Abbott

Cardiac Rhythm Management

AVEIR™ AR ATRIAL LEADLESS PACEMAKER SYSTEM

Medicare Reimbursement Guide

Effective October 1st, 2024

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.

NATIONAL AVEIR™ LEADLESS PACEMAKERS MEDICARE REIMBURSEMENT GUIDE

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

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

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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™ AR ATRIAL LEADLESS PACEMAKER (LP) SYSTEM

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 ATRIAL LEADLESS PACEMAKER (LP) SYSTEM

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 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, 2024 - December 31, 2024

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	2024 WORK RVU	2024 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	$461

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

Potential CPT‡ code crosswalks for 0824T			
CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 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	$487

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

Category III Coding Crosswalk Examples

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

Potential CPT‡ Code Crosswalks for 0825T			
CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 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	$461

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

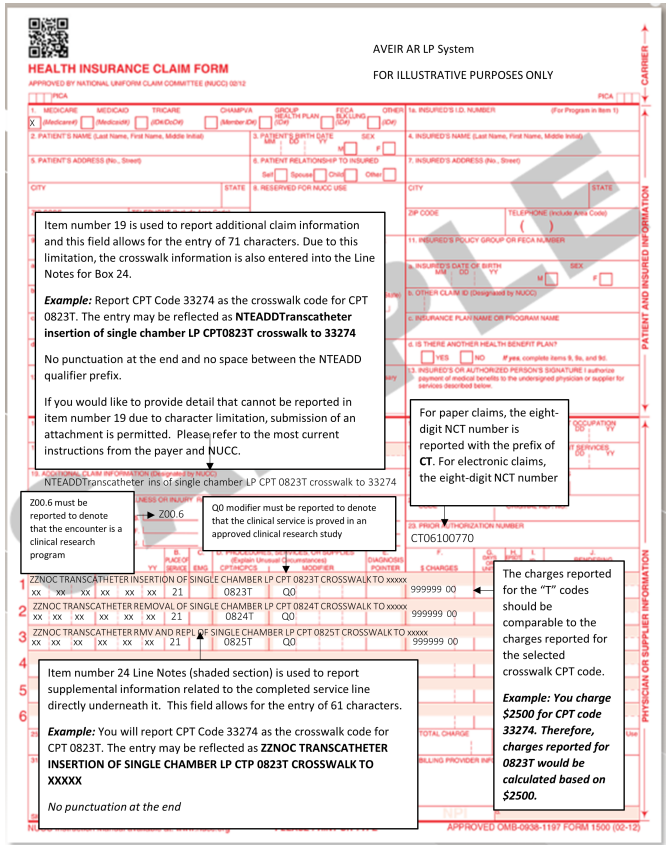
Potential CPT‡ Code Crosswalks for 0826T			
CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 NATIONAL MEDICARE AVERAGE
93279	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system or leadless pacemaker system in one cardiac chamber	0.65	$66

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, 2024 - December 31, 2024

SAMPLE CMS 1500 FORM
AVEIR™ AR Atrial LP FOR ILLUSTRATIVE PURPOSES ONLY



AVEIR™ AR ATRIAL LEADLESS PACEMAKER (LP) SYSTEM

Hospital Inpatient 000000 - National

ICD-10 PCS CODE	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	MEDICARE NATIONAL RATE
	AVEIR™ AR: Insertion		
02H63NZ	Insertion of Intracardiac Pacemaker into Right Atrium, Percutaneous Approach	228 with MCC	$35,463
		229 without MCC	$22,106
	AVEIR™ AR Removal or Revision		
02PA3NZ	Removal of Intracardiac Pacemaker from Heart, Percutaneous Approach	228 with MCC	$35,463
02WA3NZ	Revision of Intracardiac Pacemaker from Heart, Percutaneous Approach	229 without MCC	$22,106
	AVEIR™ DR: Upgrade (AR insertion/ VR existing)		
X2H63V9	Insertion of Dual-Chamber Intracardiac Pacemaker into Right Atrium, Percutaneous Approach	228 with MCC	$35,463
		229 without MCC	$22,106

Effective Dates: October 1, 2024 - September 30, 2025

AVEIR™ AR ATRIAL LEADLESS PACEMAKER SYSTEM

Hospital Outpatient 000000 - National

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE NATIONAL RATE
	INSERTION			
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	J1	5224	$18,565
	REMOVAL			
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	J1	5183	$3,037
	REMOVAL & REPLACEMENT			
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	J1	5224	$18,565
	PROGRAMMING DEVICE EVALUATION			
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	Q1	5741	$36
	INTERROGATION			
93288	Interrogation device evaluation (in person) with analysis, review and report by physician or other qualified healthcare professional, includes connection, recording, and connection per patient encounter; single, dual or multiple lead pacemaker system, or leadless pacemaker system	Q1	5741	$36

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

J1: Hospital Part B services paid through a comprehensive APC
Q1: STV-Packaged Codes

AVEIR™ AR ATRIAL LEADLESS PACEMAKER (LP) SYSTEM

HCPCS Device Category C-Codes

C-CODE	DESCRIPTION
	AR Insertion (de novo)
C1786	Pacemaker, single-chamber rate responsive (implantable)
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser
	AR Insertion to upgrade to DR (existing VR)
*C1889	Implantable/insertable device, not otherwise classified

*A new C-code assignment with the TPT assignment for AVEIR™ DR & AR upgrades.

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

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

Commercial (Private) Payers

Coverage for leadless pacemakers varies by payer policy.

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

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.

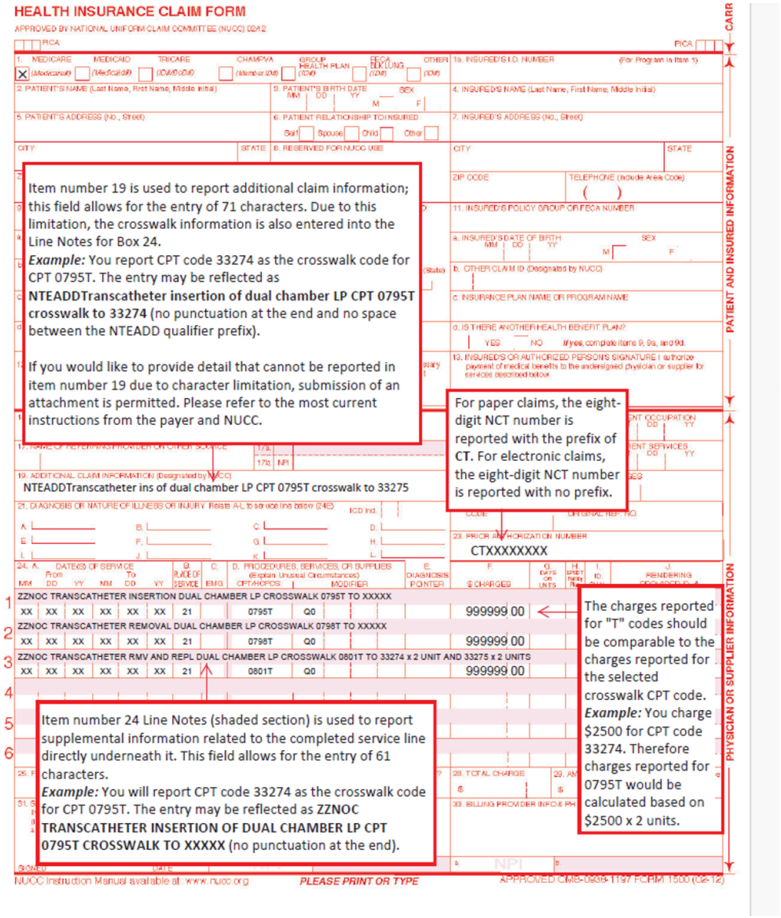
Intended Use: The AVEIR™ Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle and/or right atrium. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac 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:

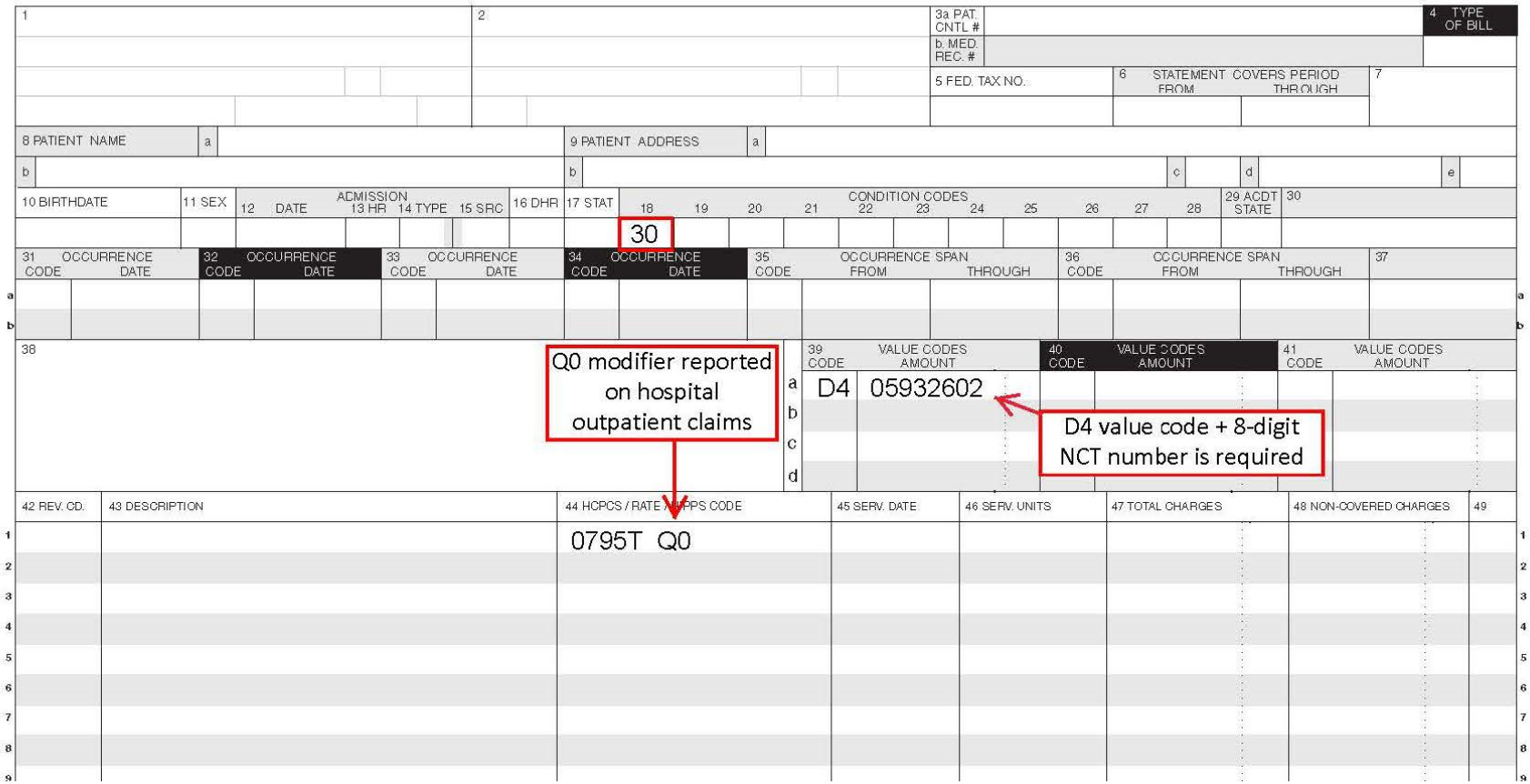
- Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.
- Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker 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, Valve damage and/or regurgitation, Heart failure, Pneumothorax/hemothorax, Cardiac arrhythmias, Diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation, Palpitations, Hypotension, Syncope, Cerebrovascular accident, Infection, Hypersensitivity reaction to device materials, contrast media, medications, or direct toxic effect of contrast media on kidney function, Pacemaker syndrome, Inability to interrogate or program the LP due to programmer or LP malfunction, Intermittent or complete loss of pacing and/or 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.

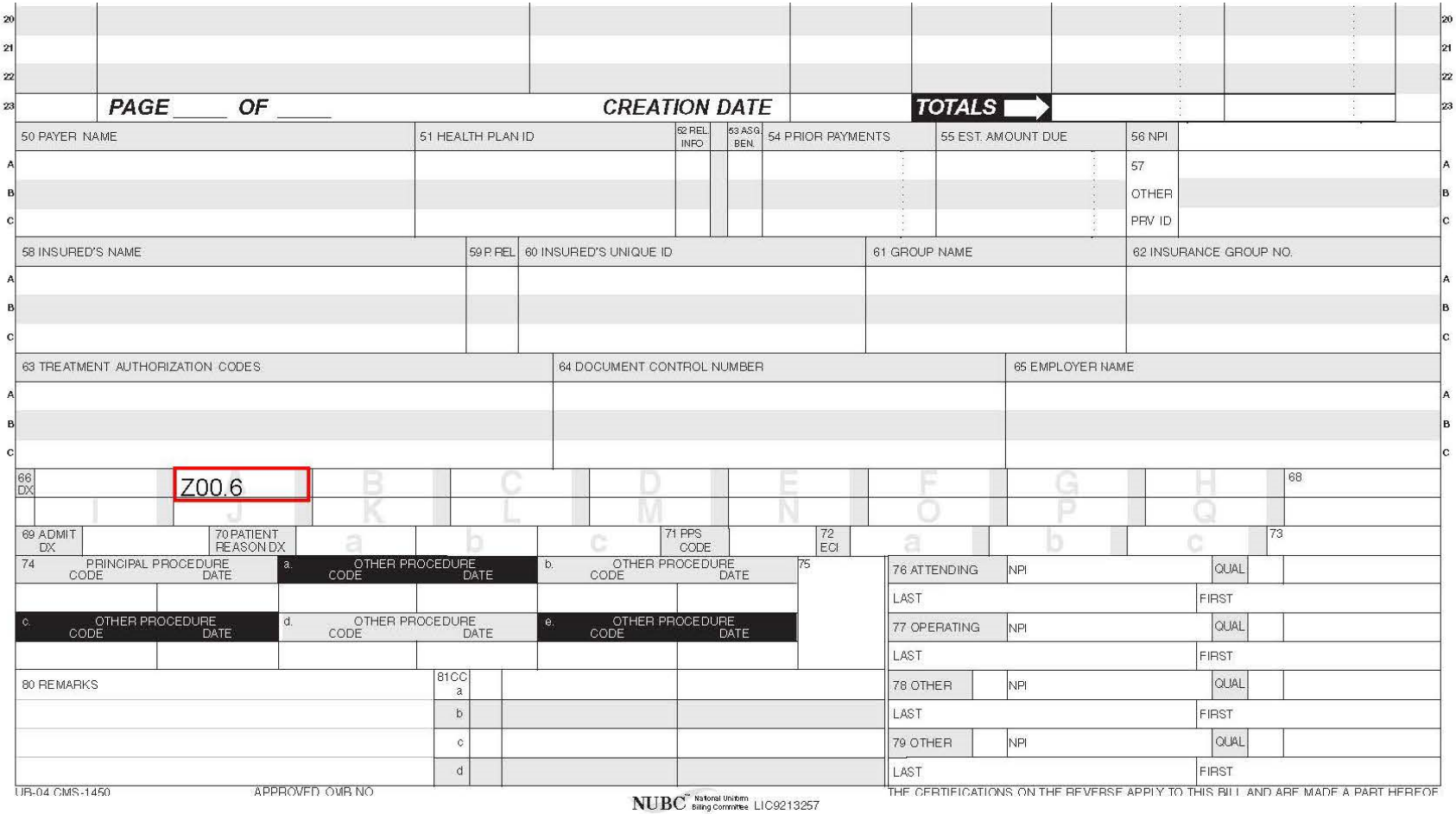
SAMPLE CMS 1500 FORM
AVEIR™ AR Atrial LP FOR ILLUSTRATIVE PURPOSES ONLY



SAMPLE CMS UB-04 FORM
AVEIR™ AR Atrial LP FOR ILLUSTRATIVE PURPOSES ONLY



SAMPLE CMS UB-04 FORM (Continued..)
AVEIR™ AR Atrial LP FOR ILLUSTRATIVE PURPOSES ONLY



1. FY2025 IPPS Final Rule Home Page. U.S. Centers for Medicare and Medicaid Services. [cited: August 2024].
https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page

2. CY2024 MPFS Final Rule Home Page. U.S. Centers for Medicare and Medicaid Services. [cited: November 2023].
https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-f

3. CY2024 OPPS Final Rule Home Page. U.S. Centers for Medicare and Medicaid Services. [cited: November 2023].
https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1786-fc

4. CMS 2024 ICD-10-CM [cited: August 2023].
https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm

5. Leadless Pacemakers [cited: June 2022].
https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Leadless-Pacemakers

6. Claim Submission [cited: June 2022].
https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00232303

7. AMA CPT‡ Category III Codes, First Ten Years [cited: January 2024]
https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjU6N3r65GDAxXW4TgGHbl-D2MQFnoECBMQAQ&url=https%3A%2F%2Fwww.ama-assn.org%2Fmedia%2F9291%2Fdownload&usg=AOvVaw0ZTX992B4EB2S5k76J8slK&opi=89978449

8. AMA CPT‡ Category III codes long [cited: January 2024]
https://www.ama-assn.org/system/files/cpt-category3-codes-long-descriptors.pdf

9. National Coverage Determination Leadless Pacemakers 20.8.4 [cited: January 2024]
https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=370

10. Medicare Claims Processing Manual, Chapter 32, Section 380 - Leadless Pacemakers [cited: January 2024]
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