Abbott

Cardiac Rhythm Management

AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER SYSTEM

Medicare Reimbursement Guide

Effective October 1st, 2024

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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.

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NATIONAL AVEIR™ LEADLESS PACEMAKERS MEDICARE REIMBURSEMENT GUIDE

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

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.

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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")

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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.

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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.

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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.

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AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER (LP) SYSTEM

FDA approved June 29, 2023, the AVEIR™ DR Leadless Pacemaker (LP) System is capable of pacing and sensing in both chambers of the heart through the combination of an atrial leadless pacemaker and a ventricular leadless pacemaker. Dual chamber, leadless synchronous pacing between the atrium and the ventricle is made possible with implant-to-implant communication technology, capable of providing pacing for continuous, atrioventricular synchrony. On July 1, 2023, the American Medical Association (AMA) approved a series of Category III CPT‡ Codes to report dual chamber leadless pacemaker procedures. Category III CPT‡ codes are a set of temporary codes to report emerging technology, services, and procedures. These codes are intended to be used to track the usage of these services, and the data collected may be used to substantiate widespread usage by the AMA. However, Category III codes are not valued and assigned a federal physician fee schedule by CMS. This document provides reference material related to general considerations for physician crosswalk payment for dual chamber leadless pacemaker system procedures when performed consistent with the product's labeling.

Reporting a Category III CPT code for Physician services require special considerations, in that Category III CPT codes for Dual Chamber Leadless Pacemaker Procedures do not have an assigned payment rate (established RVU (Relative Value Unit)) in Medicare's physician fee schedule, and private insurers do not have assignment of RVUs to use as a basis for setting physician payment. Since Category III codes do not have established RVUs, prior authorization requests (please note that traditional Medicare does not require prior authorization) and claims must generally be submitted with supporting documentation and may be subject to review. Comparable Category I CPT‡ codes that are similar to the Category III code may be identified to provide accurate information to payers for consideration when they are processing claims. By providing a comparable Category I CPT‡ code, along with additional documentation, payers can better understand what took place during the procedure, and value it accordingly.

Payers will review each claim with a CPT‡ code for dual chamber leadless pacemaker procedures individually, and payment determinations will be made on a case-by-case basis. Therefore, it is strongly recommended that the provider contact payers to ensure the new Category III codes are included in contracts and to inquire about any guidelines for submission and documentation of these claims.

Recommended Supporting Documentation for Claim Submission (List is not comprehensive; check with your applicable payer)

1. A cover letter describing the services rendered and why the service was needed
2. Copy of operative report that details the procedure including provider's time and effort during procedure
    - Time, effort and equipment necessary to perform procedure
    - Include the relevant crosswalk Category I CPT‡ code for a comparable procedure while also noting any and all differences with the services provided for the dual chamber leadless pacemaker procedure with an increase or decreased percentage of the work/time associated with the referenced comparable procedure
3. Customized Letter of Medical Necessity for the patient receiving the procedure
4. Copy of FDA Approval Letter
5. Copy of published clinical data

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AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER (LP) SYSTEM

Physicians are encouraged to identify comparable crosswalk Category I CPT‡ codes to reference in supporting documentation provided with the claim submission when billing for Dual Chamber Leadless Pacemaker procedures. Since the Category III CPT‡ code does not have established RVUs, payers do not have a pre-defined reference for establishing payment. Physicians will need to document in detail the work involved with specificity of time, the complexity of the procedure, and practice expense relative to comparable procedures with established RVUs and payment amounts.

Physicians should enter the appropriate Category III CPT‡ code for the procedure and bill an amount comparable to the crosswalk code. If a comparable crosswalk includes multiple units, then the explanation line should include all activity combined into one explanation (do not enter multiple lines of crosswalk codes). Applicable Category III codes for dual chamber leadless pacemaker procedures and an example of Crosswalk comparisons are included on the following pages in this section.

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AVEIR™ DR Dual Chamber LP System Physician Coding

Category III Codes

INSERTION

CPT‡ CODE	DESCRIPTION	WORK RVU
0795T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, (right atrial and right ventricular components)	N/A

REMOVAL

CPT‡ CODE	DESCRIPTION	WORK RVU
0798T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	N/A
0799T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial component)	N/A
0800T	Transcatheter removal of permanent dual chamber leadless pacemaker (right ventricular component)	N/A

REMOVAL & REPLACEMENT

CPT‡ CODE	DESCRIPTION	WORK RVU
0801T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	N/A
0802T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial component)	N/A
0803T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right ventricular component)	N/A

UPGRADE TO DUAL CHAMBER

CPT‡ CODE	DESCRIPTION	WORK RVU
0796T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual chamber leadless pacemaker system)	N/A
0797T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, right ventricular pacemaker component (when part of a dual chamber leadless pacemaker system)	N/A

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AVEIR™ DR Dual Chamber LP System Physician Coding

PROGRAMMING DEVICE EVALUATION

CPT‡ CODE	DESCRIPTION	WORK RVU
0804T	Programming device evaluation (in person) with review and report by a physician or other qualified health care professional; leadless pacemaker system in dual cardiac chambers	N/A

Category I Code

INTERROGATION

CPT‡ CODE	DESCRIPTION	WORK RVU
93288	Interrogation device evaluation (in person) with analysis, review and report by physician or other qualified healthcare professional, includes connection, recording, and connection per patient encounter; single, dual or multiple lead pacemaker system, or leadless pacemaker system	0.43

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Category III Coding Crosswalk Examples

When considering comparable procedures, the following procedures may require similar effort, expertise, time and resource utilization.

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

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

INSERTION

Potential CPT‡code crosswalks for 0795T

CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 NATIONAL MEDICARE AVERAGE
33274*	Insertion or replacement of a permanent leadless pacemaker, right ventricular	7.8 (11.7*)	$461 ($692*)
33340^ (LAAO Procedure)	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placements(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation	14	$748

*If inserting 2 devices, provider can report 2 units; second unit will be discounted to 50%; reimbursement will adjust to 1.5 units.

^33340 is an additional option when inserting 2 units.

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

UPGRADE

Potential CPT‡ code crosswalks for 0796T, 0797T

CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 NATIONAL MEDICARE AVERAGE
33274	Insertion or replacement of a permanent leadless pacemaker, right ventricular	7.8	$461

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Category III Coding Crosswalk Examples

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

REMOVAL

Potential CPT‡ Code Crosswalks for 0798T, 0799T, 0800T

CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 NATIONAL MEDICARE AVERAGE
33275*	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance, when performed.	8.59 (12.88*)	$487 ($731*)
33236^	Removal of permanent epicardial pacemaker and electrodes by thoracotomy; single lead system, atrial or ventricular	12.73	$760

*If removing both devices, provider can report 2 units; second unit will be discounted to 50%; reimbursement will adjust to 1.5 units.

^33236 is an additional option when removing both units.

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

REMOVAL & REPLACEMENT

Potential CPT‡ Code Crosswalks for 0801T, 0802T, 0803T

CPT‡ CODE	DESCRIPTION	2024 WORK RVU	2024 NATIONAL MEDICARE AVERAGE
33274*	Insertion or replacement of a permanent leadless pacemaker, right ventricular	7.8 (11.7*)	$461 ($692*)

*If removing/replacing both devices, provider can report 2 units; second unit will be discounted 50%, reimbursement to 1.5 units

It is strongly encouraged that physicians include op notes detailing the effort and time of the removal portion of the procedure to support adequate reimbursement.

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Category III Coding Crosswalk Examples

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

PROGRAMMING

Potential CPT‡ Code Crosswalks for 0804T

CPT‡ CODE	DESCRIPTION	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	.65* (.98*)	$66 ($99*)
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minute face-to-face time with physician or other qualified health care professional	0.91	$49
95984+	Each additional 15 minutes (List separately in addition to code for primary procedure)	0.8	$43

*Provider can report 2 units; second unit will be discounted to 50%; reimbursement will adjust to 1.5 units

+Can only be reported in conjunction with CPT 95983

Note: The Category I CPT‡ code represented in the above tables are provided for convenience for illustrative purposes only and are not meant to be all-inclusive. Physicians are responsible for providing all information payers may require in support of a claim including selecting the appropriate Category I CPT‡ code comparator and for explaining how the work involved, including the time and complexity of the procedure and the practice expense, is similar to the procedure taking place.

Please note that where a Category III code is available it MUST be reported. Any comparator CPT‡ code identified should be included only in the supporting documentation submitted with the claim.

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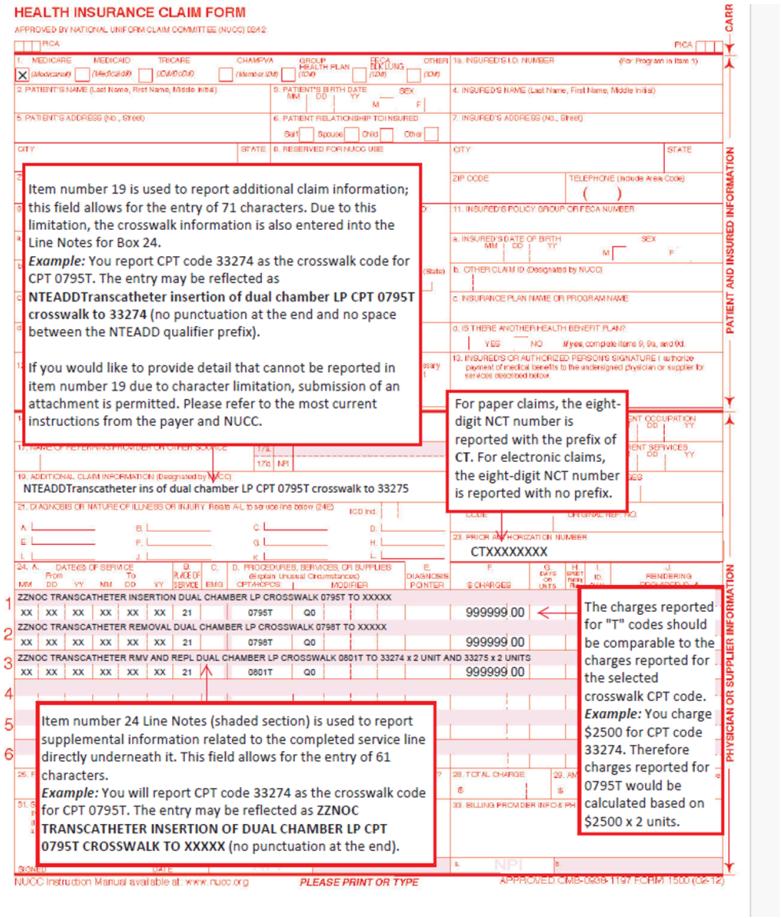
SAMPLE CMS 1500 FORM

AVEIR™ DR Dual Chamber LP System FOR ILLUSTRATIVE PURPOSES ONLY



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AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER (LP) SYSTEM

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE NATIONAL RATE
	INSERTION			
0795T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, (right atrial and right ventricular components)	J1	5224	$18,565
	REMOVAL			
0798T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	J1	5183	$3,037
0799T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial component)	J1	5183	$3,037
0800T	Transcatheter removal of permanent dual chamber leadless pacemaker (right ventricular component)	J1	5183	$3,037
	REMOVAL AND REPLACEMENT			
0801T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	J1	5224	$18,565
0802T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial component)	J1	5224	$18,565
0803T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right ventricular component)	J1	5224	$18,565

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J1: Hospital Part B services paid through a comprehensive APC

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AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER (LP) SYSTEM

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE NATIONAL RATE
	PROGRAMMING AND DEVICE EVALUATION			
0804T	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; leadless pacemaker system in dual cardiac chambers	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

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Q1: STV-Packaged Codes

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AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER (LP) SYSTEM

ICD-10 PCS CODE	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	MEDICARE NATIONAL RATE
	AVEIR™ DR: De Novo Insertion		
X2H63V9+ X2HK3V9	Insertion of Dual-Chamber Intracardiac Pacemaker into Right Ventricle, Percutaneous Approach	228 with MCC	$35,463
		229 without MCC	$22,106
	AVEIR™ DR: Upgrade (AR insertion w/ VR Existing)		
X2H63V9	Insertion of Dual-Chamber Intracardiac Pacemaker into Right Atrium, Percutaneous Approach	228 with MCC	$35,463
		229 without MCC	$22,106
	AVEIR™ DR: Upgrade (VR Insertion w/ AR Existing)		
02HK3NZ	Insertion of Dual-Chamber Intracardiac Pacemaker into Right Ventricle, Percutaneous Approach	228 with MCC	$35,463
		229 without MCC	$22,106

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AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER (LP) SYSTEM

HCPCS Device Category C-Codes

C-CODE	DESCRIPTION
	LEADLESS PACEMAKERS
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation

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.

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.

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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, 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.

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MEDICARE ADDITIONAL PAYMENT

Medicare provides a pathway for additional device reimbursement when certain new medical technologies are used for eligible cases on Medicare beneficiaries in the hospital inpatient and outpatient settings. The new technology add-on payment (NTAP) and transitional pass-through (TPT) payment are two types of add-on payments. The purpose of NTAP and TPT payments is to ensure Medicare beneficiaries' access to technologies that are too new to be well represented in the data CMS uses to set rates under Medicare's Inpatient Prospective Payment System (IPPS) and Outpatient Prospective Payment System (OPPS), respectively. In other words, NTAP and TPT payments are intended to minimize cost and payment barriers that would otherwise inhibit the adoption of new, outcome- improving technologies for Medicare beneficiaries. A criterion for both NTAP and TPT applications is that the new medical technology represents a substantial clinical improvement over current therapy options. In both cases, CMS determined the AVEIR™ DR Dual Chamber Leadless Pacemaker (LP) System met this criterion.

NTAP and TPT payments are available when the AVEIR™ DR Dual Chamber LP System is used on traditional Medicare beneficiaries for eligible cases in the hospital inpatient and outpatient settings.

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Hospital Inpatient – New Technology Add-On Payment (NTAP)

The NTAP reimburses procedures performed in the hospital inpatient setting for costs related to their use of eligible new technologies in addition to the prospective diagnosis related group (MS-DRG) payment. The NTAP amount is the lesser of 65 percent of the cost of the new medical technology or 65 percent of the amount by which the costs of the case exceed the standard MS-DRG payment.

NTAP Payment Example (does not represent any known hospital)

	DESCRIPTION		CALCULATION
	Hospital Charges (entire hospital stay, including device)	A	
	Hospital Inpatient Charge Ratio (published by Medicare; hospital specific)	B	
NTAP ELIGIBILITY	Total Hospital Case Cost	C	A X B
	Hospital Specific Reimbursement MS-DRG 228 or 229	D	228 or 229
	Hospital Case Cost Minus MS-DRG Payment (hospital case cost must exceed MS-DRG payment)	E	C - D
NTAP PAYMENT	65% of Hospital Case Cost Minus MS-DRG Payment	F	E X .65
	65% of New Medical Technology (set by Medicare during NTAP application process)	G	
	NTAP Payment Amount	H	Lesser of F and G
TOTAL REIMBURSEMENT	NTAP Payment + MS-DRG 228		D+H

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Hospital Outpatient – Transitional Pass-Through (TPT) Payment

The TPT payment reimburses hospitals for costs related to their use of eligible new technologies in the outpatient setting in addition to the prospective ambulatory payment classification (APC) payment. The amount of the TPT payment is the hospital's charge for the device adjusted to the actual cost for the device minus the device related portion of APC. The TPT payment amount varies depending on, among other things, the amount a hospital charges for the AVEIR™ DR System and the hospital's cost-to-charge (CCR) ratio.

TPT Payment Example (does not represent any known hospital)

	DESCRIPTION		CALCULATION
Transitional Pass-Through (TPT) Payment	Hospital Charge for AVEIR™ DR Dual Chamber LP	A	
	Implantable Device Cost to Charge Ratio (Published by Medicare; varies for each specific hospital)	B	
	Hospital Cost for AVEIR™ DR Dual Chamber LP	C	A X B
	Device Related Portion of APC 5224 (offset)* (Published by Medicare)	D	$5,755
	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

***TPT applies to Traditional Medicare patients only.**

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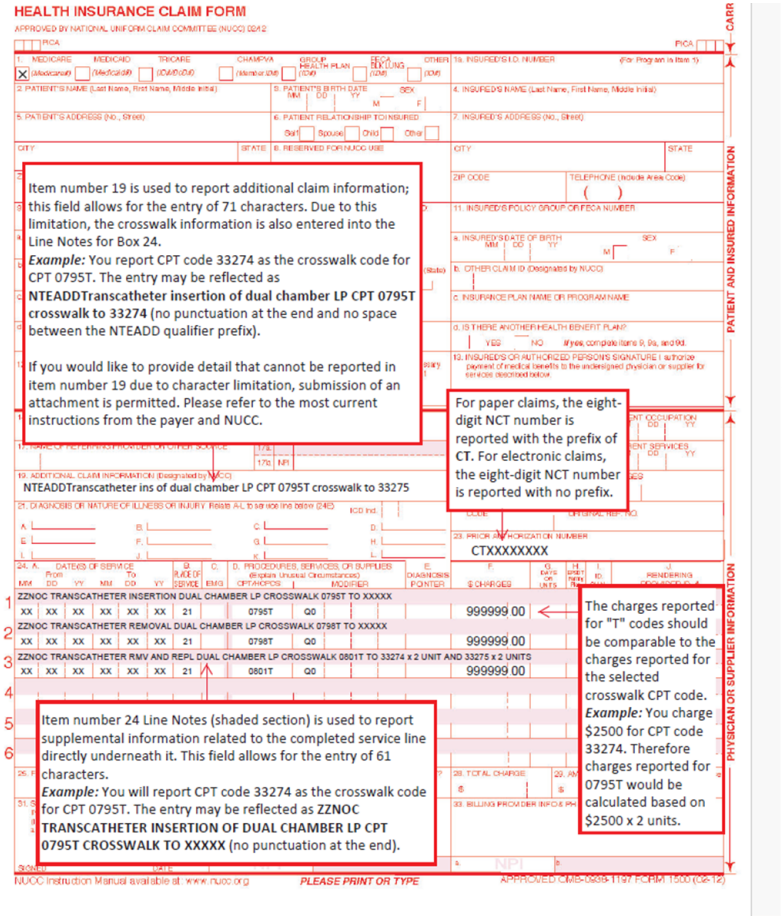
SAMPLE CMS 1500 FORM
AVEIR™ DR Dual Chamber LP System FOR ILLUSTRATIVE PURPOSES ONLY



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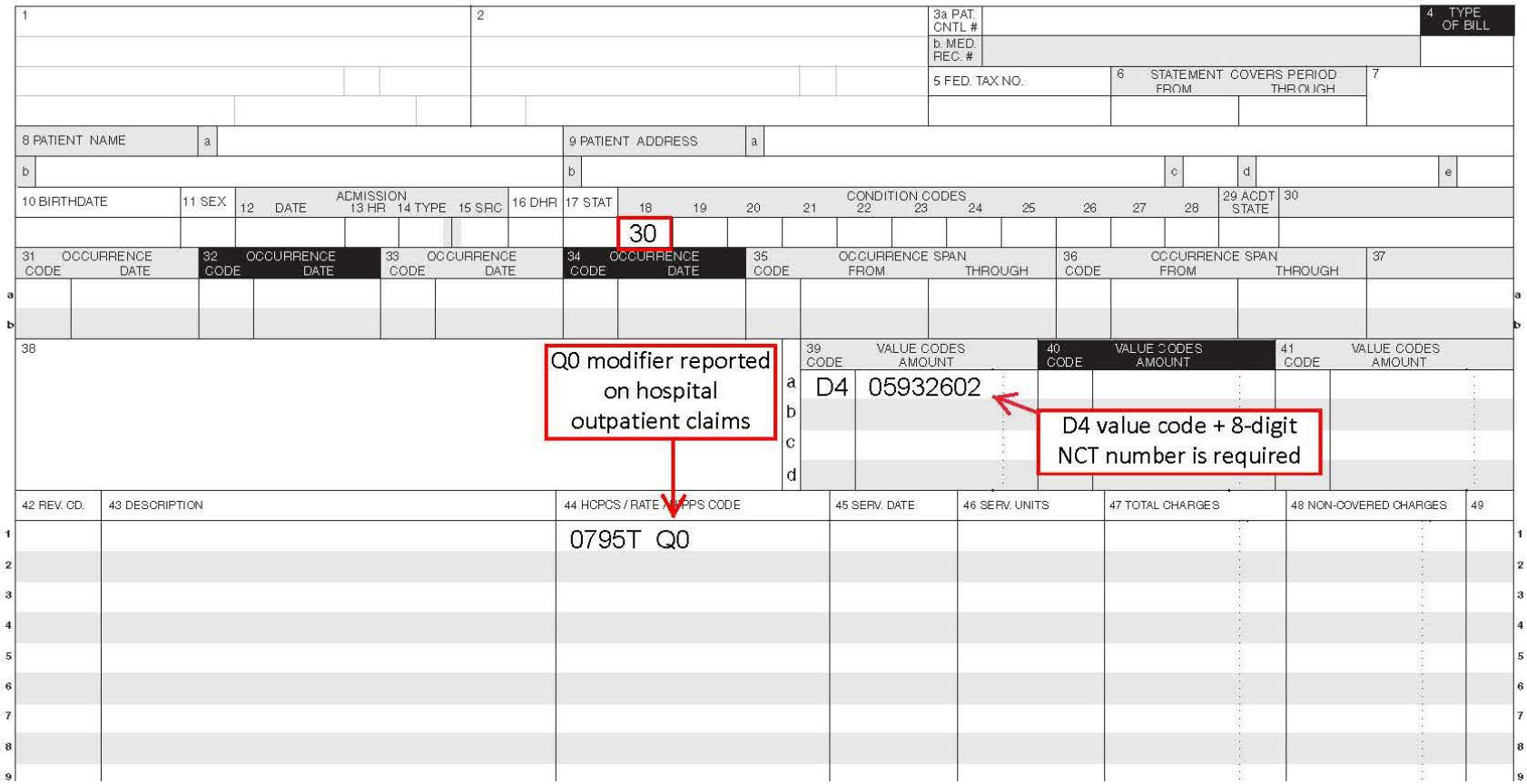
SAMPLE CMS UB-04 FORM
AVEIR™ DR Dual Chamber LP System FOR ILLUSTRATIVE PURPOSES ONLY



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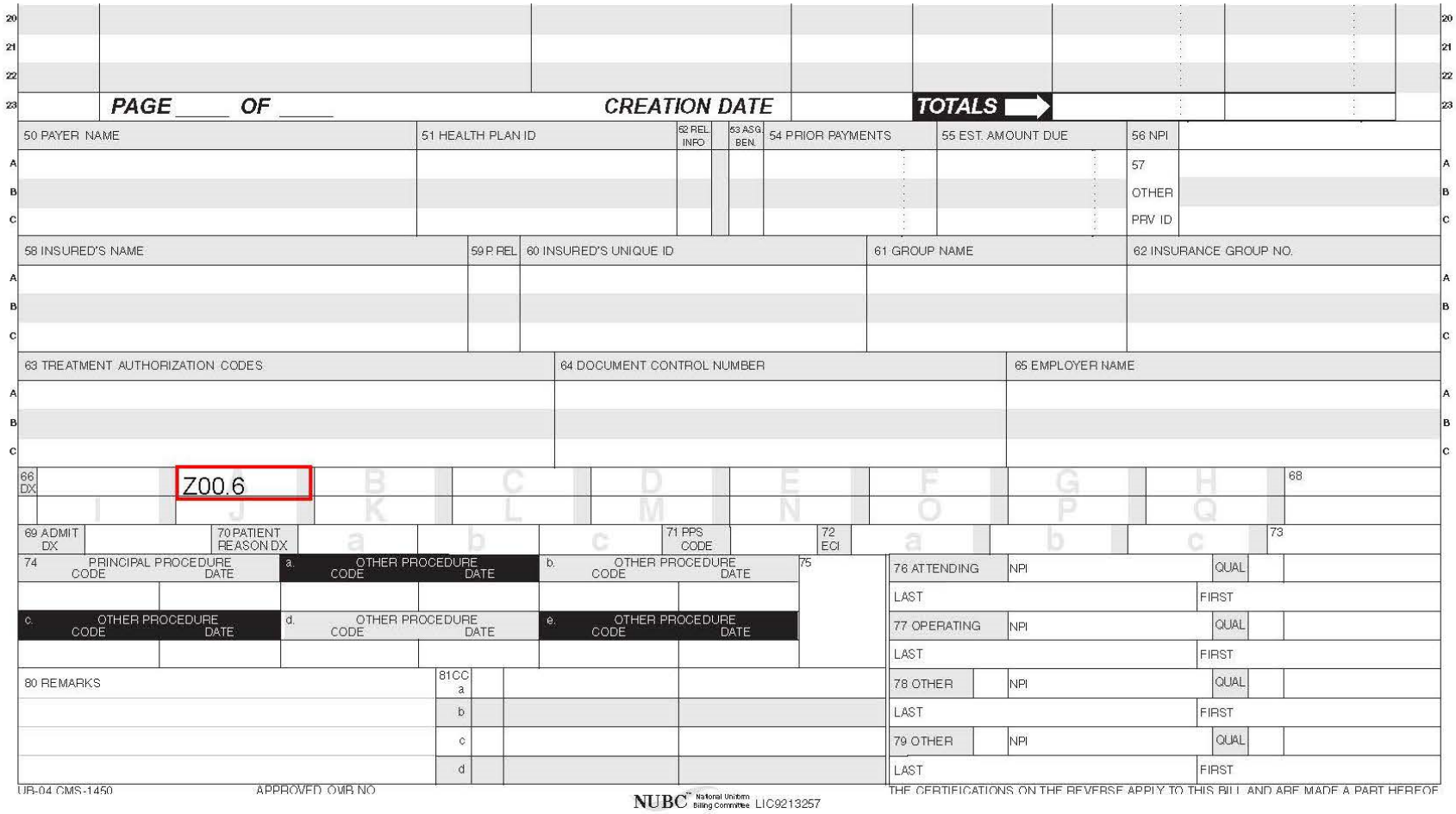
SAMPLE CMS UB-04 FORM (Continued..)
AVEIR™ DR Dual Chamber LP System FOR ILLUSTRATIVE PURPOSES ONLY



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