AVEIR™ AR Atrial Leadless Pacemaker (LP) System

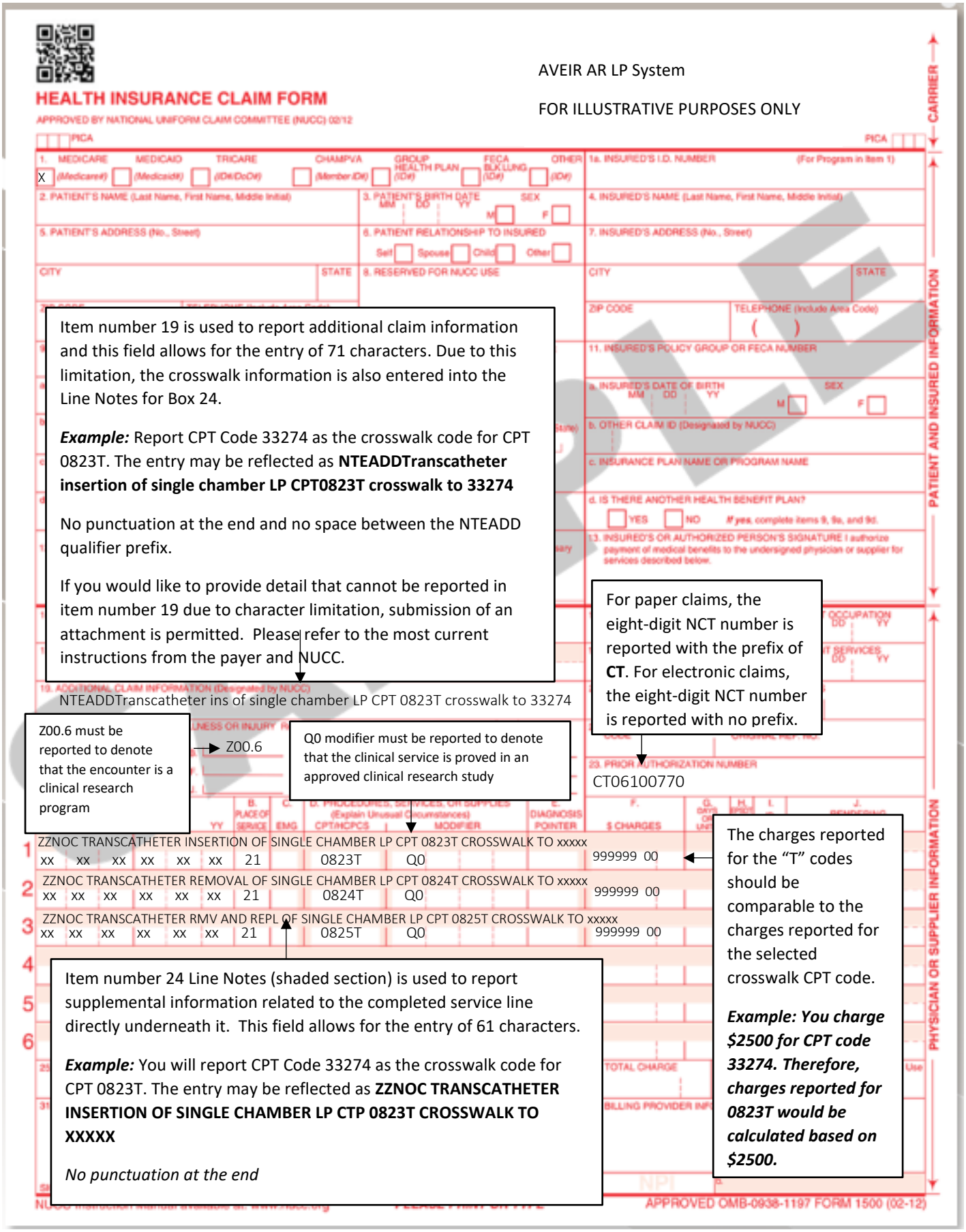
Medicare Coverage with Evidence Development Study Information: Professional

This document summarizes billing information for the:
AVEIR™ AR Atrial Leadless Pacemaker (LP) System per the CMS NCD 20.8.4[1]. It is the physician's responsibility to determine appropriate coding for a particular patient and/or procedure. Any claim should be coded appropriately and supported with adequate documentation in the medical record.

CODES/MODIFIERS/OTHERS	WHEN USED?
DIAGNOSIS CODES	
Applicable primary diagnosis codes	All cases
Z00.6*: Encounter for examination for normal comparison and control in clinical research program	All cases
Applicable secondary diagnosis codes	When appropriate
CPT‡ CODE & MODIFIER	
0823T: Insertion of a permanent single-chamber leadless pacemaker, right atrial	All cases
Modifier Q0*: Investigational clinical service provided in a clinical research study that is in an approved clinical research study	All cases
NCT NUMBER	
06100770*	All cases

***These codes are required by The Centers of Medicare and Medicaid to be included on each Traditional Medicare and Medicare Advantage claim.**

SAMPLE PROFESSIONAL CLAIM FORM



Item number 19 is used to report additional claim information and this field allows for the entry of 71 characters. Due to this limitation, the crosswalk information is also entered into the Line Notes for Box 24.

Example: Report CPT Code 33274 as the crosswalk code for CPT 0823T. The entry may be reflected as **NTEADDTranscatheter insertion of single chamber LP CPT0823T crosswalk to 33274**

No punctuation at the end and no space between the NTEADD qualifier prefix.

If you would like to provide detail that cannot be reported in item number 19 due to character limitation, submission of an attachment is permitted. Please refer to the most current instructions from the payer and NUCC.

For paper claims, the eight-digit NCT number is reported with the prefix of **CT**. For electronic claims, the eight-digit NCT number is reported with no prefix.

Z00.6 must be reported to denote that the encounter is a clinical research program

Q0 modifier must be reported to denote that the clinical service is proved in an approved clinical research study

The charges reported for the "T" codes should be comparable to the charges reported for the selected crosswalk CPT code.

Example: You charge $2500 for CPT code 33274. Therefore, charges reported for 0823T would be calculated based on $2500.

Item number 24 Line Notes (shaded section) is used to report supplemental information related to the completed service line directly underneath it. This field allows for the entry of 61 characters.

Example: You will report CPT Code 33274 as the crosswalk code for CPT 0823T. The entry may be reflected as **ZZNOC TRANSCATHETER INSERTION OF SINGLE CHAMBER LP CTP 0823T CROSSWALK TO XXXXX**

No punctuation at the end

Important Safety Information

Rx only

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

Indications: The Aveir™ Leadless Pacemaker system is indicated for management of one or more of the following permanent conditions: Syncope, Pre-syncope, Fatigue, Disorientation. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-chamber pacing is indicated for patients exhibiting: Sick sinus syndrome, Chronic, symptomatic second- and third-degree AV block , Recurrent Adams-Stokes syndrome, Symptomatic bilateral bundle-branch block when tachyarrhythmia and other causes have been ruled out. Atrial pacing is indicated for patients with: Sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular pacing is indicated for patients with: Significant bradycardia and normal sinus rhythm with only rare episodes of AV block or sinus arrest, Chronic atrial fibrillation, Severe physical disability. MR Conditional: The Aveir Leadless Pacemaker is conditionally safe for use in the MRI environment and according to the instructions in the MRI-Ready Leadless System Manual.

Intended Use: The Aveir™ Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle and/or right atrium. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy within the implanted chamber for the target treatment group. The LP is also intended to operate optionally with another co-implanted LP to provide dual-chamber pacing therapy.

The Aveir™ Delivery Catheter is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation includes implanting an LP within the target chamber of the heart.

Contraindications: Use of the Aveir™ Leadless Pacemaker is contraindicated in these cases:
Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.

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

Adverse Events: Potential complications associated with the use of the Aveir™ Leadless Pacemaker system are the same as with the use of single or dual chamber pacemakers with active fixation pacing leads including, but not limited to: Cardiac perforation, Cardiac tamponade, Pericardial effusion, Pericarditis, Endocarditis, Valve damage or regurgitation, Heart failure, Pneumothorax/hemothorax, Cardiac arrhythmias, Diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation, Palpitations, Hypotension, Syncope, Cerebrovascular accident, Infection, Hypersensitivity reaction to device materials, contrast media, medications, or direct toxic effect of contrast media on kidney function, Pacemaker syndrome, Inability to interrogate or program the LP due to programmer or LP malfunction, Intermittent or complete loss of capture, pacing or sensing (non-battery related), Oversensing, Increased capture threshold, Inappropriate sensor response, Corrupted, intermittent, or loss of i2i communications, Interruption of desired LP function due to electrical interference, either electromyogenic or electromagnetic, Battery malfunction/ premature battery depletion, Device-related complications (Premature deployment, Device dislodgement/embolization of foreign material, Inability to release/re-dock of the LP from the catheter, Helix distortion), Additional surgery or intervention, Death. As with any percutaneous catheterization procedure, potential complications include, but are not limited to: Vascular access complications; such as perforation, dissection, puncture, groin pain, Bleeding or hematoma, Thrombus formation, Thromboembolism, Air embolism, Local and systemic infection, Peripheral nerve damage. General surgery risks and complications from comorbidities; such as, dyspnea, respiratory failure, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death.

References:

1) National Coverage Determination Leadless Pacemakers 20.8.4: NCD - Leadless Pacemakers (20.8.4) (cms.gov)
2) Medicare Claims Processing Manual, Chapter 32, Section 380 - Leadless Pacemakers**:** Medicare Claims Processing Manual (cms.gov)
3) CMS-1500 Paper Form: Interactive CMS-1500 (palmettogba.com)
4) CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 3815: R3815CP (cms.gov)
5) 2024 ICD-10-CM. https://www.cms.gov/medicare/icd-10/2024-icd-10-cm

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