Abbott

Cardiac Rhythm Management

AVEIR™ LEADLESS PACEMAKER SYSTEM

MEDICARE COVERAGE GUIDE

Effective January 1st, 2025

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.

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.

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.

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.

MEDICARE COVERAGE

LEADLESS PACEMAKER THERAPY

The leadless pacemaker procedure using AVEIR™ 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 NCD: Leadless Pacemakers (20.8.4) for more information https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=370. 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")

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™ 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™ 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™ VR Ventricular LP, AVEIR™ VR Ventricular LP CED study to meet these coverage requirements and has obtained approval. The AVEIR™ VR Ventricular LP CED study has a clinical trial number to be utilized only for patients indicated for AVEIR™ 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™ 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™ 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.
Is the AVEIR™ VR Ventricular LP CED study study the same as AVEIR™ VR's Leadless Pacemaker FDA post-approval study (PAS)? No. They are two separate studies with two different NCT numbers. The AVEIR™ 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.

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™ VR Ventricular LP CED study? The AVEIR™ 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™ 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™ 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™ 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.

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.

Reimbursement Hotline

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MEDICARE COVERAGE

LEADLESS PACEMAKER THERAPY

The leadless pacemaker procedure using AVEIR™ AR Atrial 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 NCD: Leadless Pacemakers (20.8.4) for more information https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=370. 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	06100770 (For paper claims, Report: CT06100770)	06100770
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")

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™ AR Atrial 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™AR Atrial 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™ AR Atrial LP, AVEIR™ AR Atrial LP CED study to meet these coverage requirements and has obtained approval. The AVEIR™ AR Atrial LP CED study has a clinical trial number to be utilized only for patients indicated for AVEIR™ AR Atrial LP.	Medicare coverage is now available for AVEIR™ AR Leadless Pacemaker implant procedures for any Medicare beneficiaries indicated for a leadless pacemaker and included in the AVEIR™ AR Atrial LP CED study.
How do I report that the AVEIR™ AR Atrial 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™ AR Atrial LP CED study is NCT06100770.	The inclusion of the AVEIR™ AR Atrial LP CED study NCT number (NCT 06100770) is required for CMS coverage purposes.
Is the AVEIR™ AR Atrial LP CED study the same as AVEIR™ AR's Leadless Pacemaker FDA post-approval study (PAS)? No. They are two separate studies with two different NCT numbers. The AVEIR™ AR Atrial 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 06100770) assigned to the AVEIR™ AR Atrial LP CED study is unique to the AVEIR™ AR Leadless Pacemaker. The inclusion of the unique AVEIR™ AR Atrial LP CED study NCT number (NCT 006100770) is a requirement for CMS coverage for AVEIR™ AR LP procedures.

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™ AR Atrial LP CED study? The AVEIR™ AR Atrial 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™ AR Atrial 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™ AR Atrial LP CED study NCT number (NCT 06100770) required to be reported on private payer or Medicaid patient claims for coverage? The NCT number (NCT 06100770) does not apply to private payers or Medicaid. The AVEIR™ AR Atrial LP CED study NCT number (NCT 06100770) is required for Medicare beneficiaries' coverage only, including Fee-For-Service and Medicare Advantage.	AVEIR™ AR Atrial LP CED study NCT number (NCT 06100770) 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.

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.

Reimbursement Hotline

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MEDICARE COVERAGE

LEADLESS PACEMAKER THERAPY

The leadless pacemaker procedure using AVEIR™ DR Dual Chamber LP 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 NCD: Leadless Pacemakers (20.8.4) for more information https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=370. 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	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")

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™ 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?
Is AVEIR™ DR Dual Chamber 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™ DR Dual Chamber LP, AVEIR™ DR Dual Chamber LP CED study to meet these coverage requirements and has obtained approval. The AVEIR™ DR Dual Chamber LP CED study study has a clinical trial number to be utilized only for patients indicated for AVEIR™ DR Dual Chamber LP.	Medicare coverage is now available for AVEIR™ DR Dual Chamber Leadless Pacemaker Leadless Pacemaker implant procedures for any Medicare beneficiaries indicated for a leadless pacemaker and included in the AVEIR™ DR Dual Chamber LP CED study.
How do I report that the AVEIR™ 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™ 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™ DR Dual Chamber LP CED study the same as AVEIR™ DR Dual Chamber Leadless Pacemaker's FDA post-approval study (PAS)? No. They are two separate studies with two different NCT numbers. The AVEIR™ 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.

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™ DR Dual Chamber LP CED study? The AVEIR™ 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™ 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™ 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™ 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.

COVERAGE WITH EVIDENCE DEVELOPMENT FAQs (continued)

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
If a patient with an existing AVEIR™ VR ventricular leadless pacemaker is being upgraded to a dual chamber leadless pacemaker with an AVEIR™ AR atrial component, what NCT number would apply? NCT 05932602 for the AVEIR™ 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™ AR atrial leadless pacemaker is being upgraded to a dual chamber leadless pacemaker with an AVEIR™ VR ventricular component, what NCT number would apply? NCT 05932602 for the AVEIR™ 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.

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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