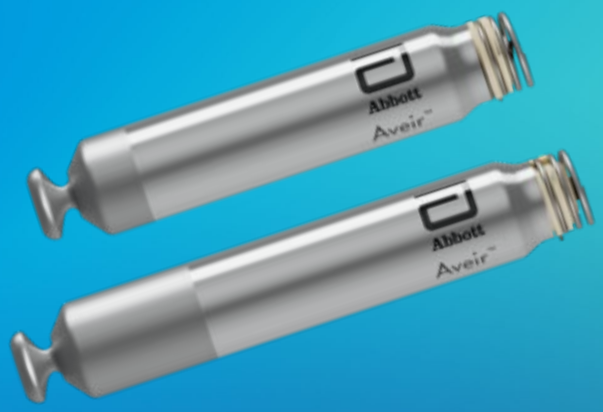
HEALTH ECONOMICS & REIMBURSEMENT

AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER SYSTEM

Transitional Pass-Through (TPT) Payment Overview



OVERVIEW

This document provides reference material related to general guidelines for physician and hospital services coverage, payment and coding considerations for dual chamber leadless pacemaker procedures using the AVEIR™ DR Dual Chamber Leadless Pacemaker System when performed consistent with its labeling.

Disclaimer

This material and the information contained herein is for general information purposes only and is not intended, and does not constitute, legal, reimbursement, business, clinical, or other advice. Furthermore, it is not intended to and does not constitute a representation or guarantee of reimbursement, payment, or charge, or that reimbursement or other payment will be received. It is not intended to increase or maximize payment by any payer. Abbott makes no express or implied warranty or guarantee that the list of codes and narratives in this document is complete or error-free. Similarly, nothing in this document should be viewed as instructions for selecting any particular code, and Abbott does not advocate or warrant the appropriateness of the use of any particular code. The ultimate responsibility for coding and obtaining payment/reimbursement remains with the customer. This includes the responsibility for accuracy and veracity of all coding and claims submitted to third-party payers. In addition, the customer should note that laws, regulations, and coverage policies are complex and are updated frequently, and, therefore, the customer should check with its local carriers or intermediaries often and should consult with legal counsel or a financial, coding, or reimbursement specialist for any questions related to coding, billing, reimbursement, or any related issues. This material reproduces information for reference purposes only. It is not provided or authorized for marketing use.

Effective July 1, 2024, a newly created Level II HCPCS Code (C1605) can be used to bill for the AVEIR™ DR Dual Chamber Leadless Pacemaker System. This code describes the actual device in the hospital outpatient setting for Medicare fee for service patients and may be billed in addition to the implant procedure codes described by Category III CPT‡ Codes 0795T and 0801T.

The AVEIR™ DR Dual Chamber Leadless Pacemaker System HCPCS Code Eligible for Transitional Pass-Through Payment:[2]

HCPCS	Description
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation

Medicare determines the incremental TPT payment on a case-by-case basis depending on, among other things, the following

- The amount a **hospital charges for AVEIR™ DR Dual Chamber Leadless Pacemaker System.**
- **Hospital's specific cost-to-charge ratio (CCR) for Implantable Medical Devices**, which Medicare publishes annually and varies for each specific hospital.
- The **device related portion of the relevant HCPCS procedure code**, which is also referred to as the device offset.

ILLUSTRATIVE TPT PAYMENT CALCULATION

FOR ILLUSTRATIVE PURPOSES ONLY

Scenario illustrated is for example only. This does not constitute coding guidance.

	DESCRIPTION		CALCULATION
Transitional Pass-Through (TPT) Payment	Hospital Charge for AVEIR™ DR LP System	A	
	Implantable Device Cost to Charge Ratio (published by Medicare; varies for each specific hospital)	B	
	Hospital Cost for AVEIR™ DR LP System	C	A x B
	Device-Related Portion of APC 5224 (offset)*; (published by Medicare)	D	$11,828
	Transitional Pass-Through Payment	E	C - D
APC Payment	Medicare Reimbursement APC 5224 (hospital specific)	F	
Total Reimbursement	**TPT Payment Amount + Procedure Payment**		**E + F**

*The device offset will change per CMS policy. Per the 2025 Outpatient Prospective Payment System Final Rule, CMS has updated the device offset for C1605 to $11,828.

TPT applies to Traditional Medicare patients only.

FOR ILLUSTRATIVE PURPOSES ONLY (does not represent any known hospital)

Scenario illustrated is for example only. This does not constitute coding guidance.

	DESCRIPTION	CALCULATION		AMOUNT
Transitional Pass-Through (TPT) Payment	Hospital Charge for AVEIR™ DR LP System	A		$77,142
	Implantable Device Cost to Charge Ratio (published by Medicare; varies for each specific hospital)	B		0.35
	Hospital Cost for AVEIR™ DR LP System	C	A x B	$27,000
	Device-Related Portion of APC 5224 (offset)*; (published by Medicare)	D		$11,828
	Transitional Pass-Through Payment	E	C - D	$15,172
APC Payment	Medicare Nat Avg Reimbursement (CY 2024) APC 5224 (hospital specific)	F		$19,071
Total Reimbursement	**TPT Payment Amount + Procedure Payment**		**E + F**	**$34,243**

*The device offset will change per CMS policy. Per the 2025 Outpatient Prospective Payment System Final Rule, CMS has updated the device offset for C1605 to $11,828.

TPT applies to Traditional Medicare patients only.

APPLICABLE AVEIR™ DR CATEGORY III CPT CODES

When utilizing the new device category HCPCS Code C1605 in appropriate cases, it should always be billed with the following Category III CPT‡ Code

CPT‡ CODE*	DESCRIPTION	APC
0795T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, (right atrial and right ventricular components)	5224
0801T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	5224

*The AMA defines CAT III CPT‡ codes, as “a set of temporary codes for emerging technology, services, and procedures[4].” Unlike CAT I CPT‡ Codes, CAT III CPT‡ Codes do not have an assigned payment rate (established RVUs), and private insurers do not have assignment of RVU’s to use as a basis for setting physician payment. Remember, as always, the existence of CAT III Codes does not guarantee payment by payers; reimbursement is subject to decisions of Medicare and commercial payers.

FREQUENTLY ASKED QUESTIONS (FAQ)

1 How long is the TPT payment in place for the AVEIR™ DR Dual Chamber Leadless Pacemaker System?

The TPT payment for AVEIR™ DR Dual Chamber Leadless Pacemaker System is effective July 1, 2024. Medicare allows for TPT payments for up to three years. As such, it is expected the incremental TPT payment will be effective through June 30, 2027.[1]

2 Does the TPT payment apply to cases where patients are upgrading from a single-chamber pacemaker to a dual chamber system?

No, the approved TPT is specific to AVEIR™ DR Dual Chamber Leadless Pacemaker System implants.

3 What procedure codes are eligible for TPT payment in the hospital outpatient setting?

Category III CPT‡ procedure codes 0795T and 0801T are eligible for TPT payment when coded with the correct HCPCS code (C1605).

4 Where can a hospital find its specific cost-to-charge-ratio (CCR) used in the TPT payment calculation?

The provider specific CCRs are part of the Outpatient impact files found on CMS's website at **2025 NFRM OPPS Facility-Specific Impacts**.[6] Please note that CCRs are published annually. Additionally, you may contact your Medicare Administrative Contractor to find out your hospital's CCR for purposes of new technology payments from CMS.

5 What is the device offset?

The device offset is the device related portion of the applicable APC. It is a fixed amount that is published annually by Medicare and can be found in the OPPS Addendum P.[3]

6 What are some Medicare reimbursement/coding considerations for eligible procedures that include the use of AVEIR™ DR Dual Chamber Leadless Pacemaker System in the hospital outpatient setting?

- CED study coding for AVEIR™ DR including the National Clinical Trial (NCT) number for AVEIR™ DR: 05932602
- Appropriate CPT‡ code(s) at the discretion of the provider
- Device HCPCS code C1605 (this code describes the device and may be billed in addition to the implant procedure codes described by Category III CPT‡ codes 0795T and 0801T), and
- Device revenue code when billing for a procedure

7 Does the TPT payment apply to leadless pacemaker cases performed in the inpatient setting or an ambulatory surgery center (ASC)?

No, TPT payment only applies to cases that take place in the hospital outpatient setting. It does not apply to cases that take place in the hospital inpatient setting and ASCs.

Please note that Medicare has published Leadless place-of-services restrictions in transmittal 3815. Medicare will only pay claims for leadless pacemakers when services are provided in Indian Health Service Provider Based Facility, Inpatient Hospital, Outpatient Hospital, and Military Treatment Facility.[5] Therefore, leadless pacemaker procedures aren't covered in the ASC setting by Medicare.

8 Will hospitals receive TPT payment when furnishing the AVEIR™ DR LP System to Medicare Advantage patients or patients with commercial insurance?

No. TPT payment is part of the Medicare methodology for fee-for-service patients only. The payments are not applicable to commercial and Medicare Advantage beneficiaries. Please contact your Medicare Advantage Plan, and other key commercial payers in your market, to discuss their coverage requirements and reimbursement amounts as well as prior authorization requirements applicable to AVEIR™ DR LP system cases.

For reimbursement questions about the AVEIR™ Leadless Pacemaker System, please contact Abbott's Reimbursement Hotline (855-569-6430) or send us an email at LeadlessReimbursement@Abbott.com.

AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER 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.

References

1. July 2024 Update of the Hospital Outpatient Prospective Payment System. https://www.cms.gov/files/document/r12665cp.pdf
2. Centers for Medicare and Medicaid. Medicare Claims Processing Manual Chapter 4: Medicare Claims Processing Manual (hhs.gov)
3. 2025 CMS-1809-FC OPPS Fee Schedule: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1809-fc
4. AMA CPT‡ Category III codes long: CPT‡ Category III codes long descriptors (ama-assn.org) https://www.ama-assn.org/system/files/cpt-category3-codes-long-descriptors.pdf
5. Centers for Medicare and Medicaid Services. Medicare Claims Processing Manual 100-04, Transmittal 3815. National Coverage Determination (NCD20.8.4): Leadless Pacemakers. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3815CP.pdf
6. Centers for Medicare and Medicaid Services. FY 2025 Facility Specific Impact File: 2025 NFRM OPPS Facility-Specific Impacts

Information contained herein for DISTRIBUTION in the U.S. use ONLY.

Abbott

One St. Jude Medical Dr., St. Paul, MN 55117, USA, Tel: 1.651.756.2000

3200 Lakeside Dr., Santa Clara, CA. 95054 USA, Tel: 1.800.227.9902

www.cardiovascular.abbott


Abbott