
0804T	Programming device evaluation (in person) with review and report by a physician or other qualified health care professional; leadless pacemaker system in dual cardiac chambers	N/A

### **Category I Code**

#### INTERROGATION

CPT‡ CODE	DESCRIPTION	WORK RVU
93288	Interrogation device evaluation (in person) with analysis, review and report by physician or other qualified healthcare professional, includes connection, recording, and connection per patient encounter; single, dual or multiple lead pacemaker system, or leadless pacemaker system	0.43

	RO MEDICARE COVERAGE MED	DICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING   REFERENCES   CLOSING FORMS   REFERENCES   CLOSING
AVEIR <sup>™</sup> VR Ventr	icular Leadless Pacemaker System		AVEIR™ DR Dual Chambeı	r Leadless Pacemaker System
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

### Category III Coding Crosswalk Examples

When considering comparable procedures, the following procedures may require similar effort, expertise, time and resource utilization.

(Coding options/examples presented below have been reviewed with independent consultants and certified coders)

#### Coding Crosswalk Options: AVEIR™ DR Dual Chamber LP System Insertion

#### INSERTION

Potential CPT‡ code	Potential CPT‡ code crosswalks for 0795T				
CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 NATIONAL MEDICARE AVERAGE		
33274*	Insertion or replacement of a permanent leadless pacemaker, right ventricular	7.8 (11.7*)	\$461 (\$692*)		
33340^ (LAAO Procedure)	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placements(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation	14	\$748		

\*If inserting 2 devices, provider can report 2 units; second unit will be discounted to 50%; reimbursement will adjust to 1.5 units.

^33340 is an additional option when inserting 2 units.

#### Coding Crosswalk Options: AVEIR™ DR Dual Chamber LP System Upgrade

#### UPGRADE

Pote	Potential CPT code crosswalks for 0796T, 0797T				
	CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 NATIONAL MEDICARE AVERAGE	
	33274	Insertion or replacement of a permanent leadless pacemaker, right ventricular	7.8	\$461	

AVEIR<sup>TM</sup> Leadless Pacemakers Medicare Reimbursement Guide

	RO MEDICARE COVERAGE ME	DICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING FORMS REFERENCES CLOSING
AVEIR <sup>™</sup> VR Ventr	ricular Leadless Pacemaker System		AVEIR™ DR Dual Chamber I	Leadless Pacemaker System
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

### Category III Coding Crosswalk Examples

Coding Crosswalk Options: AVEIR<sup>TM</sup> DR Dual Chamber LP System Removal

REMOVAL

Potential CPT Code	Crosswalks for 0798T, 0799T, 0800T		
CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 NATIONAL MEDICARE AVERAGE
33275*	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance, when performed.	8.59 (12.88*)	\$487 (\$731*)
33236^	Removal of permanent epicardial pacemaker and electrodes by thoracotomy; single lead system, atrial or ventricular	12.73	\$760

\*If removing both devices, provider can report 2 units; second unit will be discounted to 50%; reimbursement will adjust to 1.5 units.

^33236 is an additional option when removing both units.

#### Coding Crosswalk Options: AVEIR<sup>™</sup> DR Dual Chamber LP System Removal & Replacement

#### **REMOVAL & REPLACEMENT**

Potential CPT Cod	Potential CPT Code Crosswalks for 0801T, 0802T, 0803T				
CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 NATIONAL MEDICARE AVERAGE		
33274*	Insertion or replacement of a permanent leadless pacemaker, right ventricular	7.8 (11.7*)	\$461 (\$692*)		

\*If removing/replacing both devices, provider can report 2 units; second unit will be discounted 50%, reimbursement to 1.5 units

It is strongly encouraged that physicians include op notes detailing the effort and time of the removal portion of the procedure to support adequate reimbursement.

	RO MEDICARE COVERAGE ME	DICARE REIMBURSEMENT	MEDICARE B ADDITIONAL REIMBURSEMENT F	ILLING   REFERENCES   CLOSING
AVEIR™ VR Vent	ricular Leadless Pacemaker System		AVEIR™ DR Dual Chamber Le	eadless Pacemaker System
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

### Category III Coding Crosswalk Examples

Coding Crosswalk Options: AVEIR™ DR Dual Chamber LP System Programming

#### PROGRAMMING

CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 NATIONAL MEDICARE AVERAGE
93279*	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system or leadless pacemaker system in one cardiac chamber	.65* (.98*)	\$66 (\$99*)
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minute face-to-face time with physician or other qualified health care professional	0.91	\$49
95984+	Each additional 15 minutes (List separately in addition to code for primary procedure)	0.8	\$43

\*Provider can report 2 units; second unit will be discounted to 50%; reimbursement will adjust to 1.5 units

+Can only be reported in conjunction with CPT 95983

Note: The Category I CPT<sup>+</sup> codes represented in the above tables are provided for convenience for illustrative purposes only and are not meant to be all-inclusive. Physicians are responsible for providing all information payers may require in support of a claim including selecting the appropriate Category I CPT<sup>+</sup> code comparator and for explaining how the work involved, including the time and complexity of the procedure and the practice expense, is similar to the procedure taking place.

Please note that where a Category III code is available it MUST be reported. Any comparator CPT<sup>‡</sup> code identified should be included only in the supporting documentation submitted with the claim.

	RO MEDICARE COVERAGE MED	ICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING   REFERENCES   CLOSING FORMS
AVEIR <sup>TM</sup> VR Ventr	icular Leadless Pacemaker System		AVEIR™ DR Dual Chambei	r Leadless Pacemaker System
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

### SAMPLE CMS 1500 FORM AVEIR™ DR Dual Chamber LP FOR ILLUSTRATIVE PURPOSES ONLY

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ATTENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TOINSUR	b har	7. INSURED'S ADDRESS (No., Street)	
Y a	TATE 8. RESERVED FOR NUCC USE	nar	GTY .	STATE
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limitation, the crosswalk information		2	11. INSURED'S POLICY GROUP OR FECA NUMBER	
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item number 19 due to character lim		1	services described below.	
attachment is permitted. Please refe			For paper claims, the eight-	
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instructions from the payer and not			reported with the prefix of	
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ADDITIONAL CLAM INFORMATION (Designated by MCC)	170, NPI		the eight-digit NCT number	
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r characters.		2	28, TO AL CHARGE 29, AM	
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for CPT 0795T. The entry may be r			\$2500 x 1	
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0795T CROSSWALK TO XXXXX (no		- I		

AVEIR™ Leadless Pacemakers Medicare Reimbursement Guide

	NTRO MEDICARE COVERAGE M	IEDICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING REFERENCES CLOSING
AVEIR™ VR Ventricular Leadless Pacemaker System			AVEIR™ DR Dual Chamber	Leadless Pacemaker System
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE NATIONAL RATE
	INSERTION			
0795T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, (right atrial and right ventricular components)	J1	5224	\$18,585
	REMOVAL			
0798T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	J1	5183	\$3,040
0799T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial component)	J1	5183	\$3,040
0800T	Transcatheter removal of permanent dual chamber leadless pacemaker (right ventricular component)	J1	5183	\$3,040
	REMOVAL AND REPLACEMENT			
0801T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	J1	5224	\$18,585
0802T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial component)	J1	5224	\$18,585
0803T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right ventricular component)	J1	5224	\$18,585

Effective Dates: January 1, 2024 - December 31, 2024

J1: Hospital Part B services paid through a comprehensive APC

<b>→</b> Abbott IN	TRO MEDICARE COVERAGE ME	EDICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING   REFERENCES   CLOSING FORMS
AVEIR™ VR Ventricular Leadless Pacemaker System			AVEIR™ DR Dual Chambe	r Leadless Pacemaker System
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE NATIONAL RATE
	PROGRAMMING AND DEVICE EVALUATION			
0804T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review, and report by physician or other qualified healthcare professional; leadless pacemaker system in dual cardiac chambers	Q1	5741	\$36
	INTERROGATION			
93288	Interrogation device evaluation (in person) with analysis, review and report by physician or other qualified healthcare professional, includes connection, recording, and connection per patient encounter; single, dual or multiple lead pacemaker system, or leadless pacemaker system	Q1	5741	\$36

Effective Dates: January 1, 2024 - December 31, 2024

Q1: STV-Packaged Codes

C Abbott	INTRO MEDICARE COVERAGE M	AEDICARE REIMBURS	EMENT AD	MEDICARE	BILLING FORMS	REFERENCES	CLOSING
AVEIR™ VR Ventricular Leadless Pacemaker System				AVEIR™ DR Dual Chambe	er Leadless Pa	cemaker System	
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL IN	PATIENT	ADDITIONAL CODES	DITIONAL CODES IMPORTANT SAFETY II		ORMATION

ICD-10 PCS CODE	DESCRIPTION		MEDICARE NATIONAL RATE
	AVEIR DR: De Novo Insertion		
X2H63V9+	Insertion of Dual-Chamber Intracardiac Pacemaker into Right Ventricle Percutaneous Approach		\$35,279
X2HK3V9			\$22,262
	AVEIR DR: Upgrade (AR insertion w/ VR Existing)		
X2H63V9		228 with MCC	\$35,279
7200203	Insertion of Dual-Chamber Intracardiac Pacemaker into Right Atrium, Percutaneous Approach	229 without MCC	\$22,262
	AVEIR DR: Upgrade (VR Insertion w/ AR Existing)		
02HK3N7	Insertion of Dual-Chamber Intracardiac Pacemaker into Right Ventricle. Percutaneous Approach	228 with MCC	\$35,279
02111JNZ	msertion of Duat-Chamber intracardiac Facemaker into hight ventricle, Ferculaneous Approach	229 without MCC	\$22,262

Effective Dates: October 1, 2023 - September 30, 2024

C Abbott	INTRO MEDICARE COVERAGE ME	EDICARE REIMBURSE	EMENT AD		BILLING   REFERENCES   CLOSING FORMS
AVEIR™ VR Ventricular Leadless Pacemaker System				AVEIR™ DR Dual Chamber L	eadless Pacemaker System
PHYSICIAN CROSSWALK				ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

### HCPCS Device Category C-Codes

C-CODE	DESCRIPTION				
	LEADLESS PACEMAKERS				
C1899*	1899* Implantable/insertable device, not otherwise classified				
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser				

\*Applies to de novo AVEIR DR procedures, as well as AR upgrades when the patient has an existing VR device.

### ICD-10-CM (International Classification of Diseases, Tenth Revision, Clinical Modification) Diagnosis Codes

Diagnosis codes are used by both hospitals and physicians to document the indication for the procedure. For Cardiac Pacemaker, Implantable Cardioverter Defibrillator (ICD) and Implantable/Insertable Cardiac Monitors (ICM) patients, there are many possible diagnosis code scenarios and a wide variety of possible combinations. The possible scenarios and combinations are too numerous to capture in this document. The customer should check with their local carriers or intermediaries and should consult with legal counsel or a financial, coding or reimbursement specialist for coding, reimbursement or billing questions related to ICD-10-CM diagnosis codes. Diagnosis is the sole responsibility of the physician and reimbursement support provided is not intended to affect the physician's independent clinical judgment.

### **Commercial (Private) Payers**

Coverage for leadless pacemakers varies by payer policy.

We encourage providers to contact non-Medicare payers to confirm coverage prior to performing the procedure.

C Abbott	INTRO MEDICARE COVERAGE MEI	DICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING REFERENCES CLOSING
AVEIR <sup>TM</sup> VR Ventricular Leadless Pacemaker System			AVEIR™ DR Dual Chamber I	Leadless Pacemaker System
PHYSICIAN CROSSWALK	HOSPITAL OUTPATIENT	HOSPITAL INPATIENT	ADDITIONAL CODES	IMPORTANT SAFETY INFORMATION

#### 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>™</sup> 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<sup>TM</sup> 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, 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, 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 pacing and/or sessing due to dislodgement or mechanical malfunction of the LP (non-battery related), Loss of capture or sensing due to embolization of desired LP function due to electrical interference, either electromyogenic or electromagnetic, Battery malfunction/ premature battery depletion, Device-related complications include, but are not limited to: Vascular access complications; such as perforation, dissection, puncture, groin pain, Bleeding or hematoma, Thrombosmolism, Air embolism, Local and systemic infection, Peripheral nerve damage. General surgery risks and complications from comorbidities; such as hypotension, dyspnea, respiratory failure, spncope, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death.

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C Abbott	INTRO	MEDICARE COVERAGE	MEDICARE REIMBURSEMENT	MEDICARE ADDITIONAL REIMBURSEMENT	BILLING FORMS	REFERENCES	CLOSING
		AVEI	R™ DR Dual Chamber Leadles	s Pacemaker System			

### MEDICARE ADDITIONAL PAYMENT

Medicare provides a pathway for additional device reimbursement when certain new medical technologies are used for eligible cases on Medicare beneficiaries in the hospital inpatient and outpatient settings\*. The payment pathway in the hospital inpatient setting is the new technology add-on payment (NTAP) pathway. The purpose of NTAP is to ensure Medicare beneficiaries' access to technologies that are too new to be well represented in the data CMS uses to set rates under Medicare's Inpatient Prospective Payment System (IPPS). In other words, NTAP payments are intended to minimize cost and payment barriers that would otherwise inhibit the adoption of new, outcome-improving technologies for Medicare beneficiaries. A criterion for NTAP applications is that the new medical technology represents a substantial clinical improvement over current therapy options. CMS determined the AVEIR<sup>TM</sup> DR Dual Chamber Leadless Pacemaker (LP) met this criterion.

NTAP payments will be available when the AVEIR<sup>TM</sup> DR Dual Chamber LP is used on traditional Medicare beneficiaries for eligible cases in the hospital inpatient setting. In addition, CMS announced that the AVEIR<sup>TM</sup> DR Dual Chamber LP maps to Medicare Severity Diagnosis Related Group (MS-DRGs) 228 and 229 for inpatient hospital services\*\*.

\*CMS 2022; Process and Information Required to Determine Eligibility of Drugs, Biologicals, and Radiopharmaceuticals for Pass-Through Payment Status and New Technology Ambulatory Payment Classification (APC). \*\*FY2024 IPPS Final Rule; US Centers for Medicare and Medicaid Services. FY 2024 IPPS Final Rule Home Page | CMS.

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## Hospital Inpatient – New Technology Add-On Payment (NTAP)

The NTAP reimburses procedures performed in the hospital inpatient setting for costs related to their use of eligible new technologies in addition to the prospective diagnosis related group (MS-DRG) payment. The NTAP amount is the lesser of 65 percent of the cost of the new medical technology or 65 percent of the amount by which the costs of the case exceed the standard MS-DRG payment.

#### NTAP Payment Example (does not represent any known hospital)

	DESCRIPTION		CALCULATION
	Hospital Charges	۸	
	(entire hospital stay, including device)	A	
	Hospital Inpatient Charge Ratio	D 228 E C F E G H Lesser	
	(published by Medicare; hospital specific)		
	Total Hospital Case Cost	С	A X B
	Hospital Specific Reimbursement MS-DRG 228 or 229	D	228 or 229
NTAP ELIGIBILITY	Hospital Case Cost Minus MS-DRG Payment		C - D
	Hospital Charges (entire hospital stay, including device) Hospital Inpatient Charge Ratio (published by Medicare; hospital specific) Total Hospital Case Cost Hospital Case Cost Hospital Specific Reimbursement MS-DRG 228 or 229 Hospital Case Cost Minus MS-DRG Payment (hospital case cost must exceed MS-DRG payment) 65% of Hospital Case Cost Minus MS-DRG Payment 65% of New Medical Technology (set by Medicare during NTAP application process) NTAP Payment Amount	L	C-D
	65% of Hospital Case Cost Minus MS-DRG Payment	F	E X .65
NTAP PAYMENT	65% of New Medical Technology	C	
NIAP PAIMENT	(set by Medicare during NTAP application process)	G	
	NTAP Payment Amount	Н	Lesser of F and G
TOTAL REIMBURSEMENT	NTAP Payment + MS-DRG 228		D+H

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MEDICARE COVERAGE INTRO

MEDICARE REIMBURSEMENT

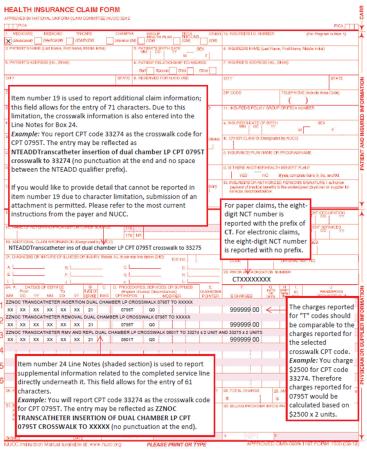
MEDICARE ADDITIONAL REIMBURSEMENT

REFERENCES CLOSING

AVEIR<sup>™</sup> VR Ventricular Leadless Pacemaker System

AVEIR<sup>TM</sup> DR Dual Chamber Leadless Pacemaker System

### SAMPLE CMS 1500 FORM AVEIR<sup>™</sup> VR Ventricular LP FOR ILLUSTRATIVE PURPOSES ONLY



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AVEIR<sup>™</sup> VR Ventricular Leadless Pacemaker System

AVEIR<sup>TM</sup> DR Dual Chamber Leadless Pacemaker System

# SAMPLE CMS UB-04 FORM AVEIR™ VR Ventricular LP FOR ILLUSTRATIVE PURPOSES ONLY

1		2			3a PAT. CNTL #		.4	TYPE OF BILL
					b. MED. REC. #			
					5 FED. TAX NO.	6 STATEMENT CO FROM	VERS PERIOD 7 THR OUGH	
				h h				
8 PATIENT	NAME a		9 PATIENT ADDRESS a		12		20 20	
b	***		d			c d		e
10 BIRTHDA	ATE 11 SEX 12 DATE	ADMISSION 13 HR 14 TYPE 15 SRC 16	OHR 17 STAT 18 19 20	CONDITION C 21 22 23	ODES 24 25	29 A0 26 27 28 STA	CDT 30	down d
			30					
31 OCC CODE	URRENCE 32 OCCURREN DATE CODE D	ICE 33 OCCURRENCE ATE CODE DATE	34 OCCURRENCE 35 CODE DATE CODE	OCCURRENCE	SPAN 36 THROUGH CC	CCCURRENCE S	PAN 37 THROUGH	
0000	0.000	0000 0000		1100	in in its court	11100		
38	ll		Q0 modifier reported	39 VALUE C CODE AMO	ODES 40 UNT CODE	VALUE CODES AMOUNT	41 VALUE CODES CODE AMOUNT	ŝ
						1000000	JOBE AMBORT	
			on nospital	D4 0595.				
			outpatient claims			4 value code + 8-		
					NO	CT number is requ	uired	
								1
42 REV. CD.	43 DESCRIPTION		44 HCPCS / RATE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGE	ES 49
			0795T Q0					_
						1		

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AVEIR<sup>TM</sup> DR Dual Chamber Leadless Pacemaker System

### SAMPLE CMS UB-04 FORM (Continued..) AVEIR™ VR Ventricular LP FOR ILLUSTRATIVE PURPOSES ONLY

PAGE OF		CREATION	DATE	TOTAL		1	1
PAYER NAME	51 HEALTH PLAN	ID SC REL INFO	53 ASG BEN 54 PRIOR PAYN	1EN1S 55EST.	AMOUNT DUE	56 NPI	
						57	
					2	OTHER	
					2	PRV ID	
NSURED'S NAME	59 P. REL	60 INSURED'S UNIQUE ID		61 GROUP NAME		62 INSURANCE GRC	IUP NO.
		1			1	5	
TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL N	IUMBER		65 EMPLOYER N	AME		
Z00.6	3 C	D	E	F	G	H	68
		M	N	0	P	Q	
ADMIT 70 PATIENT DX REASON DX	b	C 71 PPS CODE	72 ECI	a	b	C	73
PRINCIPAL PROCEDURE a. OTH CODE DATE CODE	IER PROCEDURE DATE	b. OTHER PROCEDU CODE	RE 75 DATE 75	76 AT TENDING	NPI	QUAL	
				LAST	l'a.	FIRST	
OTHER PROCEDURE d. OTH CODE DATE CODE	ER PROCEDURE DATE	e. OTHER PROCEDU CODE	RE DATE	77 OPERATING	NPI	QUAL	
				LAST		FIRST	
REMARKS	81CC a		J.	78 OTHER	NPI	QUAL	
HEMARNS	b			LAST		FIRST	I
	D D						
HE MIAHAS	c			79 OTHER	NPI	QUAL	

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AVEIR<sup>TM</sup> DR Dual Chamber Leadless Pacemaker System

### SAMPLE CMS 1500 FORM AVEIR™ DR Dual Chamber LP FOR ILLUSTRATIVE PURPOSES ONLY

T BCA		PICA T		
MEDICARE MEDICAID TRICARE CHAMPYA GROUP HEATH PLANECA	OTHER 19. INSURED'S LO. NUMBER	(For Program in Item 1)		
(Madecarad) (Medicaldd) (DAMCOD) (Mamber Dat) (DMCCAR) ATTENT'S NAME (Last Name, Riet Name, Midde Nited) S. PATTENT'S BIRTH DATE (95)	004			
	4. INSURED'S NAME (Last Name, F	inst Name, Middle Initial)		
ATIENT'S ADDRESS (No., Street) 6. PATIENT RELATIONSHIP TO INSURED	7. INSURED'S ADDRESS (No., She	10		
Sait Spouse Child Con	× 🗆 🗌			
Y STATE 8. RESERVED FOR NUCC USE	CITY	STATE		
	ZIP CODE T			
Item number 19 is used to report additional claim information;	219 0006	ELEPHONE (Include Area Code)		
this field allows for the entry of 71 characters. Due to this	D. 11. INSURED'S POLICY GROUP OF	A FECA NUMBER		
imitation, the crosswalk information is also entered into the				
Line Notes for Box 24.	a. INSURED'S DATE OF BRTH MM   DO   YY	SEX		
Example: You report CPT code 33274 as the crosswalk code for		M		
CPT 0795T. The entry may be reflected as	(State) b. OTHER CLAIM ID (Designated by	NVGQ		
NTEADDTranscatheter insertion of dual chamber LP CPT 0795T	C. INSURANCE PLAN NAME OF PE	OSRAMINAME		
crosswalk to 33274 (no punctuation at the end and no space				
between the NTEADD qualifier prefix).	0. IS THERE ANOTHER HEALTH B			
		es, complete items 9, 9a, and 9d.		
If you would like to provide detail that cannot be reported in	13. INSURED'S OR AUTHORIZED F payment of medical benefits to th services described below.	e undersigned physician or supplier for		
item number 19 due to character limitation, submission of an	service described below.			
attachment is permitted. Please refer to the most current	For paper claims, th	e eight-		
instructions from the payer and NUCC.	digit NCT number is	digit NCT number is		
	reported with the p	refix of		
172 NR	CT. For electronic cl	aims,		
ADDITIONAL CLAIM INFORMATION (Designated by MCC)	the eight-digit NCT i	number 🚌		
TEADDTranscatheter ins of dual chamber LP CPT 0795T crosswalk to 33275	is reported with no	prefix.		
DLAGNOBIS OF NATURE OF ILLINESS OF INJURY. Relate AL to service line below (24E) ICD Ind.	0.08	TONAL REP. NO.		
	23. PRICE AN HORIZATION NUM	69		
F R H	CTXXXXXXXX			
A. DATE(S) OF SERVICE     B. C. D. PROCEDURES, SERVICES, OF SUPPLIES     From     To     R/0E 0F     emain trusted Croumstances)     DU	E F. G. H	L L J. BT ID RENDERING		
DD YY MM DD YY SERVICE EMG CPT/HCPCS MODIFIER P	KGNOSIS DAYS DAYS DAYS DAYS DAYS DAYS DAYS DAY	ID. PENDERING		
NOC TRANSCATHETER INSERTION DUAL CHAMBER LP CROSSWALK 0795T TO XXXXX		The charges reporte		
X XX XX XX XX XX 21 0795T Q0 0795T Q0 0795T Q0 0795T Q0 0795T Q0 0795T Q0 0795T TO XXXXX	999999 00 <	for "T" codes should		
X XX XX XX XX XX 21 0798T Q0	999999 00	be comparable to th		
NOC TRANSCATHETER RMV AND REPL DUAL CHAMBER LP CROSSWALK 0801T TO 33274 x 2		charges reported for		
( XX XX XX XX XX 21 0801T Q0	999999 00	the selected		
a service a service se	_ I _ I _ I	crosswalk CPT code.		
there exists a 24 line Nation (she did another) is used to see at		Example: You charge		
Item number 24 Line Notes (shaded section) is used to report		\$2500 for CPT code		
supplemental information related to the completed service lin	e	33274. Therefore		
directly underneath it. This field allows for the entry of 61		charges reported for		
characters. Example: You will report CPT code 33274 as the crosswalk cod	2 28. TOTAL CHARGE 29. A	0795T would be		
	e a a a a a a a a a a a a a a a a a a a	calculated based on		
for CPT 0795T. The entry may be reflected as ZZNOC		\$2500 x 2 units.		
		\$2500 x 2 units.		

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### SAMPLE CMS UB-04 FORM AVEIR™ DR Dual Chamber LP FOR ILLUSTRATIVE PURPOSES ONLY

		2			Ba PAT. DNTL #		4	4 TYPE OF BILL
				1	D. MED. REC. #			
					5 FED. TAX NO.	6 STATEMENT CO FROM	VERS PERIOD 7 THR OUGH	
PATIENT NAME	a		9 PATIENT ADDRESS a	-40			76	
	24X		d			c d		e
BIRTHDATE	11 SEX 12 DATE	AEMISSION E 13 HR 14 TYPE 15 SRO	16 DHR 17 STAT 18 19 20	CONDITION CO 21 22 23	DES 24 25	26 27 28 ST/	CDT 30 ATE	
			30					
OCCURREN		ENCE 33 OCCURREN DATE CODE DA	CE 34 OCCURRENCE 35 TE CODE DATE CODI	OCCURRENCE FROM	SPAN 36 THROUGH CC	CCCURRENCE S	PAN 37 THROUGH	
			Q0 modifier reported	39 VALUE CO CODE AMOU	DES 40 NT CODE	VALUE CODES AMOUNT	41 VALUE CODES CODE AMOUNT	.s
				<sup>a</sup> D4 05932				
				b		4 value code + 8-	digit	÷
			outputient claims	c		T number is req		÷
				d			ulleu	
2 REV. CD. 43 D	ESCRIPTION		44 HCPCS / RATE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGE	ES 49
			0795T Q0					
					-			

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MEDICARE REIMBURSEMENT

MEDICARE ADDITIONAL REIMBURSEMENT

REFERENCES

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### SAMPLE CMS UB-04 FORM (Continued..) AVEIR™ DR Dual Chamber LP FOR ILLUSTRATIVE PURPOSES ONLY

	PAGE OF		CREATION	DATE	TOTAL			
PAYER	NAME	51 HEALTH PLAN	1.0.0.0.0			AMOUNT DUE	56 NPI	42
-							57	
						1	OTHER	
							PRV ID	
NSURE	ED'S NAME	59 P. REL	60 INSURED'S UNIQUE ID		61 GROUP NAME		62 INSURANCE GROU	JP NO.
TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL	64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME			
	Z00.6	BC	D	E	F	G	-	68
		K L	I IN	N	0	P	Q	
ADMIT DX	70 PATIENT REASON DX	i b	71 PPS CODE	72 ECI	a	b	C	73
C	PRINCIPAL PROCEDURE a. COD	OTHER PROCEDURE E DATE	b. OTHER PROCED CODE	DATE 75	76 ATTENDING	NPI	QUAL	
					LAST		FIRST	
c	OTHER PROCEDURE d. COD	DTHER PROCEDURE	e. OTHER PROCED CODE	URE DATE	77 OPERATING	NPI	QUAL	
		level 1			LAST		FIRST	
REMAR	IKS	81CC a			78 OTHER	NPI	QUAL	
		b			LAST		FIRST	
		c			79 OTHER	NPI	QUAL	
		d			LAST		FIRST	

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