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MEDICAL POLICY – 2.02.515

Leadless Cardiac Pacemakers

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Introduction

A pacemaker is a small device that corrects an abnormal heart rhythm (arrhythmia). It is placed in the chest, just under the skin near the collarbone. A conventional pacemaker has a battery (pulse generator) with wires (leads) that connect from the shoulder vein to the heart. When the heart is beating too slow, too fast, or at an irregular rate, the pacemaker sends electrical pulses to keep the heart beating properly. The most common problems with this kind of pacemaker come from the leads and from the surgical site. Another pacemaker option is a leadless pacemaker. It is a self-contained device that does not have wires and is smaller than a conventional pacemaker. It is inserted through a long, thin tube (catheter) from the leg vein into the heart. This policy describes when a leadless cardiac pacemaker may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Medical Necessity

Micra transcatheter pacing system	**The Micra single chamber transcatheter pacing system may be considered medically necessary in individuals when BOTH of the following conditions are met:**
	• The individual has **ONE** of the following conditions:
	  ○ Symptomatic paroxysmal arteriovenous block; **or**
	  ○ Permanent high-grade arteriovenous block; **or**
	  ○ Symptomatic bradycardia-tachycardia syndrome; **or**
	  ○ Sinus node dysfunction (sinus bradycardia or sinus pauses).
	AND
	• The individual has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as **ANY** of the following:
	  ○ History of an endovascular or cardiovascular implantable electronic device (CIED) infection or who are at high risk for infection (see **Related Information**); **or**
	  ○ Limited access for transvenous pacing given venous anomaly, occlusion of axillary veins or planned use of such veins for a semi-permanent catheter or current or planned use of an arteriovenous fistula for hemodialysis; **or**
	  ○ Presence of a bioprosthetic tricuspid valve
	
	The Micra single chamber transcatheter pacing system is considered investigational in all other situations in which the above criteria are not met.
	
	The Aveir single chamber transcatheter pacing system is considered investigational for all indications.
	
	The Aveir DR dual chamber pacing system is considered investigational for all indications.

Contraindications

As per the FDA label, the Micra Model MC1VR01 (Micra VR) and Model MC1AVR1 (Micra AV) pacemakers are contraindicated for individuals who 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

As per the FDA label, the Micra Model MC1VR01 and Model MC1AVR1 pacemakers are also contraindicated for individuals who have 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 to obtain telemetry communication within <12.5 cm (4.9 in)
- Known intolerance to titanium, titanium nitride, parylene C, primer for parylene C, polyether ether ketone, siloxane, nitinol, platinum, iridium, liquid silicone rubber, silicone medical adhesive, and heparin or sensitivity to medical contrast which cannot be adequately premedicated

As per the FDA label, Micra pacemakers should not be used in individuals for whom a single dose of 1.0 mg dexamethasone acetate cannot be tolerated because the device contains a molded and cured mixture of dexamethasone acetate with the target dosage of 272 µg dexamethasone acetate. It is intended to deliver the steroid to reduce inflammation and fibrosis.

For the MRI contraindications for individuals with a Micra MRI device, refer to the Medtronic MRI Technical Manual.

As per the FDA label, some individuals will not benefit from the AV synchronous (VDD) mode supported by the Micra Model MC1AVR1 pacemaker. Individuals with the following conditions should instead be considered for a dual-chamber transvenous pacing system:

- Sinus node dysfunction;

Contraindications

- High sinus rates requiring atrial tracking;
- Weak atrial contraction;
- Symptoms during loss of atrioventricular (AV) synchrony;
- Frequent premature atrial or ventricular contractions.

Documentation Requirements

The individual's medical records submitted for review for the Micra single chamber transcatheter pacing system should document that medical necessity criteria are met. The record should include the following:

- Documentation that the individual has one of these conditions: symptomatic paroxysmal or permanent high-grade arteriovenous block, or symptomatic bradycardia-tachycardia syndrome, or sinus node dysfunction (sinus bradycardia or sinus pauses)

AND

- Documentation that the individual has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker such as: an endovascular or cardiovascular implantable electronic device infection or who are at high risk for infection, , limited access for transvenous pacing due to venous anomaly, occlusion of axillary veins, or planned use of such veins for a semi-permanent catheter or current or planned use of an AV fistula for hemodialysis, or the individual has a bioprosthetic tricuspid valve

Coding

Code	Description
CPT	
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
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; complete system (i.e., right atrial and right ventricular pacemaker components)

Code	Description
0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., 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 (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), 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 (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; dual-chamber system (i.e., right atrial and right ventricular pacemaker components)
0802T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right atrial pacemaker component
0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0823T	Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (e.g., interrogation or programming), when performed (new code effective 1/1/2024)
0824T	Transcatheter removal of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography), when performed (new code effective 1/1/2024)
0825T	Transcatheter removal and replacement of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral

Code	Description
	venography, cavography) and device evaluation (e.g., interrogation or programming), when performed (new code effective 1/1/2024)
Code	**Code Description**
HCPCS	
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation (new code effective 7/1/2024)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Physical Disability and Infection Risk

Clinical input suggests that severe physical disability encompasses a variety of comorbidities where conventional pacemaker placement would confer undue short- or long-term risk or further compromise a limited ability to meet activities of daily living, including compliance with postoperative care instructions. Examples include individuals with short, expected lifespan, individuals with end-stage heart, lung, neurologic, or skeletal conditions, and individuals with mental health or developmental challenges.

The 2019 European Heart Rhythm Association (EHRA) international consensus paper on the prevention, diagnosis, and treatment of cardiac implantable electronic device (CIED) infections has been endorsed by the Heart Rhythm Society (HRS) and lists the following non-modifiable patient-related risk factors for CIED infections:

- End-stage renal disease;
- Corticosteroid use;
- Renal failure;
- History of device infection;

- Chronic obstructive pulmonary disease;
- Heart failure (New York Heart Association [NYHA] Class ≥II);
- Malignancy;
- Diabetes mellitus.

High-Grade Atrioventricular Block

Atrioventricular block occurs when there is interference of the electrical signals from the atrium to the ventricle. AV block is categorized based on severity. First degree AV block occurs when signals are transferred more slowly than normal. Second-degree AV block is divided into Type I and Type II. Type I is also called Mobitz Type I or Wenckebach's AV block. There is gradually slower activity which may produce skipped heartbeats. Second-degree Type II is also called Mobitz Type II where more signals fail to reach the ventricles, resulting in a slower and more abnormal heart rhythm. Second-degree AV block can be paroxysmal (not persistent) or permanent. Additionally, high-degree AV block is a form of second-degree AV block in which the conduction ratio is high representing multiple atrial contractions that are not conducting to the ventricle; however, there is still some AV conduction and as such is not a third-degree AV block. Third-degree AV block is a complete block of the electrical signals; while the ventricles contract on their own, the consequences are reduced and irregular heart rate and reduced cardiac output.

Individuals with rare episodes of AV block or sinus arrest generally do not require pacing intervention, although symptomatic individuals might have significant need for pacing. The Micra VR and Aveir devices are indicated when there is infrequent AV block. The Micra AV device is indicated with infrequent or chronic AV block. These definitions come from the intended use definitions of the devices and clinical input. Note that there is no strict definition of the frequency of episodes or the degree of symptoms.

VDD Pacing

VDD pacing is a pacing mode used in pacemakers whereby sensing occurs in both the atrium and ventricle, with pacing only occurring in the ventricle. The first letter (V) indicates that the

Ventricle is the pacing chamber, the second letter (D) indicates that both the atrium and ventricle are the sensing chambers, and the third letter (D) indicates that the mode of operation is dual (inhibited and triggered). Uses of VDD pacing include pacemaker syndrome where there is reduced coordination between the atrial and ventricular contractions resulting in lower cardiac output, and when individuals with an implant have complete AV block with preserved sinus functioning. VDD is used in dual chamber transvenous pacemakers and in single-chamber ventricular pacemakers with leads that float in the atrium for sensing. The Micra AV leadless pacemaker supports VDD pacing.

Atrioventricular Synchrony

Devices that support maintenance of AV synchrony can sense atrial electrical activity and pace the ventricular chamber accordingly. Pacemakers maintaining AV synchrony may lead to less morbidity and mortality than ventricular stimulation alone and reduce the risk of pacemaker syndrome. The Micra AV device provides AV synchronous ventricular pacing similar to a transvenous VDD system. The implanted device depends on the appropriate sensing of atrial mechanical signals to achieve AV synchrony. The level of AV synchrony may vary in individual recipients and may not be predictable prior to implant. The manufacturer cautions that loss of AV synchrony can be caused by the interference of mechanical vibrations stemming from various activities and environments.

Pacemaker Syndrome

In pacemaker syndrome there is reduced coordination between atrial contraction and ventricular contraction, resulting in reduced cardiac output. The syndrome is most commonly seen in the setting of a single-chamber ventricular pacemaker with ventricular sensing and pacing, as with no atrial sensing the ventricles contract at the programmed rate independently from atrial contraction.

Device Retrieval and Replacement

Leadless pacemakers have a limited lifespan. Removal of devices can be complicated by encapsulation due to fibrosis. Devices can instead be deactivated and remain in place, with another device implanted. Use of deactivated and activated devices might result in electromagnetic interference. Based on bench testing, the current recommendation for device end of service care includes adding a replacement device with or without explantation of the deactivated implant. Explantation of the deactivated implant should be performed by a clinician with expertise in the removal of implanted leads. Use of co-implanted deactivated and activated devices has not been clinically tested, and as such Plans will need to consider the medical necessity of repeat implantation. The Aveir device features helix-based active fixation designed to facilitate device removal with a dedicated retrieval catheter; however, limited data are available on retrieval success rates.

Mechanical Interference

For axillary transvenous pacemakers, there is a concern that leads or the generator could be impacted by the recoil of using a firearm (e.g., rifles or shotguns). Thus, leadless cardiac pacemakers can provide an alternative for individuals who suffer lead fracture or malfunction from mechanical stress and may be considered when axillary venous access is present only on a side of the body that would not allow use of equipment producing such mechanical stress (e.g., a firearm).

Evidence Review

Description

Pacemakers are intended to be used as a substitute for the heart's intrinsic pacing system to correct cardiac rhythm disorders. Conventional pacemakers consist of two components: a pulse generator and electrodes (or leads). Pacemakers are considered life-sustaining, life-supporting class III devices for individuals with a variety of bradyarrhythmias. Even though the efficacy and safety profile of conventional pacemakers are excellent, in a small proportion of individuals, they

may result in lead complications and the requirement for a surgical pocket. Further, some individuals are medically ineligible for conventional pacemakers due to lack of venous access and recurrent infection. Leadless pacemakers are single-unit devices that are implanted in the heart via femoral access, thereby eliminating the potential for complications as a result of leads and surgical pocket. The Micra and Aveir single-chamber transcatheter pacing systems and the Aveir dual-chamber pacing system are the only commercially available leadless pacemakers in the US approved by the US Food and Drug Administration (FDA).

Background

Conventional Pacemakers

Pacemakers are intended to be used as a substitute for the heart's intrinsic pacing system to correct cardiac rhythm disorders. By providing an appropriate heart rate and heart rate response, cardiac pacemakers can reestablish effective circulation and more normal hemodynamics that are compromised by a slow heart rate. Pacemakers vary in system complexity and can have multiple functions as a result of the ability to sense and/or stimulate both the atria and the ventricles.

Transvenous pacemakers or pacemakers with leads (hereinafter referred to as conventional pacemakers) consist of two components: a pulse generator (i.e., battery component) and electrodes (i.e., leads). The pulse generator consists of a power supply and electronics that can provide periodic electrical pulses to stimulate the heart. The generator is commonly implanted in the infraclavicular region of the anterior chest wall and placed in a pre-pectoral position; in some cases, a subpectoral position is advantageous. The unit generates an electrical impulse, which is transmitted to the myocardium via the electrodes affixed to the myocardium to sense and pace the heart as needed.

Conventional pacemakers are also referred to as single-chamber or dual-chamber systems. In single-chamber systems, only one lead is placed, typically in the right ventricle. In dual-chamber pacemakers, two leads are placed-one in the right atrium and the other in the right ventricle. Single-chamber ventricular pacemakers are more common.

Annually, approximately 200,000 pacemakers are implanted in the US and 1 million worldwide.[1] Implantable pacemakers are considered life-sustaining, life-supporting class III devices for individuals with a variety of bradyarrhythmias. Pacemaker systems have matured over the years

with well-established, acceptable performance standards. As per the FDA, the early performance of conventional pacemaker systems from implantation through 60 to 90 days have usually demonstrated acceptable pacing capture thresholds and sensing. Intermediate performance (90 days through more than 5 years) has usually demonstrated the reliability of the pulse generator and lead technology. Chronic performance (5-10 years) includes a predictable decline in battery life and mechanical reliability, but a vast majority of individuals receive excellent pacing and sensing free of operative or mechanical reliability failures.

Even though the safety profile of conventional pacemakers is excellent, they are associated with complications particularly related to leads. Most safety data on the use of conventional pacemakers come from registries from Europe, particularly from Denmark where all pacemaker implants are recorded in a national registry. These data are summarized in **Table 1**. It is important to recognize that valid comparison of complication rates is limited by differences in definitions of complications, which results in a wide variance of outcomes, as well as by the large variance in follow-up times, use of single-chamber or dual-chamber systems, and data reported over more than two decades.[2] As such, the following data are contemporary and limited to single-chamber systems when reported separately.

In many cases when a conventional pectoral approach is not possible, alternative approaches such as epicardial pacemaker implantation and trans-iliac approaches have been used.[3] Cohen et al (2001) reported outcomes from a retrospective analysis of 123 individuals who underwent 207 epicardial lead implantations.[4] Congenital heart disease was present in 103 (84%) of the individuals. Epicardial leads were followed for 29 months (range 1 to 207 months). Lead failure was defined as the need for replacement or abandonment due to pacing or sensing problems, lead fracture, or phrenic/muscle stimulation. The 1-, 2-, and 5-year lead survival was 96%, 90%, and 74%, respectively. Epicardial lead survival in those placed by a subxiphoid approach was 100% at 1 year and at 10 years, by the sternotomy approach (93.9% at 1 year and 75.9% at 10 years) and lateral thoracotomy approach (94.1% at 1 year and 62.4% at 10 years).

Doll et al (2008) reported results of a randomized controlled trial comparing epicardial implantation versus conventional pacemaker implantation in 80 individuals with indications for cardiac resynchronization therapy.[5] The authors reported that the conventional pacemaker group had a significantly shorter intensive care unit stay, less blood loss, and shorter ventilation times while the epicardial group had less exposure to radiation and less use of contrast medium. The left ventricular pacing threshold was similar in the two groups at discharge but longer in the epicardial group during follow-up. Adverse events were also similar in the two groups. The following events were experienced by one (3%) individual each in the epicardial group: pleural

puncture, pneumothorax, wound infection, acute respiratory distress syndrome, and hospital mortality.

As a less invasive alternative to the epicardial approach, the trans-iliac approach has also been utilized. Data using trans-iliac approach is limited. Multiple other studies with smaller sample size report a wide range of lead longevity.

Harake, et al (2018) reported a retrospective analysis of five individuals who underwent a transvenous iliac approach (median age 26.9 years).[6] Pacing indications included AV block in three individuals and sinus node dysfunction in two individuals. After a median follow-up of 4.1 years (range 1.0-16.7 years), outcomes were reported for four individuals. One individual underwent device revision for lead position-related groin discomfort; a second individual developed atrial lead failure following a Maze operation and underwent lead replacement by the iliac approach. One individual underwent heart transplantation six months after implant with only partial resolution of pacing-induced cardiomyopathy. Tsutsumi et al (2010) reported a case series of four individuals from Japan in whom conventional pectoral approach was precluded due to recurrent lead infections (n=1), superior vena cava obstruction following cardiac surgery (n=2) and a postoperative dermal scar (n=1). The mean follow-up was 24 months, and the authors concluded the iliac vein approach was satisfactory and a less invasive alternative to epicardial lead implantation. However, the authors reported that the incidence of atrial lead dislodgement using this approach in the literature ranged from 7 to 21%. Experts who provided clinical input reported that trans-iliac or surgical epicardial approach requires special expertise and long-term performance is suboptimal.[7]

Table 1. Reported Complication Rates with Conventional Pacemakers

Complications	Rates, %[8,9,10,a]
Traumatic complications	
RV perforation	0.2 to 0.8
RV perforation with tamponade	0.07 to 0.4
Pneumo(hemo)thorax	0.7 to 2.2
Pocket complications	
Including all hematomas, difficult to control bleeding, infection, discomfort, skin erosion	4.75

Complications	Rates, %[8,9,10,a]
Including only those requiring invasive correction or reoperation	0.66 to 1.0
Lead-related complications	
Including lead fracture, dislodgement, insulation problem, infection, stimulation threshold problem, diaphragm, or pocket stimulation, other	1.6 to 3.8
All system-related infections requiring reoperation or extraction	0.5 to 0.7

Adapted from US Food and Drug Administration executive summary memorandum (2016).[11]

[a] Rates are for new implants only and ventricular single-chamber devices when data were available. Some rates listed in this column are for single- and dual-chamber devices when data were not separated in the publication. Note that Micra transcatheter pacing system is a single-chamber device.

RV: right ventricle.

Potential Advantages of Leadless Cardiac Pacemakers Over Conventional Pacemakers

The potential advantages of leadless pacemakers fall into three categories: avoidance of risks associated with intravascular leads in conventional pacemakers, avoidance of risks associated with pocket creation for placement of conventional pacemakers, and an additional option for individuals who require a single-chamber pacer.[12]

Lead complications include lead failure, lead fracture, insulation defect, pneumothorax, infections requiring lead extractions and replacements that can result in a torn subclavian vein or the tricuspid valve. In addition, there are risks of venous thrombosis and occlusion of the subclavian system from the leads. Use of a leadless system eliminates such risks with the added advantage that an individual has vascular access preserved for other medical conditions (e.g., dialysis, chemotherapy).

Pocket complications include infections, erosions, and pain that can be eliminated with leadless pacemakers. Further, a leadless cardiac pacemaker may be more comfortable and appealing because unlike conventional pacemakers, individuals are unable to see or feel the device or have an implant scar on the chest wall.

Leadless pacemakers may also be a better option than surgical endocardial pacemakers for individuals with no vascular access due to renal failure or congenital heart disease.

Atrioventricular Synchrony

The Micra AV device supports maintenance of atrioventricular (AV) synchrony by sensing atrial mechanical contraction (A4 signal). Several small-cohort studies have investigated the relationship between parameters (e.g., clinical and echocardiographic) and A4 signal amplitude. Briongos-Figuero et al (2023) investigated clinical and echocardiographic predictors of optimal AV synchrony, defined as ≥85% of total cardiac cycles being synchronous, in individuals with successful Micra AV implant (N=43). The authors performed univariate analyses followed by multivariate analysis. They found diabetes and chronic obstructive pulmonary disease to be associated with A4 signal amplitude, however no echocardiographic parameters were associated with A4 signal amplitude.[13] Troisi et al (2024) studied the relationship between echocardiographic parameters and A4 signal amplitude in individuals implanted with Micra AV (N=21). The authors concluded echocardiographic parameters, particularly related to left atrial function, may be related to successful AV synchrony.[14] Kawatani et al (2024) et al studied predictors of AV synchrony in individuals with Micra AV implants (N=50). Participants were stratified into 2 groups, high and low A4 amplitude. In a multivariate analysis, maximum deflection index was the only parameter associated with low A4 amplitude.[15] These studies were exploratory and results among the studies were inclusive. More research in larger cohort studies is needed to produce more conclusive evidence on parameters that are predictive of AV synchrony.

Battery Life and Device Retrieval

Currently, real-world evidence of long-term battery life for leadless pacemakers is limited. Breeman et al (2023) studied the battery life of the Micra VR after implantation (N=153). The manufacturer's predicted battery life for the Micra VR is 12 years. Using mixed models to assess changes in electrical parameters over time, the authors concluded that for a majority of individuals the expected battery longevity is >8 years.[16] Due to the limited lifespan of leadless pacemakers, they are designed to be retrievable (e.g., the helix fixation design of the Aveir devices). However, evidence on the safety and success of device retrieval is limited to case reports.[17,18,19]

Anatomical Placement

Li et al (2023) studied different anatomical placements in the ventricular septum of the Micra VR (N=15) and found no impact on safety or electrical characteristics of the device.[20] In a large cohort study in individuals with Micra AV or Micra VR implants (N=358) by Shantha et al (2023), the authors found apical septum placement was associated with a higher risk of pacing-induced cardiomyopathy compared to mid/high septum placement.[21] Larger randomized studies are needed to confirm how anatomical placement of the device impacts safety and effectiveness.

Leadless Cardiac Pacemakers in Clinical Development

Leadless pacemakers are self-contained in a hermetically sealed capsule. The capsule houses a battery and electronics to operate the system. Similar to most pacing leads, the tip of the capsule includes a fixation mechanism and a monolithic controlled-release device. The controlled-release device elutes a glucocorticosteroid to reduce acute inflammation at the implantation site. Leadless pacemakers have rate-responsive functionality, and current device longevity estimates are based on bench data. Estimates have suggested that these devices may last over ten years, depending on the programmed parameters.[11]

Four systems are currently being evaluated in clinical trials:

1. The Micra Transcatheter Pacing System (Medtronic)
2. The Aveir VR Leadless Pacemaker (Abbott; formerly Nanostim, St. Jude Medical)
3. The Aveir DR Dual Chamber Leadless Pacemaker System (Abbott)
4. The WiCS Wireless Cardiac Stimulation System (EBR Systems).

The first three devices are free-standing capsule-sized devices that are delivered via femoral venous access using a steerable delivery sheath. However, the fixing mechanism differs between the Micra and Aveir devices. In the Micra Transcatheter Pacing System, the fixation system consists of four self-expanding nitinol tines, which anchor into the myocardium; for the Aveir devices, there is a screw-in helix that penetrates into the myocardium. In the Micra and Aveir devices, the cathode is steroid eluting and delivers pacing current; the anode is located in a titanium case. The fourth device, WiCS system differs from the other devices; this system requires implanting a pulse generator subcutaneously near the heart, which then wirelessly

transmits ultrasound energy to a receiver electrode implanted in the left ventricle. The receiver electrode converts the ultrasound energy and delivers electrical stimulation to the heart sufficient to pace the left ventricle synchronously with the right.[11]

Of these four, only the Micra and Aveir single-chamber transcatheter pacing systems and the Aveir dual-chamber transcatheter pacing system are approved by the FDA and commercially available in the US. Multiple clinical studies of the Aveir predecessor device, Nanostim, have been published,[1,22,23,24,25,26] but trials have been halted due to the migration of the docking button in the device and premature battery depletion. These issues have since been addressed with the Aveir device.[27]

The Micra is about 25.9 mm in length and introduced using a 23 French catheter via the femoral vein to the right ventricle. It weighs about 1.75 grams and has an accelerometer-based rate response.[28]

The Aveir VR is about 42 mm in length and introduced using a 25 French catheter to the right ventricle. It also weighs about three grams and uses a temperature-based rate response sensor.[29]

The atrial Aveir DR is about 32.3 mm in length and weighs about 2.1 grams. The ventricular Aveir DR is about 38.0 mm in length and weighs about 2.4 grams. Both are introduced using a 25 French catheter. The system uses a temperature-based rate response.[30]

Summary of Evidence

For individuals with a guidelines-based indication for a ventricular pacing system who are medically eligible for a conventional pacing system who receive a single-chamber transcatheter pacing system, the evidence includes a systematic review, pivotal prospective cohort studies, a postapproval prospective cohort study, a Medicare registry, and a retrospective US FDA database analysis. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Results at 6 months and 1 year for the Micra pivotal study reported high procedural success (>99%) and device effectiveness (pacing capture threshold met in 98% patients). Most of the system- or procedure-related complications occurred within 30 days. At one year, the incidence of major complications did not increase substantially from six months (3.5% at six months vs 4% at one year). Results of the Micra postapproval study were consistent with the pivotal study and showed a lower incidence of

major complications up to 30 days postimplantation as well as 1 year (1.5% and 2.7%, respectively). In both studies, the point estimates of major complications were lower than the pooled estimates from six studies of conventional pacemakers used as a historical comparator. While Micra device eliminates lead- and surgical pocket-related complications, its use can result in potentially more serious complications related to implantation and release of the device (traumatic cardiac injury) and less serious complications related to the femoral access site (groin hematomas, access site bleeding). Initial data from a Medicare registry found a significantly higher rate of pericardial effusion and/or perforation within 30 days in individuals with the leadless Micra pacemaker compared to individuals who received a transvenous device; however, overall 6-month complication rates were significantly lower in the Micra group in the adjusted analysis (p=.02). In a real-world study of Medicare patients, the Micra device was associated with a 41% lower rate of reinterventions and a 32% lower rate of chronic complications compared with transvenous pacing, with no significant difference in adjusted all-cause mortality at 3 years despite the higher comorbidity index for individuals implanted with a Micra device. However, individuals receiving the Micra device experienced significantly more other complications, driven by higher rates of pericarditis. No significant differences were noted in the composite endpoint of time to heart failure hospitalization or death for the full cohort (p=.28) or the subgroup without a history of heart failure (p=.98). It is also unclear whether all individuals were considered medically eligible for a conventional pacing system. A single-arm study of the Micra AV device reported that 85.2% of individuals with complete AV block and normal sinus rhythm successfully achieved a >70% resting AV synchrony (AVS) rate at one month postimplant and that AVS rates could be further enhanced with additional device programming. However, clinically meaningful rates of AVS are unknown. Longer-term device characterization is planned in the Micra AV Post-Approval Registry through 3 years. The Aveir pivotal prospective cohort study primary safety and efficacy outcomes at 6 weeks exceeded performance goals for complication-free rate and composite success rate (96.0% and 95.9%, respectively). Results at 6 months were similar and at 1 year were 93.2% and 91.5%, respectively. Incidence of major complications at 1 year was 6.7% compared to 4.0% in the Micra pivotal trial. The 2-year survival estimate of 85.3% is based on Phase 1 performance with the predecessor Nanostim device. Considerable uncertainties and unknowns remain in terms of the durability of the devices and device end-of-life issues. Early and limited experience with the Micra device has suggested that retrieval of these devices is unlikely because in due course, the device will be encapsulated. There are limited data on device-device interactions (both electrical and mechanical), which may occur when there is a deactivated Micra device alongside another leadless pacemaker or when a leadless pacemaker and transvenous device are both present. Although the Aveir device is

specifically designed to be retrieved when therapy needs evolve or the device needs to be replaced, limited data are available on retrieval outcomes. While the current evidence is encouraging, overall benefit with the broad use of FDA-approved single-chamber transcatheter pacing systems compared with conventional pacemakers has not been shown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with a guidelines-based indication for a ventricular pacing system who are medically ineligible for a conventional pacing system who receive a single-chamber transcatheter pacing system, the evidence includes subgroup analysis of a pivotal prospective cohort study and a postapproval prospective cohort study for the Micra device. It is unclear whether the Aveir pivotal study enrolled individuals medically ineligible for a conventional pacing system. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Information on the outcomes in the subgroup of individuals from the postapproval study showed that the Micra device was successfully implanted in 98% to 99% of cases, and safety outcomes were similar to the original cohort. Even though the evidence is limited, and long-term effectiveness and safety are unknown, the short-term benefits outweigh the risks because the complex trade-off of adverse events for these devices needs to be assessed in the context of the life-saving potential of pacing systems for individuals ineligible for conventional pacing systems. There are little data available regarding outcomes associated with other alternatives to conventional pacemaker systems such as epicardial leads or transiliac placement. Epicardial leads are most relevant for the individual who is already going to have a thoracotomy for treatment of their underlying condition (e.g., congenital heart disease). Epicardial leads are associated with a longer intensive care unit stay, more blood loss, and longer ventilation times compared to conventional pacemaker systems. The evidence for transiliac placement is limited to small case series and the incidence of atrial lead dislodgement using this approach in the literature ranged from 7 to 21%. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with a guidelines-based indication for a dual-chamber pacing system who are medically eligible for a conventional pacing system who receive a dual-chamber leadless pacing system, the evidence includes a pivotal prospective single cohort study. Relevant outcomes are freedom from complications and adequate atrial capture threshold and sensing amplitude. Results from 3 months and 6 months or the pivotal study reported freedom from complications in 90.3% and 89.1% of individuals, respectively, and adequate atrial capture threshold and

sensing amplitude in 90.2% and 90.8% of individuals, respectively. Acute and long-term events will be captured in a post approval study through 9 years. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with a guidelines-based indication for a dual-chamber pacing system who are medically ineligible for a conventional pacing system who receive a dual-chamber leadless pacing system, no evidence was identified that exclusively enrolled individuals who were medically ineligible for a conventional pacing system. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 2**.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06100770[a,b]	Aveir AR Coverage With Evidence Development (CED) Study	586	Jan 2031 (ongoing)
NCT05932602[a,b]	The AVEIR DR Coverage With Evidence Development (DRIVE) Study	2812	Oct 2025 (ongoing)
NCT05935007[a]	Aveir Dual-Chamber Leadless Pacemaker Real-World Evidence Post-Approval Study	1805	Jan 2030 (ongoing)
NCT05856799	Danish Randomized Trial on VDD Leadless Atrial Tracking With MicraTM AV Transcatheter Pacing System vs Transvenous DDD Pacing in Elderly Patients With AV-block	80	Aug 2025 (ongoing)
NCT05817695	Effect of Different Pacing Sites on Cardiac Synchronization and Tricuspid Regurgitation After Leadless Pacemaker Implantation	40	May 2023 (ongoing)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04559945[a,b]	The LEADLESS II IDE Study (Phase II): A Safety and Effectiveness Trial for a Leadless Pacemaker System	326	Aug 2023 (ongoing)
NCT05528029	International Leadless Pacemaker Registry (i-LEAPER)	2000	Dec 2024 (recruiting)
NCT04253184[a]	Micra AV Transcatheter Pacing System Post-Approval Registry (Micra AV PAS)	802	Apr 2025 (ongoing)
NCT05498376	The Leadless AV Versus DDD Pacing Study: A Randomized Controlled Single-center Trial on Leadless Versus Conventional Cardiac Dual-chamber Pacing (LEAVE DDD)	100	Feb 2026 (recruiting)
NCT04235491[a,b]	Longitudinal Coverage With Evidence Development Study on Micra AV Leadless Pacemakers (Micra AV CED)	37,000	Jun 2027 (ongoing)
NCT04051814	A Retrospective Trial to Evaluate the Micra Pacemaker	500	May 2025 (recruiting)
NCT03039712[a,b]	Longitudinal Coverage With Evidence Development Study on Micra Leadless Pacemakers (Micra CED)	37,000	Jun 2027 (ongoing)
NCT04926792	Taiwan Registry for Leadless Pacemaker	300	Jun 2025 (not yet recruiting)
NCT05252702[a]	Aveir Dual-Chamber Leadless i2i IDE Study	550	Nov 2025 (recruiting)
NCT02536118[a,b]	Micra Transcatheter Pacing System Post-Approval Registry	3100	Aug 2026 (ongoing)
NCT05336877[a,b]	Aveir Single-Chamber Leadless Pacemaker Coverage With Evidence Development (ACED) Post-Approval Study	8744	Jan 2028 (recruiting)
NCT04798768[a,b]	Effectiveness of the EMPOWER Modular Pacing System and EMBLEM Subcutaneous ICD to Communicate Antitachycardia Pacing (MODULAR ATP)	300	Dec 2030 (ongoing)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

[b] Denotes CMS-approved study.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2023 Input

Clinical input was sought to help determine whether the use of an Aveir or Micra AV transcatheter pacing system for an individual with a guidelines-based indication for a ventricular pacing system would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice depending on individual medical eligibility for a conventional pacing system. In response to requests, clinical input was received from two respondents, including one specialty society-level response including physicians with academic medical center affiliation and one physician-level response with academic affiliation identified through a specialty society.

For individuals with a guidelines-based indication for a ventricular pacing system who are medically ineligible for a conventional pacing system who receive a Micra AV or Aveir transcatheter pacing system, clinical input supports this use provides a clinically meaningful improvement in net health outcomes and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected individuals when both conditions below are met:

- The individual has significant bradycardia and:
    - Normal sinus rhythm with rare episodes of 2° or 3° atrioventricular (AV) block or sinus arrest and severe physical disability or short expected lifespan; OR
    - Chronic atrial fibrillation.
- The individual has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as any of the following:

- History of an endovascular or cardiovascular implantable electronic device (CIED) infection or who are at high risk for infection;
- Limited access for transvenous pacing given venous anomaly, occlusion of axillary veins, or planned use of such veins for a semi-permanent catheter or current or planned use of an arteriovenous fistula for hemodialysis;
- Presence of a bioprosthetic tricuspid valve.

For individuals with a guidelines-based indication for a ventricular pacing system who are medically eligible for a conventional pacing system who receive a Micra AV or Aveir transcatheter pacing system, clinical input indicates this use is consistent with generally accepted medical practice but reports mixed support that this use provides a clinically meaningful improvement in net health outcomes.

2019 Input

Clinical input was sought to help determine whether the use of leadless cardiac pacemakers for individuals with a guidelines-based indication for a ventricular pacing system would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from two respondents, including one specialty society-level response and one physician-level response identified through specialty societies including physicians with academic medical center affiliations.

For individuals with a guidelines-based indication for a ventricular pacing system who are medically ineligible for a conventional pacing system who receive a Micra transcatheter pacing system, clinical input supports this use provides a clinically meaningful improvement in net health outcomes and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected individuals when both conditions below are met:

- The individual has symptomatic paroxysmal or permanent high-grade arteriovenous block or symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses).
- The individual has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as any of the following:

- History of an endovascular or CIED infection or who are very high-risk for infection
- Limited access for transvenous pacing given venous anomaly, occlusion of axillary veins or planned use of such veins for a semi-permanent catheter or current or planned use of an AV fistula for hemodialysis
- Presence of a bioprosthetic tricuspid valve

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology Foundation et al

In 2012, The American College of Cardiology Foundation (ACCF), American Heart Association (AHA), and the Heart Rhythm Society (HRS) issued a focused update of the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities.[87] These guidelines included recommendations regarding permanent pacemaker implantation in individuals with class I or II indications.

Heart Rhythm Society

In 2020, the Heart Rhythm Society (HRS), along with the International Society for Cardiovascular Infectious Diseases (ISCVID) and several other Asian, European and Latin American societies, endorsed the European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections.[88] The

consensus states that for individuals at high risk of device-related infections, avoiding a transvenous system, and implanting an epicardial system, may be preferential. It makes the following statements regarding leadless pacemakers:

- 'There is hope that 'leadless' pacemakers will be less prone to infection and can be used in a similar manner [as epicardial systems] in high-risk patients.'
- 'In selected high-risk patients, the risk of infection with leadless pacemakers appears low. The device also seems safe and feasible in patients with pre-existing cardiovascular implantable electronic device infection and after extraction of infected leads.'

National Institute for Health and Care Excellence

In 2018, the NICE issued evidence-based recommendations on leadless cardiac pacemaker implantation for adults with bradyarrhythmias.[89] The guidance states that the evidence "on the safety of leadless cardiac pacemaker implantation for bradyarrhythmias shows that there are serious but well-recognized complications. The evidence on efficacy is inadequate in quantity and quality:

- For people who can have conventional cardiac pacemaker implantation, leadless pacemakers should only be used in the context of research
- For people in whom a conventional cardiac pacemaker implantation is contraindicated following a careful risk assessment by a multidisciplinary team, leadless cardiac pacemakers should only be used with special arrangements for clinical governance, consent and audit or research."

This guidance is awaiting development as of April 2023 with expected publication in June 2024.

Medicare National Coverage

The Centers for Medicare & Medicaid (CMS) cover leadless pacemakers under coverage with evidence development criteria when procedures are performed in prospective longitudinal studies approved by the FDA using "leadless pacemakers … in accordance with the FDA approved label for devices that have either:

- An associated ongoing FDA approved post-approval study; or
- Completed an FDA post-approval study.

Each study must be approved by CMS and as a fully-described, written part of its protocol, must address the following research questions:

- What are the peri-procedural and post-procedural complications of leadless pacemakers?
- What are the long-term outcomes of leadless pacemakers?
- What are the effects of patient characteristics (age, gender, comorbidities) on the use and health effects of leadless pacemakers?"[90]

The following six studies are currently approved by CMS[91]:

- Aveir AR Coverage With Evidence Development (CED) Study (ARRIVE) (NCT06100770); CMS approval date: 01/18/24;
- Aveir DR CED Study (NCT05932602); CMS approval date: 10/31/23;
- Aveir VR Coverage With Evidence Development Post-Approval Study (NCT05336877); CMS approval date: 6/21/22;
- Effectiveness of the EMPOWER Modular Pacing System and EMBLEM Subcutaneous ICD to Communicate Antitachycardia Pacing (NCT04798768); CMS approval date: 1/20/22;
- The LEADLESS II IDE Study (Phase II): A Safety and Effectiveness Trial for a Leadless Pacemaker System (NCT04559945); CMS approval date: 3/16/21;
- Longitudinal Coverage with Evidence Development Study on Micra AV Leadless Pacemakers (Micra AV CED) (NCT04235491); CMS approval date: 2/5/2020;
- The Micra CED Study (NCT03039712); CMS approval date: 03/09/17
- Micra Transcatheter Pacing System Post-Approval Registry (NCT02536118); CMS approval date: 02/09/17 (see **Table 2** for additional details).

Regulatory Status

In April 2016, the Micra transcatheter pacing system (Medtronic) was approved by the FDA through the premarket approval process (PMA number: P150033) for use in individuals who have experienced one or more of the following conditions:

- Symptomatic paroxysmal or permanent high-grade arteriovenous block in the presence of atrial fibrillation
- Paroxysmal or permanent high-grade arteriovenous block in the absence of atrial fibrillation, 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

In January 2020, the Micra AV Transcatheter Pacing System Model MC1AVR1 and Application Software Model SW044 were approved as a PMA supplement (S061) to the Micra system described above. The Micra AV includes an enhanced algorithm to provide AV synchronous pacing.

In November 2021, the FDA issued a letter to health care providers regarding the risk of major complications related to cardiac perforation during implantation of leadless pacing systems.[31] Specifically, the FDA states that "real-world use suggests that cardiac perforations associated with Micra leadless pacemakers are more likely to be associated with serious complications, such as cardiac tamponade or death, than with traditional pacemakers." This letter has been removed from the FDA website as of April 2024.

In March 2022, the Aveir VR Leadless Pacemaker was approved by the FDA through the premarket approval process (PMA number: P150035) for use in individuals with bradycardia and:

- Normal sinus rhythm with only rare episodes of AV 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.

In June 2023, a premarket approval application supplement with expanded indications to include dual-chamber pacing with the Aveir DR Leadless System was approved by the FDA (PMA number: P150035) for use in individuals with one or more of the following permanent conditions:

- Snycope;
- Pre-syncope;
- Fatigue;
- Disorientation

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

- Dual-Chamber Pacing is indicated for individuals exhibiting:
- Sick sinus syndrome;
- Chronic, symptomatic second- and third-degree atrioventricular block;
- Recurrent Adams-Stokes syndrome;
- Symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out.

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History

Date	Comments
10/01/19	New policy, approved September 10, 2019, effective January 3, 2020. Policy created with literature review through May 2019. The Micra transcatheter pacing system may be considered medically necessary in patients who are not eligible for conventional pacemakers when all of the specified conditions are met.
10/01/20	Annual Review, approved September 1, 2020. Policy updated with literature review through May, 2020; references added. Policy statements unchanged.
08/01/21	Annual Review, approved July 9, 2021. Policy updated with literature review through April 2, 2021; no references added. Policy statements unchanged.
08/01/22	Annual Review, approved July 12, 2022. Policy updated with literature review through April 22, 2022; references added. Investigational policy statement added for the Aveir transcatheter pacing system for all indications.
09/27/22	Minor correction to cardiovascular implantable electronic device infection statement within the Document Requirements section.
09/01/23	Policy renumbered, approved August 8, 2023, from 2.02.32 to 2.02.515 Leadless Cardiac Pacemakers. Policy updated with literature review through March 20, 2023; references added. Added policy statement that dual chamber leadless pacemakers are considered investigational. Changed the wording from "patient" to "individual" throughout the policy for standardization. Added CPT codes 0795T-0803T effective 7/1/2023.
01/01/24	Coding update. Added new CPT codes 0823T-0826T.
08/01/24	Annual Review, approved July 8, 2024. Policy updated with literature review through March 14, 2024; references added. Minor editorial refinements made to dual chamber leadless pacemaker policy statement; policy intent unchanged. Other policy statements unchanged. Removed CPT code 0826T. Added new HCPCS code C1605 effective 7/1/2024.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.