

MEDICAL POLICY – 2.02.515

Leadless Cardiac Pacemakers

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None

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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	<p data-bbox="586 294 1446 415">The Micra single chamber transcatheter pacing system may be considered medically necessary in individuals when BOTH of the following conditions are met:</p> <ul data-bbox="586 426 1446 640" style="list-style-type: none"> <li data-bbox="586 426 1446 464">• The individual has ONE of the following conditions: <ul data-bbox="643 474 1446 640" style="list-style-type: none"> <li data-bbox="643 474 1446 512">○ Symptomatic paroxysmal arteriovenous block; or <li data-bbox="643 522 1446 560">○ Permanent high-grade arteriovenous block; or <li data-bbox="643 571 1446 609">○ Symptomatic bradycardia-tachycardia syndrome; or <li data-bbox="643 619 1446 640">○ Sinus node dysfunction (sinus bradycardia or sinus pauses). <p data-bbox="586 651 656 680">AND</p> <ul data-bbox="586 693 1446 1176" style="list-style-type: none"> <li data-bbox="586 693 1446 814">• The individual has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as ANY of the following: <ul data-bbox="643 825 1446 1176" style="list-style-type: none"> <li data-bbox="643 825 1446 947">○ History of an endovascular or cardiovascular implantable electronic device (CIED) infection or who are at high risk for infection (see Related Information); or <li data-bbox="643 957 1446 1129">○ 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 <li data-bbox="643 1140 1446 1176">○ Presence of a bioprosthetic tricuspid valve <p data-bbox="586 1230 1425 1352">The Micra single chamber transcatheter pacing system is considered investigational in all other situations in which the above criteria are not met.</p> <p data-bbox="586 1407 1360 1486">The Aveir single chamber transcatheter pacing system is considered investigational for all indications.</p> <p data-bbox="586 1541 1409 1663">The insertion, removal, or replacement of the Aveir DR dual chamber leadless pacemaker system is considered investigational for all indications.</p>

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, the Micra Model MC1VR01 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) (new code effective 7/1/2023)



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) (new code effective 7/1/2023)
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) (new code effective 7/1/2023)
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) (new code effective 7/1/2023)
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 (new code effective 7/1/2023)
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) (new code effective 7/1/2023)
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



Code	Description
	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)
0826T	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, leadless pacemaker system in single-cardiac chamber (new code effective 1/1/2024)

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

Infection Risk

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 \geq 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.

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 patients 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 patient 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 are the only commercially available leadless pacemakers in the U. S. approved by the 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 U. S. 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%) patient 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.

Harakeet 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 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
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 U.S. 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.

Dual Chamber Leadless Pacemakers

The Aveir DR (Dual-Chamber) Leadless Pacemaker System is in an ongoing evaluation of individuals who need DDD(R) pacing. A prospective, multicenter, nonrandomized, single arm study, n =300, 190 had sinus-node dysfunction and 100 had AV block as the primary pacing indication. The implantation procedure was successful in 98.3% of the participants. The primary safety end point was freedom from complications (either device or procedure-related serious

adverse events) at 90 days was met in 90.3% of the individuals. There were 35 device or procedure-related serious adverse events in 29 of the participants. The first primary performance end point of adequate atrial capture threshold and sensing amplitude was met in 90.2% of participants. The second primary performance end point of at least 70% AV synchrony at 90 days was met in 97.3% of participants. The study is ongoing, and the participants will be followed for 12 months post-implant. The trial was sponsored by the manufacturer, Abbott Medical and is expected to be completed in 2025. (NCT05252702).

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

Three 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); and (3) the WiCS Wireless Cardiac Stimulation System (EBR Systems). The first two 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 two 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 device, there is a screw-in helix that penetrates into the myocardium. In both devices, the cathode is steroid eluting and delivers pacing current; the anode is located in a titanium case. The third 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 three, only the Micra and Aveir single-chamber transcatheter pacing systems are approved by the FDA and commercially available in the U. S. Multiple clinical studies of the Aveir



predecessor device, Nanostim, have been published^{1,13,14,15,16,17} 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.¹⁸

The Micra is about 26 mm in length and introduced using a 23 French catheter via the femoral vein to the right ventricle. It weighs about two grams and has an accelerometer-based rate response.¹⁹

The Aveir 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.²⁰

As per the FDA label, the Aveir Leadless Pacemaker Model LSP112V is contraindicated in the following situations:

- Use of any pacemaker is contraindicated in individuals with a co-implanted implantable cardioverter-defibrillator because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.
- Single-chamber ventricular demand pacing is relatively contraindicated in individuals who have demonstrated pacemaker syndrome, have retrograde ventriculoatrial conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing.
- Programming of rate-responsive pacing is contraindicated in individuals with intolerance of high sensor-driven rates.
- Use is contraindicated in individuals 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 contained in the device and a thorough history of allergies must be discussed.

The Aveir Leadless Pacemaker is conditionally safe for use in the magnetic resonance imaging (MRI) environment when used according to the instructions in the MRI-Ready Leadless System Manual (which includes equipment settings, scanning procedures, and a listing of conditionally



approved components). Scanning under different conditions may result in severe patient injury, death, or device malfunction.

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 pivotal prospective cohort studies, a postapproval prospective cohort study, a Medicare registry, and a retrospective 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 procedural-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 1 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 need for dual chamber, right atrial and right ventricle pacing, the evidence includes an industry sponsored, ongoing, prospective, multicenter, non-randomized, single-arm pivotal clinical trial. The primary safety end point and the primary and secondary performance outcome measures were all met at 90 days. The 300 enrollees are to be followed for 12 months post-implant. The evidence is promising but not complete and is therefore 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			
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)



NCT No.	Trial Name	Planned Enrollment	Completion Date
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

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



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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. 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.

National Institute for Health and Care Excellence

In 2018, the NICE issued evidence-based recommendations on leadless cardiac pacemaker implantation for adults with bradyarrhythmias.⁴⁹ 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.

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.⁵⁰ 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.'

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?"⁵¹



The following six studies are currently approved by CMS⁵²:

- Aveir VR Coverage With Evidence Development Post-Approval Study (NCT05336877); CMS approval date: 6/2/22;
- 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.²¹ 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."

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, the Aveir DR (Dual) Leadless System was approved by the FDA through the premarket approval process (PMA 150035 S003) for use in individuals who require right ventricle pacing and right atrial pacing to treat slow or abnormal heart rhythms.

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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.

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. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

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.



Discrimination is Against the Law

Premera Blue Cross (Premera) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). Premera provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, contact the Civil Rights Coordinator. If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator — Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-4535, Fax: 425-918-5592, TTY: 711, Email AppealsDepartmentInquiries@Premera.com. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Ave SW, Room 509F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at <https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status>, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at <https://fortress.wa.gov/oic/online-services/cc/pub/complaintinformation.aspx>.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-722-1471 (TTY: 711).

注意: 如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY: 711)。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-722-1471 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телетайп: 711).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-722-1471 (TTY: 711).

MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totagi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ຄ່າ, ຄືມາດຕະການໃຫ້ທ່ານ. ໂທ 800-722-1471 (TTY: 711).

注意事項: 日本語を話される場合、無料の言語支援をご利用いただけます。800-722-1471 (TTY: 711) まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-722-1471 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំណប់ឡើង។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም ኣርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው፡ 711)፡

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajjila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

मिथान सिछि: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS: 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجہ: اگر بہ زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.