Corporate Medical Policy

Leadless Cardiac Pacemakers

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Description of Procedure or Service

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.

Conventional Pacemakers
Transvenous pacemakers or pacemakers with leads (referred to in this policy as conventional pacemakers) consist of two components: a pulse generator (ie, battery component) and electrodes (ie, 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 1 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 United States and 1 million worldwide. Implantable pacemakers are considered life-sustaining, life-supporting class III devices for patients with a variety of bradyarrhythmias. Pacemaker systems have matured over the years with well-established, acceptable performance standards. As per the U.S. Food and Drug Administration (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 patients 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 comes from registries from Europe, particularly from Denmark where all pacemaker implants are recorded in a national registry. 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 2 decades. 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, alternate approaches such as epicardial pacemaker implantation and trans-iliac approaches have been used. Cohen et al (2001) reported outcomes from a retrospective analysis of 123 patients who underwent 207 epicardial lead implantations. Congenital heart disease was present in 103 (84%) of the patients. 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 an RCT comparing epicardial implantation vs conventional pacemaker implantation in 80 patients with indications for cardiac resynchronization therapy. The authors report that the conventional pacemaker group had significantly shorter ICU 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 alternate to 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 and colleagues (2018) reported a retrospective analysis of 5 patients who underwent a transvenous iliac approach (median age 26.9 years). Pacing indications included AV block in three patients and sinus node dysfunction in two patients. After a median follow-up of 4.1 years (range 1.0-16.7 years), outcomes were reported for 4 patients. One patient underwent device revision for lead position-related groin discomfort; a second patient developed atrial lead failure following a Maze operation and underwent lead replacement by the iliac approach. One patient underwent heart transplantation six months after implant with only partial resolution of pacing-induced cardiomyopathy. Tsutsumi et al (2010) reported a case series of 4 patients 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 authors concluded the iliac vein approach was satisfactory and less invasive alternative to epicardial lead implantation. However, the authors report that 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 require special expertise and long-term performance is suboptimal.

Leadless Cardiac 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 patients who require a single-chamber pacer.

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 a patient has vascular access preserved for other medical conditions (eg, 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, patients 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 patients with no vascular access due to renal failure or congenital heart disease.

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 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 10 years, depending on the programmed parameters.

Clinical Development
Three systems are currently being evaluated in clinical trials: (1) the Micra Transcatheter Pacing System (Medtronic), (2) the Aveir VR Leadless Pacemaker (Abbot; formerly Nanostim, St. Jude Medical); (3) the Aveir DR Dual Chamber Leadless Pacemaker System (Abbott) and (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.

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 United States. Multiple clinical studies of the Aveir predecessor device, Nanostim, have been published 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.

The Micra is about 25.9mm 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.

The Aveir VR is about 42mm in length and introduced using a 25 French catheter to the right ventricle. It weighs about 3 grams and uses a temperature-based rate response sensor.

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

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 patients 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 premarket approval 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, 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." As of May 2024, this letter has been removed from the FDA website.

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

- normal sinus rhythm with only rare episodes of A-V block or sinus arrest
- chronic atrial fibrillation
- severe physical disability

Rate-Modulated Pacing is indicated for patients 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 for use in individuals with 1 or more of the following permanent conditions:

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

Rate-Modulated Pacing is indication 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 patients 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.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Leadless Cardiac Pacemakers

Policy

BCBSNC will provide coverage for leadless cardiac pacemakers when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore, member benefit language should be reviewed before applying the terms of this medical policy.

When Leadless Cardiac Pacemakers are covered

The Micra transcatheter pacing system may be considered medically necessary in individuals when both conditions below are met:

1. 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), **AND**

2. 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, **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 AV fistula for hemodialysis, **or**
    - Presence of a bioprosthetic tricuspid valve

When Leadless Cardiac Pacemakers are not covered

The Micra 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.

Policy Guidelines

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 post approval prospective cohort study, a Medicare registry, and a retrospective FDA database analysis. 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 1 year, the incidence of major complications did not increase substantially from 6 months (3.5% at 6 months vs 4% at 1 year). Results of the Micra post-approval study were consistent with the pivotal study and showed a lower incidence of major complications up to 30 days post-implantation 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 6 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 patients with the leadless Micra pacemaker compared to patients 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 32% 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 patients implanted with the Micra device. However, patients 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 patients 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 post-approval prospective cohort study for the Micra device. It is unclear whether the Aveir pivotal study enrolled patients medically ineligible for a conventional pacing system. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Information on the outcomes in the subgroup of patients from the post-approval 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 may 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 patients, ineligible for conventional pacing systems. The evidence is insufficient or inconclusive 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.

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 patient 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0795T, 0796T, 0797T, 0798T, 0799T, 0800T, 0801T, 0802T, 0803T, 0804T, 0823T, 0824T, 0825T, 0826T, C1605

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.32, 7/2019

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Specialty Matched Consultant Advisory Panel review 10/2019

Medical Director review 10/2019

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Policy Implementation/Update Information

8/13/2019	New policy developed. Leadless cardiac pacemakers, specifically, the Micra transcatheter pacing system may be considered medically necessary in patients when the medical criteria are met. Added the following codes, *0387T, 0388T, 0389T, 0390T, 0391T* to "Billing/Coding" section. References added. Medical Director review 7/2019. (jd)
10/29/19	Specialty Matched Consultant Advisory Panel review 10/2019. Medical Director review 10/2019. (jd)
2/25/20	Billing/Coding section updated: removed CPT codes 0387T-0391T and added 33274 and 33275. (jd)
11/10/20	References updated. Specialty Matched Consultant Advisory Panel review 10/2020. Medical Director review 10/2020. (jd)
11/2/21	References updated. Specialty Matched Consultant Advisory Panel review 10/2021. Medical Director review 10/2021. (jd)
11/15/22	Description, including Regulatory Status, References and Policy Guidelines sections updated. Added statement to Not Covered section: "The Aveir™ single-chamber transcatheter pacing system is considered investigational for all indications." Specialty Matched Consultant Advisory Panel review 10/2022. Medical Director review 10/2022. (tm)
6/30/23	Added codes 0795T, 0796T, 0797T, 0798T, 0799T, 0800T, 0801T, 0802T, 0803T, 0804T to Billing/Coding section, effective 7/1/23. (tm)
9/12/23	CPT codes 33274 and 33275 removed from Billing/Coding section effective 4/1/23. (tm)
11/7/23	Description, Policy Guidelines and References updated, When Covered Section edited for clarity, no change to policy statement. Specialty Matched Consultant Advisory Panel review 10/2023. Medical Director review 10/2023. (tm)
12/29/23	Added codes 0823T, 0824T, 0825T and 0826T to Billing/Coding section, effective 1/1/24. (tm)
7/1/24	Description, Policy Guidelines and References updated. Added statement to Not Covered section: "The Aveir™ DR dual-chamber pacing system is considered investigational for all indications." Code C1605 added to the Billing/Coding section effective 7/1/24. Specialty Matched Consultant Advisory Panel review 6/2024. Medical Director review 6/2024. (tm)