Abbott

Cardiac Rhythm Management

AVEIR™ LEADLESS PACEMAKER SYSTEM

MEDICARE PHYSICIAN CODING & PAYMENT GUIDE

Effective January 1st, 2025

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AVEIR™ VR Ventricular Leadless Pacemaker System Introduction

The AVEIR™ 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™ 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™ Introducer and Delivery Catheter.

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AVEIR™ VR de novo

Physician National

CPT‡ CODE	DESCRIPTION	WORK RVU	MEDICARE NATIONAL RATE	
			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	$456	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	$483	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*	$64
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	$19*	$54
	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*	$43

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

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.

Effective Dates: January 1, 2025 - December 31, 2025

AVEIR™ AR Atrial Leadless Pacemaker System Introduction

The AVEIR™ AR Atrial Leadless Pacemaker (LP) System is a right atrial pacing system implanted in a patient's right atrial chamber of the heart. As a leadless pacemaker system, the AVEIR™ AR Atrial LPs do not need a connector, pacing lead, or pulse generator pocket. The LP is delivered percutaneously via the femoral vein through an AVEIR™ Introducer and Delivery Catheter.

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AVEIR™ AR de novo

FDA approved June 29, 2023, the AVEIR™ AR Atrial Leadless Pacemaker (LP) is capable of pacing and sensing in the right atrium. Atrial pacing indications include sinus mode dysfunction and normal AV and intraventricular conduction systems.

The American Medical Association (AMA) has approved a series of Category III CPT‡ codes to report right atrial single chamber leadless pacemaker procedures. The Category III CPT‡ codes became effective on January 1, 2024. 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 right atrial single chamber leadless pacemaker system procedures when performed consistent with the product's labeling.

Reporting a Category III CPT‡ Code

Physician Services Considerations for Atrial Single Chamber Leadless Pacemaker Procedures

Category III CPT‡ codes do not have an assigned payment rate (established Relative Value Unit (RVU)) in Medicare's physician fee schedule, and therefore private insurers do not have assignment of RVUs to use as a basis for setting physician payment. Since Category III CPT‡ 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 Category III CPT‡ code for right atrial single 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 CPT‡ 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‡ code for a comparable procedure while also noting any and all differences with the services provided for the right atrial single chamber leadless pacemaker procedure with an increase or decreased percentage of the work/time associated with the referenced comparable procedure

AVEIR™ AR de novo

3. Customized Letter of Medical Necessity for the patient receiving the procedure
4. Copy of FDA Approval Letter
5. Copy of published clinical data

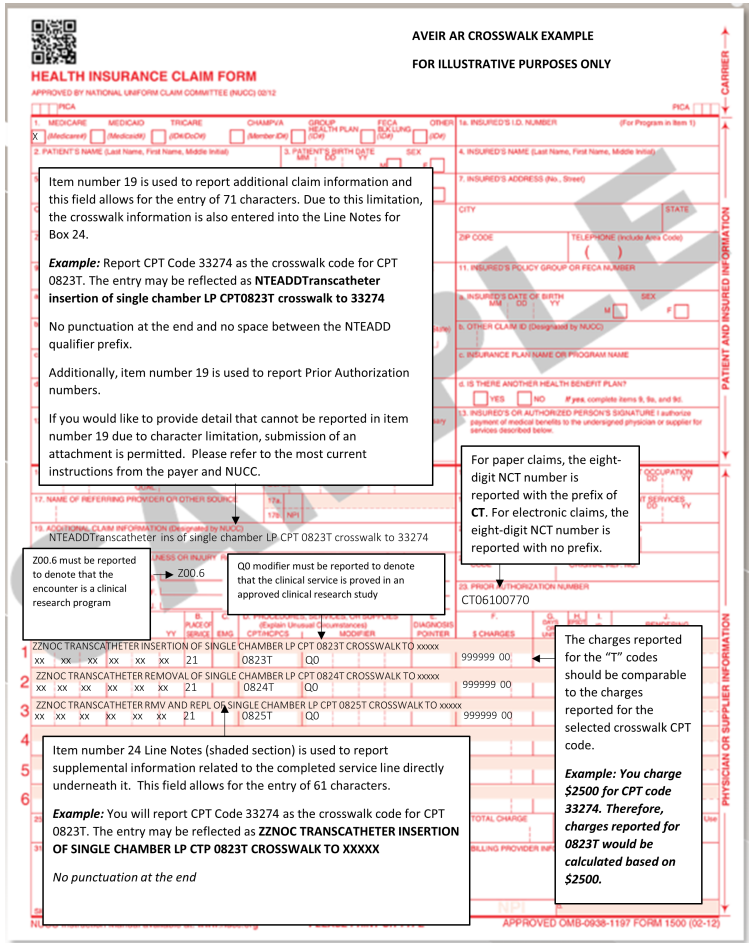
Considerations when choosing a comparable procedure to reference in supporting documentation

Physicians are encouraged to identify comparable crosswalk Category I CPT‡ codes to reference in supporting documentation provided with the claim submission when billing for leadless pacemaker procedures. 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.

Considerations when reporting a coding crosswalk on a claim

Physicians should report the appropriate Category III CPT‡ 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). An example of a crosswalk comparison is below.

AVEIR™ AR de novo



AVEIR™ AR Atrial LP System Category III CPT‡ Codes

INSERTION

CPT‡ CODE	DESCRIPTION	WORK RVU
0823T	Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	N/A

REMOVAL

CPT‡ CODE	DESCRIPTION	WORK RVU
0824T	Transcatheter removal of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography), when performed	N/A

REMOVAL & REPLACEMENT

CPT‡ CODE	DESCRIPTION	WORK RVU
0825T	Transcatheter removal and replacement of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	N/A

PROGRAMMING

CPT‡ CODE	DESCRIPTION	WORK RVU
0826T	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, leadless pacemaker system in single-cardiac chamber	N/A

Effective Dates: January 1, 2025 - December 31, 2025

Category III Coding Crosswalk Examples

When considering comparable procedures, the following procedures may require similar effort, expertise, time and resource utilization. It is strongly encouraged that physicians include operative notes detailing the effort and time of the procedure to support adequate reimbursement.

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

Coding Crosswalk Options: AVEIR™ AR Atrial Leadless Pacemaker - Insertion

Potential CPT‡ code crosswalks for 0823T			
CPT‡ CODE	DESCRIPTION	2025 WORK RVU	2025 NATIONAL MEDICARE AVERAGE
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	7.8	$456

Coding Crosswalk Options: AVEIR™ AR Atrial Leadless Pacemaker - Removal

Potential CPT‡ code crosswalks for 0824T			
CPT‡ CODE	DESCRIPTION	2025 WORK RVU	2025 NATIONAL MEDICARE AVERAGE
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed	8.59	$483

Effective Dates: January 1, 2025 - December 31, 2025

Category III Coding Crosswalk Examples

Coding Crosswalk Options: AVEIR™ AR Atrial LP System Removal & Replacement

Potential CPT‡ Code Crosswalks for 0825T			
CPT‡ CODE	DESCRIPTION	2025 WORK RVU	2025 NATIONAL MEDICARE AVERAGE
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	7.8	$456

Coding Crosswalk Options: AVEIR™ AR Atrial Leadless Pacemaker - Programming

Potential CPT‡ Code Crosswalks for 0826T			
CPT‡ CODE	DESCRIPTION	2025 WORK RVU	2025 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	0.65	$64

Note: The Category I CPT‡ code 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‡ 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 CPT‡ code is available it MUST be reported. Any comparator CPT‡ code identified should be included only in the supporting documentation submitted with the claim.

Effective Dates: January 1, 2025 - December 31, 2025

AVEIR™ DR Dual Chamber Leadless Pacemaker System Introduction

The AVEIR™ 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™ 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™ Introducer and Delivery Catheter.

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AVEIR™ DR de novo & Upgrades to DR

FDA approved June 29, 2023, the AVEIR™ 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‡ 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)

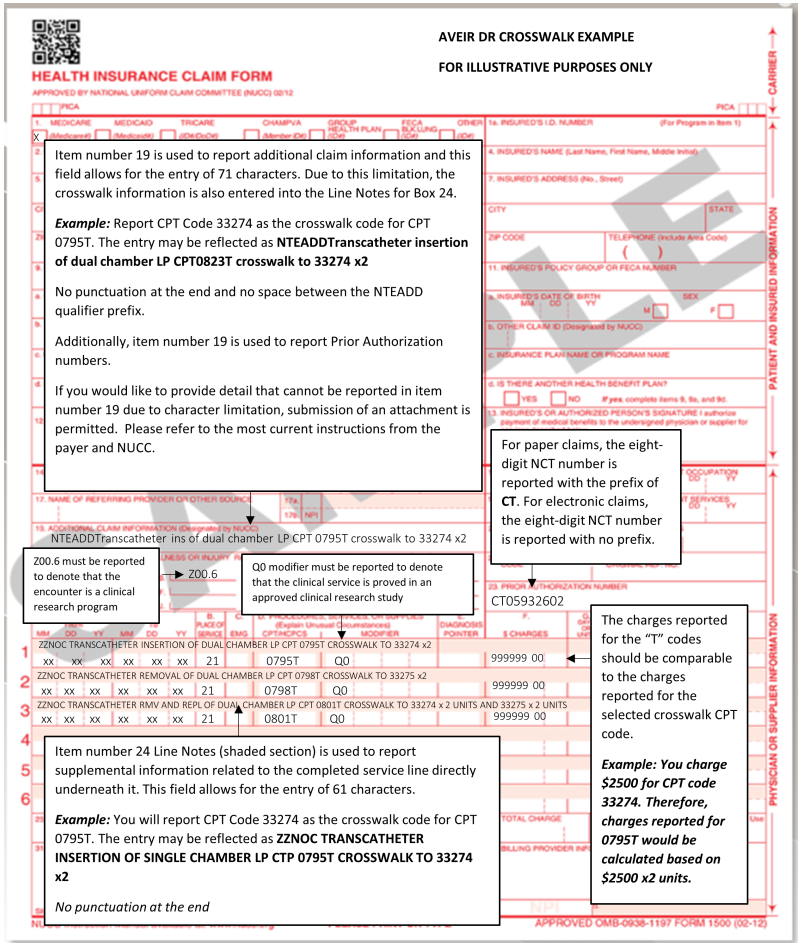
1. A cover letter describing the services rendered and why the service was needed
2. Copy of operative report that details the procedure including provider's time and effort during procedure
    - Time, effort and equipment necessary to perform procedure
    - Include the relevant crosswalk Category I CPT‡ 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

AVEIR™ DR de novo & Upgrades to DR

Physicians are encouraged to identify comparable crosswalk Category I CPT‡ codes to reference in supporting documentation provided with the claim submission when billing for Dual Chamber Leadless Pacemaker procedures. Since the Category III CPT‡ 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‡ 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.

AVEIR™ DR de novo & Upgrades to DR



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‡ CODE	DESCRIPTION	WORK RVU
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)	N/A
0797T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, right ventricular pacemaker component (when part of a dual chamber leadless pacemaker system)	N/A

Effective Dates: January 1, 2025 - December 31, 2025

AVEIR™ 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

Effective Dates: January 1, 2025 - December 31, 2025

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 crosswalks for 0795T

CPT‡ CODE	DESCRIPTION	2025 WORK RVU	2025 NATIONAL MEDICARE AVERAGE
33274*	Insertion or replacement of a permanent leadless pacemaker, right ventricular	7.8 (11.7*)	$456 ($684*)
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	$740

*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

Potential CPT‡ code crosswalks for 0796T, 0797T

CPT‡ CODE	DESCRIPTION	2025 WORK RVU	2025 NATIONAL MEDICARE AVERAGE
33274	Insertion or replacement of a permanent leadless pacemaker, right ventricular	7.8	$456

Effective Dates: January 1, 2025 - December 31, 2025

Category III Coding Crosswalk Examples

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

REMOVAL

Potential CPT‡ Code Crosswalks for 0798T, 0799T, 0800T			
CPT‡ CODE	DESCRIPTION	2025 WORK RVU	2025 NATIONAL MEDICARE AVERAGE
33275*	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance, when performed.	8.59 (12.88*)	$483 ($724*)
33236^	Removal of permanent epicardial pacemaker and electrodes by thoracotomy; single lead system, atrial or ventricular	12.73	$756

*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™ DR Dual Chamber LP System Removal & Replacement

REMOVAL & REPLACEMENT

Potential CPT‡ Code Crosswalks for 0801T, 0802T, 0803T			
CPT‡ CODE	DESCRIPTION	2025 WORK RVU	2025 NATIONAL MEDICARE AVERAGE
33274*	Insertion or replacement of a permanent leadless pacemaker, right ventricular	7.8 (11.7*)	$456 ($684*)

*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.

Effective Dates: January 1, 2025 - December 31, 2025

Category III Coding Crosswalk Examples

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

PROGRAMMING

Potential CPT‡ Code Crosswalks for 0804T

CPT‡ CODE	DESCRIPTION	2025 WORK RVU	2025 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*)	$64 ($96*)
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	$48
95984+	Each additional 15 minutes (List separately in addition to code for primary procedure)	0.8	$42

*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‡ code 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‡ 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‡ code identified should be included only in the supporting documentation submitted with the claim.

Effective Dates: January 1, 2025 - December 31, 2025

AVEIR™ VR Ventricular Leadless Pacemaker (LP) System

IMPORTANT SAFETY INFORMATION

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The Aveir™ Leadless Pacemaker system is indicated for 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 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™ 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).

AVEIR™ AR Atrial Leadless Pacemaker (LP) System

IMPORTANT SAFETY INFORMATION

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The AVEIR™ Leadless Pacemaker system is indicated for management of one or more of the following permanent conditions: Syncope, Pre-syncope, Fatigue, Disorientation. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-chamber pacing is indicated for patients exhibiting: Sick sinus syndrome, Chronic, symptomatic second- and third-degree AV block , Recurrent Adams-Stokes syndrome, Symptomatic bilateral bundle-branch block when tachyarrhythmia and other causes have been ruled out. Atrial pacing is indicated for patients with: Sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular pacing is indicated for patients with: Significant bradycardia and normal sinus rhythm with only rare episodes of AV block or sinus arrest, Chronic atrial fibrillation, Severe physical disability. MR Conditional: The AVEIR Leadless Pacemaker is conditionally safe for use in the MRI environment and according to the instructions in the MRI-Ready Leadless System Manual.

Intended Use: The AVEIR Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle and/or right atrium. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy within the implanted chamber for the target treatment group. The LP is also intended to operate optionally with another co-implanted LP to provide dual-chamber pacing therapy. The AVEIR™ Delivery Catheter is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation includes implanting an LP within the target chamber of the heart.

Contraindications: Use of the AVEIR Leadless Pacemaker is contraindicated in these cases:

- Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.
- Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing.
- Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor driven rates.
- Use is contraindicated in patients with an implanted vena cava filter or mechanical tricuspid valve because of interference between these devices and the delivery system during implantation.
- Persons with known history of allergies to any of the components of this device may suffer an allergic reaction to this device. Prior to use on the patient, the patient should be counseled on the materials (listed in the Product Materials section of the IFU) contained in the device and a thorough history of allergies must be discussed.

Adverse Events: Potential complications associated with the use of the AVEIR Leadless Pacemaker system are the same as with the use of single or dual chamber pacemakers with active fixation pacing leads including, but not limited to: Cardiac perforation, Cardiac tamponade, Pericardial effusion, Pericarditis, Endocarditis, Valve damage or regurgitation, Heart failure, Pneumothorax/hemothorax, Cardiac arrhythmias, Diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation, Palpitations, Hypotension, Syncope, Cerebrovascular accident, Infection, Hypersensitivity reaction to device materials, contrast media, medications, or direct toxic effect of contrast media on kidney function, Pacemaker syndrome, Inability to interrogate or program the LP due to programmer or LP malfunction, Intermittent or complete loss of capture, pacing or sensing (non-battery related), Oversensing, Increased capture threshold, Inappropriate sensor response, Corrupted, intermittent, or loss of i2i communications, Interruption of desired LP function due to electrical interference, either electromyogenic or electromagnetic, Battery malfunction/ premature battery depletion, Device-related complications (Premature deployment, Device dislodgement/embolization of foreign material, Inability to release/re-dock of the LP from the catheter, Helix distortion), Additional surgery or intervention, Death. As with any percutaneous catheterization procedure, potential complications include, but are not limited to: Vascular access complications; such as perforation, dissection, puncture, groin pain, Bleeding or hematoma, Thrombus formation, Thromboembolism, Air embolism, Local and systemic infection, Peripheral nerve damage. General surgery risks and complications from comorbidities; such as dyspnea, respiratory failure, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death.

AVEIR™ DR Dual Chamber Leadless Pacemaker (LP) System

IMPORTANT SAFETY INFORMATION

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The AVEIR™ Leadless Pacemaker system is indicated for management of one or more of the following permanent conditions: Syncope, Pre-syncope, Fatigue, Disorientation. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-chamber pacing is indicated for patients exhibiting: Sick sinus syndrome, Chronic, symptomatic second- and third-degree AV block , Recurrent Adams-Stokes syndrome, Symptomatic bilateral bundle-branch block when tachyarrhythmia and other causes have been ruled out. Atrial pacing is indicated for patients with: Sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular pacing is indicated for patients with: Significant bradycardia and normal sinus rhythm with only rare episodes of AV block or sinus arrest, Chronic atrial fibrillation, Severe physical disability. MR Conditional: The AVEIR Leadless Pacemaker is conditionally safe for use in the MRI environment and according to the instructions in the MRI-Ready Leadless System Manual.

Intended Use: The AVEIR Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle and/or right atrium. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy within the implanted chamber for the target treatment group. The LP is also intended to operate optionally with another co-implanted LP to provide dual-chamber pacing therapy. The AVEIR™ Delivery Catheter is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation includes implanting an LP within the target chamber of the heart.

Contraindications: Use of the AVEIR Leadless Pacemaker is contraindicated in these cases:

- Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.
- Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing.
- Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor driven rates.
- Use is contraindicated in patients with an implanted vena cava filter or mechanical tricuspid valve because of interference between these devices and the delivery system during implantation.
- Persons with known history of allergies to any of the components of this device may suffer an allergic reaction to this device. Prior to use on the patient, the patient should be counseled on the materials (listed in the Product Materials section of the IFU) contained in the device and a thorough history of allergies must be discussed.

Adverse Events: Potential complications associated with the use of the AVEIR Leadless Pacemaker system are the same as with the use of single or dual chamber pacemakers with active fixation pacing leads including, but not limited to: Cardiac perforation, Cardiac tamponade, Pericardial effusion, Pericarditis, Endocarditis, Valve damage or regurgitation, Heart failure, Pneumothorax/hemothorax, Cardiac arrhythmias, Diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation, Palpitations, Hypotension, Syncope, Cerebrovascular accident, Infection, Hypersensitivity reaction to device materials, contrast media, medications, or direct toxic effect of contrast media on kidney function, Pacemaker syndrome, Inability to interrogate or program the LP due to programmer or LP malfunction, Intermittent or complete loss of capture, pacing or sensing (non-battery related), Oversensing, Increased capture threshold, Inappropriate sensor response, Corrupted, intermittent, or loss of i2i communications, Interruption of desired LP function due to electrical interference, either electromyogenic or electromagnetic, Battery malfunction/ premature battery depletion, Device-related complications (Premature deployment, Device dislodgement/embolization of foreign material, Inability to release/re-dock of the LP from the catheter, Helix distortion), Additional surgery or intervention, Death. As with any percutaneous catheterization procedure, potential complications include, but are not limited to: Vascular access complications; such as perforation, dissection, puncture, groin pain, Bleeding or hematoma, Thrombus formation, Thromboembolism, Air embolism, Local and systemic infection, Peripheral nerve damage. General surgery risks and complications from comorbidities; such as dyspnea, respiratory failure, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death.

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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 vascular.eifu.abbott or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

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