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Medical Policy

Subject:	**Leadless Pacemaker**		
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Description/Scope

This document addresses a single chamber implantable transcatheter pacing system to monitor and regulate the heart rate and rate-responsive bradycardia.

Position Statement

Investigational and Not Medically Necessary:

Use of the leadless pacemaker is considered investigational and not medically necessary for all applications.

Rationale

The Medtronic Micra™ Model MC1VR01 single chamber implantable transcatheter pacing system (TPS) with SureScan™ technology (Medtronic, Inc., Mounds View, MN) is an MR (Magnetic Resonance) conditional programmable cardiac device that monitors and regulates the heart rate by providing rate-responsive bradycardia pacing to the right ventricle. The device senses the electrical activity of the heart, using the sensing and pacing electrodes on the titanium capsule of the device. It monitors the heart rhythm for bradycardia and responds by providing pacing therapy, based on the pacing parameters programmed into the device. The device provides rate response, controlled through an activity-based sensor, and also provides diagnostic and monitoring information for guidance in the pacing system evaluation.

The Micra TPS contains a one inch-long, self-contained pacemaker that is implanted directly into the right ventricle chamber of the heart. It works like other pacemakers to control the heartbeat but, unlike other pacemakers, the Micra TPS does not have leads and does not require a subcutaneous pocket. The Micra TPS is a single-chamber pacing system, which paces *only* the right ventricle of the heart. The Micra TPS is implanted percutaneously directly into the heart via the femoral vein using a catheter delivery system and is attached to the right ventricle with four small nictinol prongs (tines). According to the Medtronic Clinician manual for the Micra TPS device:

Patients with an implanted Micra Model MC1VR01 pacing system can safely undergo an MRI scan provided the system meets the requirements described in the Medtronic MRI Technical Manual.

The FDA clearance of this device was based on an evaluation of data from a single study. This was a prospective, multicenter, single-arm study of 719 subjects implanted with the Micra TPS with two primary outcomes: efficacy and safety. Enrolled subjects met either class I or II indications for pacing and were candidates for single-chamber pacing. The majority (64.0%) had bradycardia associated with persistent or permanent atrial tachyarrhythmia, 17.5% had sinus-node dysfunction, 14.8% had atrioventricular (AV) block. A planned interim analysis was completed when 300 subjects reached 6 months of follow-up. The primary efficacy endpoint, the percent of subjects with low and stable pacing capture thresholds at 6 months, was 98.3% (95% confidence interval [CI], 96.1-99.5; p<0.001). The primary safety endpoint, freedom from system-related or procedure-related major complications, was 96.0% (95% CI, 93.9-97.3; p<0.001). Additionally, safety outcomes were compared to historic controls from six previous transvenous pacemaker trials. While there were significant differences between the study and control subjects, the implanted study group experienced fewer hospitalizations (2.3% vs. 3.9%) and fewer system revisions (0.4% vs. 3.5%). This clinical trial will continue to follow subjects for at least an additional 12 months to evaluate the long-term performance of the Micra TPS. The evidence from this study is considered preliminary and insufficient to demonstrate the long-term safety and efficacy of the Micra TPS, as compared to conventional pacemaker devices. Further study is needed with longer term outcomes data (Reynolds, 2016).

Small studies of the Micra TPS and a similar device, the Nanostim™ Leadless Cardiac Pacemaker (LCP) (St. Jude Medical, St. Paul, MN, acquired by Abbott Laboratories, Abbott Park, IL) have reported some favorable short-term results for individuals requiring single chamber pacing. A medical device advisory by St. Jude Medical for the Nanostim was issued on October 11, 2016, due to premature battery depletion issues encountered with the device. Implantation of the Nanostim device has been halted at the present time, and the Nanostim has not been cleared by the FDA, to date. Registry data on the Micra TPS is being collected by the manufacturer in the Micra TPS Post-approval registry, which is intended to enroll 2450 subjects implanted with the Micra TPS in a global, prospective, observational, multi-site registry (NCT02536118). Registry participants will be prospectively followed for a minimum of 9 years post-implant or until registry closure. Enrolled individuals will have scheduled follow-up visits at least annually, or as prompted by reportable adverse events, with a total estimated registry duration of 11 years. The current status of the registry is active, not recruiting participants and the estimated completion date is August, 2026.

Background/Overview

The Micra Transcatheter Pacing System (TPS) (Pacemaker Model MC1VR01 and Programmer Application Software Model SW022 Version 1.1) was granted expedited priority review and clearance by the U.S. Food and Drug Administration (FDA) on April 6, 2016 for use in individuals who have slow or irregular heart rhythms and who may benefit from a single-chamber pacemaker system, or in whom placement of a traditional system is difficult. Approval was based primarily on the results of a single-arm pivotal trial,

which will continue to follow trial subjects for at least 12 months to further evaluate the long-term performance of the device.

The approved FDA indications for the Micra TPS are as follows:

The Micra Transcatheter Pacing System is indicated for use in patients who have experienced one or more of the following conditions:

- **Symptomatic paroxysmal or permanent high-grade AV block in the presence of atrial fibrillation (AF);**
- **Symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy;**
- **Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy;**
- **Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity (FDA, 2016).**

According to the FDA labeling, the Micra Model MC1VR01 pacemaker is contraindicated for individuals who already have the following types of devices implanted:

- **An implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician;**
- **An implanted inferior vena cava filter;**
- **A mechanical tricuspid valve;**
- **An implanted cardiac device providing active cardiac therapy which may interfere with the sensing performance of the Micra device.**

In addition, the device is contraindicated for persons with any of the following conditions:

- **Femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity);**
- **Morbid obesity that prevents the implanted device from obtaining telemetry communication within < 12.5 cm (4.9 in);**
- **Known intolerance to the materials listed in "Section A.1, Physical characteristics" in the Clinician Manual for the Micra TPS, or intolerance to heparin, or sensitivity to contrast media who cannot be adequately premedicated.**

Also, the Micra TPS is not for use in individuals who can't tolerate a single dose of 1.0 mg dexamethasone acetate. Magnetic resonance imaging (MRI) may be contraindicated for some individuals with an implanted Micra TPS device. The Micra TPS is currently the only leadless pacemaker that is FDA cleared for

marketing in the United States. In January 2020, the Micra AV TPS (model MC1AVR1) and application software model (SW044) were cleared as premarket approval (PMA) supplements to the original Micra TPS device. The Micra AV includes an enhanced algorithm for AV synchronous pacing.

On March 31, 2022 the FDA cleared the Aveir™ Leadless Pacemaker System (Abbot Medical, Sylmar, CA) which contains the following components:

- **Aveir Leadless Pacemaker (LSP112V);**
- **Aveir Delivery System Catheter (LSCD111);**
- **Aveir Link Module (Model LSL02).**

The Aveir Leadless Pacemaker (LP) is indicated for individuals with bradycardia and:

- **Normal sinus rhythm with only rare episodes of A-V block or sinus arrest;**
- **Chronic atrial fibrillation;**
- **Severe physical disability.**

Rate-Modulated Pacing is indicated for individuals with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.

The MR Conditional Aveir LP is conditionally safe for use in the MRI environment according to the instructions in the Abbott MRI-Ready Leadless System Manual.
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 include implanting an LP within the target chamber of the heart.

The Aveir Link Module is intended to be used in conjunction with a Merlin™ PCS Programmer to interrogate and program an Aveir LP and to monitor LP function during an implant, retrieval, or follow-up procedure.

Sensing and pacing occur between a distal electrode near the helix and the external can of the LP. The LP's proximal end has a feature for docking to delivery and retrieval catheters, providing for repositioning and retrieval capability. The LP communicates bi-directionally with the programmer system via electrical signals conducted between the implanted LP's electrodes and skin electrodes applied to the chest and connected to the programmer system. Consequently, the LP transmits signals using circuits and electrodes already provided for pacing, with data encoded in pulses delivered during the refractory period of the ventricle.
The FDA PMA decision was based on data from the global LEADLESS II phase 2 investigational device exemption (IDE) study that evaluated the Aveir VR in subjects with certain abnormal heart rhythms. The results showed the device met its pre-specified primary endpoints. A subject was considered to have met the confirmatory

effectiveness endpoint if the pacing threshold voltage is ≤ 2.0 V at 0.4 ms and the sensed R-wave amplitude is either ≥ 5.0 mV at the 6-week visit or ≥ the value at implant (Han, 2022; Reddy, 2022).

According to the FDA (SSED, 2022):

> **Phase 1 of this IDE study evaluated the safety and effectiveness of the Nanostim Leadless Pacemaker in a population indicated for a VVI(R) pacemaker. Since the Nanostim Leadless Pacemaker was modified prior to market release and renamed the Aveir Leadless pacemaker, Phase 2 of this IDE study confirmed the safety and effectiveness of these modifications in the Aveir Leadless Pacemaker.**

Notably, according to the FDA, "The Aveir Leadless System has not been marketed in the United States or any foreign country."

On January 18, 2017, the Centers for Medicare and Medicaid Services (CMS) issued a final Decision Memo regarding its national coverage analysis (NCA) for Leadless Pacemakers (CAG-00448N). The memo indicates that CMS will only cover the leadless pacemaker, in accordance with the FDA approved label, when furnished as part of CMS-approved post-approval studies or prospective longitudinal studies meeting criteria, through its Coverage with Evidence Development (CED) program. This CMS Decision Memo was issued after considering public comments submitted during two separate 30-day periods. All clinical research study protocols must be reviewed and approved by CMS. The memo includes a preliminary draft of Medicare's National Coverage Determination (NCD) for leadless pacemakers; the effective date is not yet set. According to the CMS NCA, the following summary is provided:

> **These devices have not been tested in broader, long-term studies that include real world practice settings and are currently being followed in FDA-required post-market studies…CMS believes that the evidence is promising and sufficient for coverage of leadless pacemakers when furnished in CMS-approved studies under CED. CMS believes that the available evidence is not sufficient to determine long-term health outcomes or to identify the characteristics of the patient, practitioner or facility that predict which beneficiaries are more likely to experience overall benefit or harm from leadless pacemakers. Significant questions remain regarding the potential for deterioration in left ventricular function and other long-term outcomes, as well as device longevity (CMS, 2017).**

Definitions

Arrhythmia (or dysrhythmia): Problems that affect the electrical system of the heart muscle, producing abnormal heart rhythms and may be classified as either atrial or ventricular, depending on which part of the heart they originate from.

Atrial Fibrillation (AF): A condition in which the atrium (the heart's two upper chambers) produce uncoordinated electrical signals.

Bradycardia: A condition where the individual has a slow heart rate, typically defined as a heart rate of under 60 beats per minute (BPM) in adults.

Congestive Heart Failure (CHF), also referred to as Heart Failure (HF): A condition in which the heart can't pump enough blood to the body's other organs. The "failing" heart keeps working but not as efficiently as it should. As blood flow out of the heart slows, blood returning to the heart through the veins backs up, causing congestion in the tissues.

Heart Block: A disease or inherited condition that causes a fault within the heart's natural pacemaker, due to some kind of obstruction (or "block") in the electrical conduction system of the heart. Blockages are classified based on where the blockage occurs - the SA node ("Sinoatrial block"), AV node ("AV block" or AVB), and at or below the bundle of His ("Intra-Hisian" or "Infra-Hisian block" respectively). In severe cases where the heart's ability to control and trigger heartbeats may be completely ineffective or unreliable, heart block can usually be treated by inserting an artificial pacemaker that provides correct electrical impulses to trigger heart beats, compensating for the natural pacemaker's unreliability.

Sinus Node Dysfunction (also called Sick sinus syndrome or sinoatrial node disease): A group of abnormal heart rhythms (arrhythmias) presumably caused by a malfunction of the sinus node, the heart's primary pacemaker.

Sinus Tachycardia: A sinus rhythm (emanating from the SA node) with an elevated rate of impulses, defined as a rate greater than 100 BPM in an average adult.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed

33275	**Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed**
0795T	**Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)**
0796T	**Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)**
0797T	**Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)**
0798T	**Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components)**
0799T	**Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component**
0800T	**Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)**
0801T	**Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)**
0802T	**Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device**

	evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component
0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0804T	Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers

ICD-10 Procedure

02HK3NZ	Insertion of intracardiac pacemaker into right ventricle, percutaneous approach
02PA3NZ	Removal of intracardiac pacemaker from heart, percutaneous approach

ICD-10 Diagnosis

All diagnoses

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Nanostim Leadless Pacing System
TPS

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
	06/28/2023	Updated Coding section with 07/01/2023 CPT changes, added 0795T, 0796T, 0797T, 0798T, 0799T, 0800T, 0801T, 0802T, 0803T, 0804T; also added ICD-10-PCS code 02PA3NZ.
Reviewed	02/16/2023	Medical Policy & Technology Assessment Committee (MPTAC) review.Updated Background, Index and References sections.
Reviewed	02/17/2022	MPTAC review. References were updated.
Reviewed	02/11/2021	MPTAC review. The Background and References sections were updated.
Reviewed	02/20/2020	MPTAC review. References were updated. Updated Coding section; added ICD-10-PCS code 02HK3NZ.
	12/31/2019	Updated Coding section with 01/01/2020 CPT changes; revised descriptor for 33275.
Reviewed	03/21/2019	MPTAC review. References were updated.
	12/27/2018	Updated Coding section with 01/01/2019 CPT changes; added 33274, 33275; 0387T-0391T deleted 12/31/2018.
Reviewed	03/22/2018	MPTAC review. The document header wording was updated from "Current Effective Date" to "Publish Date." References were updated.
New	05/04/2017	MPTAC review. Initial document development.