HEALTH ECONOMICS & REIMBURSEMENT

Cardiac Rhythm Management

AVEIR™ VR Leadless Pacemaker Coding Guide

TERMS AND CONDITIONS

The data contained herein may be based upon several sources, including but not limited to: primary sources, scientific literature, commercially available data sets, data/inputs provided by the customer, and various external sources.

Estimated payment information is for illustrative purposes only. This information is not intended for any other purpose.

It should also be noted that there are usually differences between modeling potential payments and actual results. Abbott does not take responsibility for any such discrepancies. There is no guarantee of the potential payments indicated. Actual payments 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 expressly not to be distributed to third parties.

NATIONAL AVIER™ VR LEADLESS PACEMAKER MEDICARE REIMBURSEMENT GUIDE

Introduction

The Aveir™ VR 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™ 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 guide. This guide and all supporting documents are available at **www.cardiovascular.abbott/us/en/hcp/reimbursement.html**

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MEDICARE COVERAGE

LEADLESS PACEMAKER THERAPY

The leadless pacemaker procedure using AVEIR™ VR 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 the NCD: Leadless Pacemakers (20.8.4). 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 BILLING SPECIFICS

For hospital outpatient procedures on type of bill (TOB) 13x or 85x, and for professional claims billed with a place of service (POS) 22 (Hospital Outpatient) or 24 (ASC), Medicare will consider coverage for the leadless pacemaker procedure only when billed with:

CLAIMS IDENTIFYING INFORMATION TO SIGNIFY PATIENT IS PARTICIPATING IN A STUDY	CED STUDY
National Clinical Trial (NCT) Number	NCT05336877
Q0 Modifier	Q0 Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Condition Code 30	30 Qualifying Clinical Trial

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)

AVEIR™ VR CED STUDIES SUBMITTED FOR APPROVAL BY CMS FOR COVERAGE

DEVICE	MODEL #	STUDY NAME/NCT #/
AVEIR™ VR Leadless Pacemaker	LSP112V	Aveir VR Coverage With Evidence Development Post-Approval Study / NCT: 05336877
Delivery Catheter	LSCD111	
Retrieval Catheter	LSCR111	
Introducer	LSN25301 and LSN25501	

COVERAGE WITH EVIDENCE DEVELOPMENT 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 Study policy relating to the AVEIR™ VR Leadless Pacemaker 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 covered by CMS? The Centers for Medicare and Medicaid has a National Coverage Determination for leadless pacemakers, Policy 20.8.4. This is a coverage with evidence development policy that is applicable to all leadless pacemaker procedures for all Medicare beneficiaries, including Medicare fee-for-service and Medicare Advantage. As part of the coverage criteria, CMS requires all patients to be included in a CMS approved study. Abbott has a real-world study for AVEIR™ VR, AVEIR™ VR Coverage with Evidence Development study (ACED) to meet these coverage requirements and has obtained approval. The ACED study has a clinical trial number to be utilized only for patients indicated for AVEIR™ VR.	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 ACED study.
How do I report that the AVEIR™ VR patient is part of a CMS approved study? Under the CMS Coverage with Evidence Development policy, CMS requires that you report a National Clinical Trial number on the applicable claim. The NCT number (NCT 05336877) for the AVEIR™ VR CED Study (ACED) is: NCT05336877	The inclusion of the ACED study NCT number (NCT 05336877) is required for CMS coverage purposes.
Is the ACED study the same as AVEIR™ VR's FDA post-approval study (PAS)? No. They are two separate studies with two different NCT numbers. The ACED study is a CMS approved Coverage with Evidence Development 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 data requirements, independent from the CED study.	The NCT number (NCT 05336877) assigned to the ACED study is unique to the AVEIR™ VR leadless pacemaker. The inclusion of the unique ACED study NCT number (NCT 05336877) is a requirement for CMS coverage for AVEIR™ VR leadless pacemaker procedures.

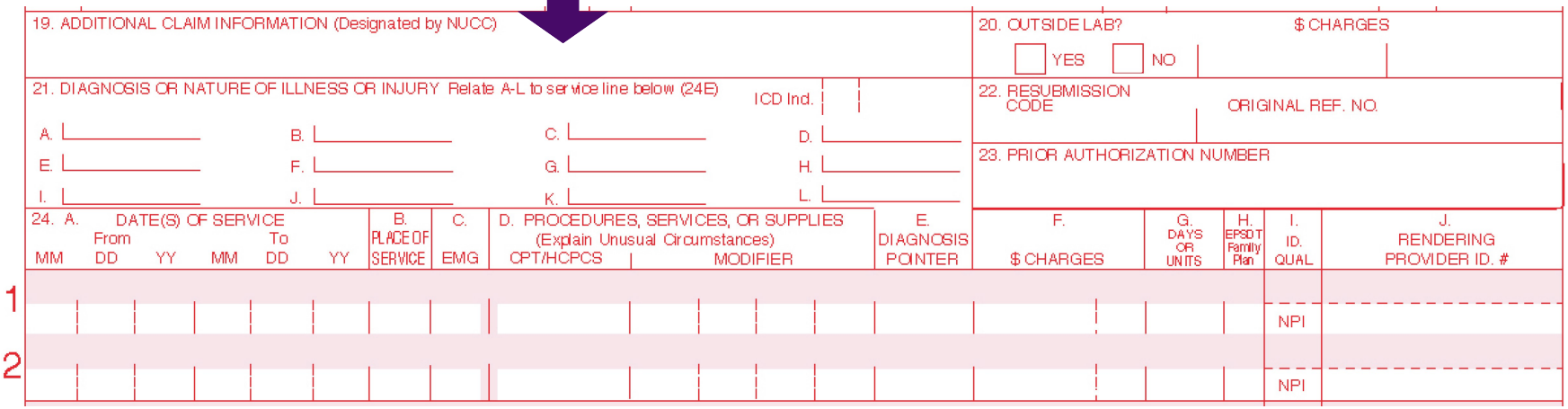
COVERAGE WITH EVIDENCE DEVELOPMENT FAQs (continued)

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
Does my hospital's Institutional Review Board (IRB) need to approve the ACED study? The ACED 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 ACED study, has requested and been granted a waiver of informed consent and a HIPAA waiver from Western IRB. The Council for International Organizations of Medical Sciences (CIOMS), in a publication issued jointly with the World Health Organization (WHO), has stated that a waiver of the informed consent requirement may be granted by an IRB, "when the research design involves no more than minimal risk and a requirement of individual informed consent would make the conduct of the research impracticable (for example, where the research involves only excerpting data from subjects' records)". (Data on file at Abbott)	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 ACED 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 ACED NCT number (NCT 05336877) is required for Medicare beneficiaries' coverage only, including Fee-For-Service and Medicare Advantage.	ACED 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	Please contact the Abbott team using these channels when needed.

CMS 1500 PAPER CLAIM

8-DIGIT CLINICAL TRIAL NUMBER

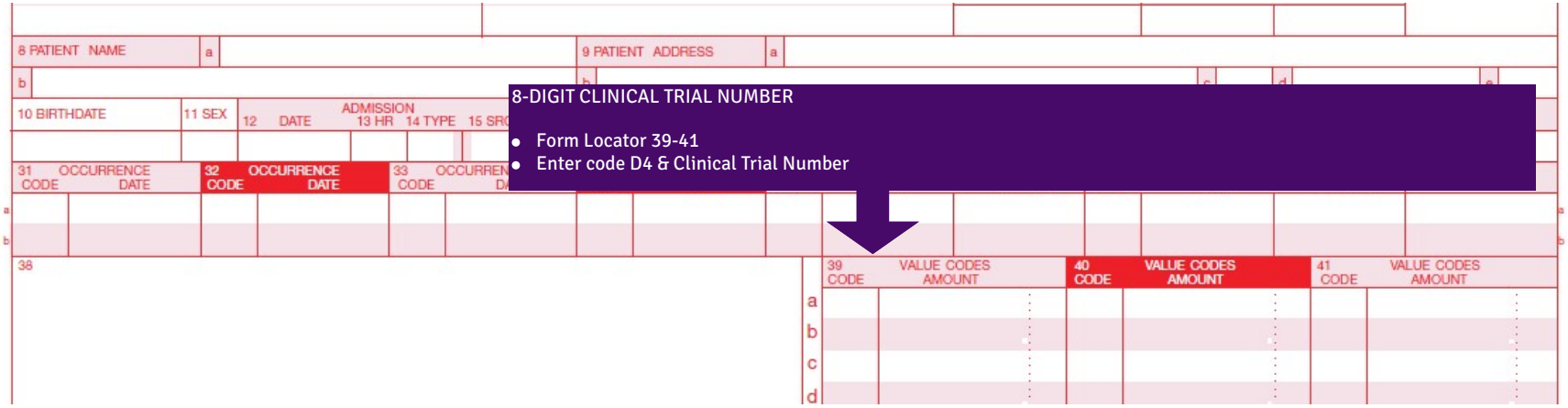
- Form Locator 19
- Preceded by "CT" if sending paper claim (CT05336877)
- NOTE: Only report 8 digits if electronic submission (05336877); see electronic claim submission instructions



UB-04 PAPER CLAIM

8-DIGIT CLINICAL TRIAL NUMBER

- Form Locator 39-41
- Enter code D4 & Clinical Trial Number



https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00232303

AVEIR™ VR LEADLESS PACEMAKER

Physician

CPT‡ CODE	DESCRIPTION	WORK RVU	MEDICARE NATIONAL RATE	
			FACILITY	NON-FACILITY
	IMPLANT			
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.	7.80	$493	NA
	REMOVAL			
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral ventriculography), when performed.	8.59	$514	NA
	IN-PERSON DEVICE FOLLOW-UP			
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	$32*	$71
93288	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system, or leadless pacemaker system	0.43	$21*	$60
	PERI-PROCEDURE DEVICE PROGRAMMING; PACEMAKER			
93286	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system, or leadless pacemaker system	0.3	$15*	$49

* Facility rates shown with an * reflect payment when modifier 26 is used (i.e. payment only for the professional component).
NA: Medicare has not established a payment amount for this code. Check with your local Medicare Administrative Contractor (MAC) to verify the payment amount.
It is incumbent upon the physician to determine which, if any, modifiers should be used first.

AVEIR™ VR LEADLESS PACEMAKER

Hospital Outpatient

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE NATIONAL RATE
	IMPLANT/REPLACEMENT			
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.	J1	5194	$16,402
	REMOVAL WITHOUT LEADLESS REPLACEMENT			
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral ventriculography), when performed.	J1	5183	$2,924
	PACEMAKER DEVICE PROGRAMMING- IN PERSON			
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	Q1	5741	$38
	PACEMAKER DEVICE INTERROGATION- IN PERSON			
93288	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system, or leadless pacemaker system	Q1	5741	$38
	PERI-PROCEDURE DEVICE PROGRAMMING; PACEMAKER			
93286	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system, or leadless pacemaker system	N	NA	NA

J1: Hospital Part B services paid through a comprehensive APC
N: Items and Services Packaged into APC Rates
Q1: STV-Packaged Codes

AVEIR™ VR LEADLESS PACEMAKER

Hospital Inpatient

ICD-10 PCS CODE	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	MEDICARE NATIONAL RATE
	LEADLESS PACEMAKERS		
02HK3NZ	Insertion of Intracardiac Pacemaker into Right Ventricle, Percutaneous approach	228 with MCC	$33,806
02PA3NZ	Removal of Intracardiac Pacemaker from Heart, Percutaneous Approach		
02WA3NZ	Revision of Intracardiac Pacemaker from Heart, Percutaneous Approach	229 without MCC	$22,643

Note: report the combination of device insertion and/or lead(s) codes that best describes the procedure performed

CC: complication or comorbidity. MCC: a major complication or comorbidity when used as a secondary diagnosis

AVEIR™ VR LEADLESS PACEMAKER

HCPCS Device Category C-Codes

C-CODE	DESCRIPTION
	LEADLESS PACEMAKERS
C1786	Pacemaker, single-chamber, rate-responsive (implantable)
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser

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™ VR LEADLESS PACEMAKER

IMPORTANT SAFETY INFORMATION

Rx Only

Brief Summary: 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: TThe 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)

REFERENCES

1. FY2023 IPPS Final Rule Home Page. U.S. Centers for Medicare and Medicaid Services. [cited: August 2022].

   https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-final-rule-home-page

2. CY2022 MPFS Final Rule Home Page. U.S. Centers for Medicare and Medicaid Services. [cited: June 2022].

   https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1751-f

3. CY2022 OPPS Final Rule Home Page. U.S. Centers for Medicare and Medicaid Services. [cited: June 2022].

   https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientpps/cms-1753-fc

4. CMS 2023 ICD-10-CM [cited: August 2022].

   https://www.cms.gov/medicare/icd-10/2023-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. Aveir VR Coverage With Evidence Development Post-Approval Study (CED) [cited: June 2022]

   https://clinicaltrials.gov/ct2/show/NCT05336877?term=NCT05336877&draw=2&rank=1

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