AVEIR™ VR

Single Chamber Leadless Pacemaker

LATEST FAQ UPDATES

HEALTH ECONOMICS & REIMBURSEMENT

Purpose of this guide

The purpose of this guide is to review the reimbursement landscape for the AVEIR VR Single Chamber Leadless Pacemaker, to include coding, coverage and payment. This content is not all-inclusive, and nothing in this document should be construed as a guarantee by Abbott regarding reimbursement or payment amounts, or that reimbursement or other payment will be received. Please consider that information contained in this document has been gathered and adapted from third-party sources and is subject to change without notice resulting from changes in laws, statutes and regulations. The healthcare provider is ultimately responsible for the accuracy and completeness of all claims submitted to third-party payers. In addition, the provider 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 or reimbursement specialist for any questions related to billing, reimbursement, or any related issue. Please see the FDA-approved label for information relevant to any prescribing decisions.

Need answers regarding AVEIR VR Coverage?

Contact

Please contact Abbott's Field Reimbursement Team and Reimbursement Hotline for further information and guidance.

Email:
leadlessreimbursement@abbott.com

Telephone:
855-569-6430

Available
Monday-Friday 8:00AM CST to 5:00PM CST

Additional Reimbursement Resources and Guides:

Reimbursement & Coding for Aveir VR | Abbott (cardiovascular.abbott).

Find your answers here!

AVEIR VR Coverage

The latest updates

1. Is AVEIR™ VR covered by CMS?

The Centers for Medicare and Medicaid has a National Coverage Determination for leadless pacemakers, Policy 20.8.4.[1] This is a Coverage with Evidence Development 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™ VR, AVEIR™ VR Coverage with Evidence Development study (ACED) to meet these coverage requirements and has obtained approval. The ACED study has a clinical trial number to be utilized only for patients indicated for AVEIR™ VR, 05336877.[2,3]

2. Do I need to pursue pre-authorizations for an AVEIR VR implants or removal?

No Prior Authorization is needed for Medicare fee-for-service patients; however Prior Authorization is typically required for Medicare Advantage and Commercial patients. We recommend that you check your local payer medical policies and requirements to understand whether or not a pre-authorization is required for this procedure. The medical policy will guide you on what clinical criteria your patient should meet in order to be covered through their insurance. The physician's justification as to why this product is medically necessary for a specific patient is typically required by a majority of payers. Please reach out to your local sales representative if you have additional questions regarding the pre-authorization and appeals process, or local medical policy criteria.

3. Is the ACED Study the same as AVEIR VR's FDA Post-Approval Study (PAS)?

No. They are two separate studies with two different NCT numbers. The PAS is a predetermined group of sites participating in a registry that was established to meet post approval data requirements, independent from the CED study. The ACED study is a CMS approved Coverage with Evidence Development Study that is required for CMS coverage. The NCT number (NCT 05336877) assigned to the ACED study is unique to the AVEIR™ VR leadless pacemaker. The inclusion of the unique ACED study NCT number (NCT 05336877) is a requirement for CMS coverage for AVEIR™ VR leadless pacemaker procedures.[2]

4. Is the ACED NCT number (NCT05336877) required to be on private pay or Medicaid claims for coverage?

The NCT number (NCT 05336877) does not apply to private payers or Medicaid. The ACED NCT number is required for Medicare beneficiaries' coverage only, including Fee-For-Service and Medicare Advantage.

5. What site of service are Leadless Pacemaker procedures covered?

According to the National Coverage Determination for Leadless Pacemaker procedures, Policy 20.8.4, the following Places of Service (POS) will cover this procedure:

1. POS 06- Indian Health Service Provider Based Facility
2. POS 21- Inpatient Hospital
3. POS 22- On-Campus Outpatient Hospital
4. POS 26- Military Treatment Facility

CMS does not cover a Leadless Pacemaker Procedure in the ASC Setting.[4]

6. Does my hospital's Institutional Review Board (IRB) need to approve the ACED study?

IRB approvals are unlikely to be required by the hospital. The ACED study involves CMS claims or clinical data that are collected in the context of healthcare delivery; the data collection involves no direct patient contact and will not influence the care a patient receives during routine interactions with the healthcare system. Abbott, being the main entity in the ACED 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)

7. How do I report that a patient indicated for the AVEIR™ VR procedure is part of Abbott's CMS approved study, ACED?

Under the CMS Coverage with Evidence Development policy, CMS requires that you report a National Clinical Trial number on the applicable claim. The NCT number for the AVEIR™ VR CED Study (ACED) is: NCT05336877.[2,3]

8. Does CMS's NCD Policy 20.8.4 apply to State Medicaid patients?

No. The National Coverage Determination, Policy 20.8.4, only applies to Medicare fee-for-service, and Medicare Advantage patients. We recommend that the provider check with the state Medicaid plan to understand the current policy requirements for a Leadless Pacemaker procedure.

AVEIR VR Coding and Payment Rates

The latest updates

Medicare Claim Form

Please find the billing requirements for both professional and institutional claim forms. As outlined in the CMS Manual Transmittal 2955, it is mandatory that the national clinical trial number be reported on the claim sheet for all Aveir VR procedures billed for Medicare beneficiaries.[4]

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)

CPT‡ Codes[5,6]

CPT‡ code	Description	2023 National Medicare Rates		
		Physician		Facility
		Facility	Non-Facility	
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*	*$469*	*NA*	*$17,178*
33275	*Transcatheter removal of permanent leadless pacemaker, **right ventricular**, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed*	*$489*	*NA*	*$2,979*
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*	*$14*	*NA*	*NA*
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 physician or other qualified healthcare professional; single lead pacemaker or leadless pacemaker system in one cardiac chamber*	*$30*	$67	$35
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*	$20	$56	$35

ICD-10 PCS Codes[8]

ICD-10 PCS Procedural Code	Description	MS-DRG Assignment	Medicare National 2023 Rate
02HK3NZ	*Insertion of Intracardiac Pacemaker in right ventricle, Percutaneous Approach*	228 w MCC* Other Cardiothoracic Procedures	$33,806
02PA3NZ	*Removal of Intracardiac Pacemaker from heart, Percutaneous Approach*		
02WA3NZ	*Revision of Intracardiac Pacemaker from heart, Percutaneous Approach*	229 w/o MCC* Other Cardiothoracic Procedures	$22,643

HCPCS Codes[7]

C-Code	Description
C-1786	*Pacemaker, single-chamber, rate-responsive, implantable*
C-1894	*Introducer/sheath, other than intracardiac electrophysiological, non-laser*

Important Safety Information

AVEIR™ VR LEADLESS PACEMAKER

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

Indications: The Aveir™ Leadless Pacemaker system is indicated for patients with significant bradycardia and:

- Normal sinus rhythm with rare episodes of A-V block or sinus arrest
- Chronic atrial fibrillation
- Severe physical disability

Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.

Intended Use: The Aveir™ Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy to the target patient population. The Aveir™ Delivery Catheter system is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation includes implanting an LP within the target chamber of the heart.

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

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

Adverse Events: Potential complications associated with the use of the Aveir™ Leadless Pacemaker system are the same as with the use of single chamber pacemakers with active fixation pacing leads including, but not limited to: Cardiac perforation, Cardiac tamponade, Pericardial effusion, Pericarditis, Valve damage and/or regurgitation, Heart failure, Pneumothorax/hemothorax, Cardiac arrhythmias, Diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation, Palpitations, Hypotension, Syncope, Cerebrovascular accident, Infection, Hypersensitivity reaction to device materials, medications, or direct toxic effect of contrast media on kidney function, Pacemaker syndrome, Inability to interrogate or program the LP due to programmer or LP malfunction, Intermittent or complete loss of pacing and/or sensing due to dislodgement or mechanical malfunction of the LP (non-battery related), Loss of capture or sensing due to embolization or fibrotic tissue response at the electrode, Increased capture threshold, Inappropriate sensor response, Interruption of desired LP function due to electrical interference, either electromyogenic or electromagnetic, Battery malfunction/ premature battery depletion, Device-related complications (Premature deployment, Device dislodgement/embolization of foreign material, Helix distortion), Death.

As with any percutaneous catheterization procedure, potential complications include, but are not limited to: Vascular access complications (such as perforation, dissection, puncture, groin pain), Bleeding or hematoma, Thrombus formation, Thromboembolism, Air embolism, Local and systemic infection, Peripheral nerve damage, General surgery risks and complications from comorbidities (such as hypotension, dyspnea, respiratory failure, syncope, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death)

Abbott Summary

Resources

1. Centers for Medicare and Medicaid: Leadless Pacemakers, Policy 20.8.4. NCD - Leadless Pacemakers (20.8.4) (cms.gov)

2. Centers for Medicare and Medicaid: Leadless Pacemakers, Coverage with Evidence Development. Leadless Pacemakers | CMS

3. Aveir VR Coverage with Evidence Development Study, Post-Approval Study (CED). Aveir VR Coverage With Evidence Development Post-Approval Study - Full Text View - ClinicalTrials.gov

4. CMS Manual System, Transmittal 3815. R3815CP (cms.gov)

5. CY2023 MPFS Final Rule Home Page. U.S. Centers for Medicare and Medicaid Services. CMS-1770-F | CMS

6. CY2023 OPPS Final Rule Home Page. U.S. Centers for Medicare and Medicaid CMS-1772-FC | CMS

7. Alpha Numeric HCPCS Codes. Alpha-Numeric HCPCS | CMS

8. Hospital Inpatient Prospective Payment- Final Rule FY2023 Payment Rates. 2023 ICD-10-PCS | CMS

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