Dual Chamber Leadless Cardiac Pacemakers

Effective: January 1, 2025

Next Review: September 2024
Last Review: October 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Dual chamber leadless pacemakers are self-contained devices that are implanted directly in the right atrium and right ventricle via femoral access. Leadless pacemakers are used in patients who are ineligible for conventional pacemakers due to complications such as lack of venous access or recurrent infection.

MEDICAL POLICY CRITERIA

I. The initial insertion or replacement of a dual chamber leadless pacemaker is considered **investigational.**

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Intracardiac Ischemia Monitoring, Surgery, Policy No. 208

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 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.

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 patients who require a single-chamber pacer.[1]

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 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 (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, 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.

DUAL CHAMBER 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 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.[2]

The Aveir DR i2i ™ is currently being evaluated in an open label prospective, multicenter, international, single-arm, pivotal investigational study designed to evaluate the clinical safety and efficacy of the Aveir DR leadless pacemaker in patients who were indicated for a dual-chamber bradycardia pacing pacemaker that stimulates the appropriate chamber of the heart when necessary or DDD(R).[3] The study was initiated February 2, 2022 and is estimated to be complete by November 2025. The primary completion date is September 2023. The study plan is to enroll up to 550 patients from up to 82 sites in the U.S., Canada, Europe and Asia-Pacific, and all patients will be followed for a minimum of 12 months post-implant. (ClinicalTrials.gov identifier NCT05252702).

REGULATORY STATUS

Aveir™ DR Leadless Pacemaker system (Abbott)

In March 2022, the Aveir™ VR Leadless Pacemaker was approved by the U.S. FDA through the premarket approval process 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 would benefit from increased stimulation rates concurrent with physical activity.

In June 2023, the Aveir™ DR Leadless Pacemaker system was approved by the FDA through the premarket approval process. The device is indicated for management of one or more of the following permanent conditions:

- syncope
- pre-syncope
- fatigue
- disorientation.

The device has multiple pacing functions including rate-modulated pacing, atrial pacing, ventricular pacing and dual chamber pacing. Each function has specific indications:

> Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.
>
> Atrial Pacing is indicated for patients with:
>
> - Sinus node dysfunction and normal AV and intraventricular conduction systems
>
> Ventricular Pacing is indicated for patients with:
>
> - Significant bradycardia and normal sinus rhythm with only rare episodes of AV block or sinus arrest
> - Chronic atrial fibrillation
> - Severe physical disability

Dual-Chamber Pacing is indicated for patients exhibiting:

- Sick sinus syndrome
- Chronic, symptomatic second- and third-degree AV block
- Recurrent Adams-Stokes syndrome
- Symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out.

MRI Conditional: The Aveir Leadless Pacemaker is conditionally safe for use in the MRI environment and according to the instructions in the MRI-Ready Leadless System Manual.

EVIDENCE SUMMARY

Conventional pacemaker systems have been in use for over 50 years and current technology has matured with significant similarities in designs across models. Extensive bench testing data with conventional pacemakers and a good understanding of operative and early postimplant safety and effectiveness are available, which limits the need for clinical data collection to understand their safety and effectiveness with regard to implantation, tip fixation, electrical measures, and rate response. As such, a randomized controlled trial comparing the leadless pacemakers with conventional pacemakers was not required by the Food and Drug Administration (FDA).

Knop (2023) published a prospective, multicenter, single-group study to evaluate the safety and performance of a dual-chamber leadless pacemaker system.[4] Patients with a conventional indication for dual-chamber pacing were eligible for participation. The primary safety end point was freedom from complications (i.e., device- or procedure-related serious adverse events) at 90 days. The first primary performance end point was a combination of adequate atrial capture threshold and sensing amplitude at three months. The second primary performance end point was at least 70% atrioventricular synchrony at three months while the patient was sitting. Among the patients (n = 300) enrolled, 190 (63.3%) had sinus-node dysfunction and 100 (33.3%) had atrioventricular block as the primary pacing indication. The implantation procedure was successful (i.e., two functioning leadless pacemakers were implanted and had established implant-to-implant communication) in 295 patients (98.3%). A total of 35 device- or procedure-related serious adverse events occurred in 29 patients. The primary safety end point was met in 271 patients (90.3%; 95% confidence interval [CI], 87.0 to 93.7), which exceeded the performance goal of 78% ($p < 0.001$). The first primary performance end point was met in 90.2% of the patients (95% CI, 86.8 to 93.6), which exceeded the performance goal of 82.5% ($p < 0.001$). The mean (±SD) atrial capture threshold was 0.82 ± 0.70 V, and the mean P-wave amplitude was 3.58±1.88 mV. Of the 21 patients (7%) with a P-wave amplitude of less than 1.0 mV, none required device revision for inadequate sensing. At least 70% atrioventricular synchrony was achieved in 97.3% of the patients (95% CI, 95.4 to 99.3), which exceeded the performance goal of 83% ($p < 0.001$). This study was (Funded by Abbott Medical; Aveir DR i2i ClinicalTrials.gov number, NCT05252702.).

Section Summary

There is not enough evidence to support the use of dual chamber leadless pacemakers for any indication.

PRACTICE GUIDELINE SUMMARY

AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION, AMERICAN HEART ASSOCIATION, AND HEART RHYTHM SOCIETY

The American College of Cardiology Foundation, American Heart Association, and Heart Rhythm Society's (2012) focused update on device-based therapy of cardiac rhythm abnormalities incorporated into their joint 2008 guidelines for device-based therapy of cardiac rhythm abnormalities does not include recommendations on leadless cardiac pacemakers.[5]

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.[6] The consensus states that for patients 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 CIED infection and after extraction of infected leads."

The Heart Rhythm Society and American College of Cardiology Foundation (2012) expert consensus statement on pacemaker device and mode selection does not include recommendations on leadless cardiac pacemakers.[7]

SUMMARY

There is not enough evidence to show that dual chamber leadless pacing systems can improve health outcomes for any indication. No evidence based clinical practice guidelines recommend dual chamber leadless pacemakers. Therefore, dual chamber leadless pacing systems are considered investigational for any indication.

REFERENCES

1. American Heart Association. Statement of the American Heart Association to the Food and Drug Administration Circulatory System Devices Panel February 18, 2016: Leadless Cardiac Pacemaker Devices. 2016. [cited 05/17/2024]. 'Available from:' https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM486235.pdf.
2. U.S. Food and Drug Administration (FDA). FDA Executive Summary Memorandum. General Issues: Leadless Pacemaker Devices Prepared for the February 18, 2016 meeting of the Circulatory System Devices Advisory Panel Gaithersburg Hilton; Gaithersburg, MD. 2016;. [cited 05/17/2024]. 'Available from:' https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM485093.pdf.

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4. Knops RE, Reddy VY, Ip JE, et al. A Dual-Chamber Leadless Pacemaker. *The New England journal of medicine.* 2023;388(25):2360-70. PMID: 37212442
5. Epstein AE, DiMarco JP, Ellenbogen KA, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology.* 2013;61(3):e6-75. PMID: 23265327
6. Blomström-Lundqvist C, Traykov V, Erba PA, et al. European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections-endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), International Society for Cardiovascular Infectious Diseases (ISCVID) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). *Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology.* 2020;22(4):515-49. PMID: 31702000
7. Gillis AM, Russo AM, Ellenbogen KA, et al. HRS/ACCF expert consensus statement on pacemaker device and mode selection. *Journal of the American College of Cardiology.* 2012;60:682-703. PMID: 22854177

CODES

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

Codes	Number	Description
	0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component
	0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
	0801T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)
	0802T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component
	0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
	0804T	Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers
HCPCS	None	

Date of Origin: *December 2018*