



## FEP Medical Policy Manual

### FEP 2.02.32 Leadless Cardiac Pacemakers

**Effective Policy Date: October 1, 2022**

**Original Policy Date: December 2019**

**Related Policies:**

None

## Leadless Cardiac Pacemakers

### Description

#### 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 2 components: a pulse generator and electrodes (or leads). Pacemakers are considered life-sustaining, life-supporting class III devices for patients with a variety of bradyarrhythmias. Even though the efficacy and safety profile of conventional pacemakers are excellent, in a small proportion of patients, they may result in lead complications and the requirement for a surgical pocket. Further, some patients 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 U.S. Food and Drug Administration.

#### OBJECTIVE

The objective of this evidence review is to determine whether the use of FDA-approved single-chamber transcatheter pacing systems in patients with a guidelines-based indication for a single-chamber ventricular pacing system improves the net health outcome.

## POLICY STATEMENT

The Micra™ single-chamber transcatheter pacing system may be considered **medically necessary** in patients when both conditions below are met:

1. The patient has symptomatic paroxysmal or permanent high-grade arteriovenous block or symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses);
2. The patient has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as any of the following:
  - o History of an endovascular or cardiovascular implantable electronic device (CIED) infection or who are at high risk for infection
  - o 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
  - o Presence of a bioprosthetic tricuspid valve.

The Micra single-chamber transcatheter pacing system is considered **investigational** in all other situations in which the above criteria are not met.

The Aveir™ single-chamber transcatheter pacing system is considered **investigational** for all indications.

## POLICY GUIDELINES

As per the U.S. Food and Drug Administration (FDA) label, the Micra Model MC1VR01 pacemaker is contraindicated for patients 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 pacemaker is also contraindicated for patients 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 contrast medical which cannot be adequately premedicated

As per the FDA label, the Micra Model MC1VR01 pacemaker should not be used in patients 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 patients with a Micra MRI device, refer to the Medtronic MRI Technical Manual.

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 patients 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).

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

## FDA REGULATORY STATUS

In April 2016, the Micra™ transcatheter pacing system (Medtronic) was approved by the U.S. Food and Drug Administration (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 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 U.S. FDA issued a letter to health care providers regarding the risk of major complications related to cardiac perforation during implantation of leadless pacing systems.<sup>21</sup> 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 U.S. 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.

## RATIONALE

### 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 U.S. Food and Drug Administration (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% of patients). Most of the system- or procedure-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 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 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 complications 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 38% lower adjusted rate of reinterventions and a 31% lower adjusted rate of chronic complications compared with transvenous pacing, with no significant difference in adjusted all-cause mortality at 2 years despite the higher comorbidity index for patients implanted with a Micra device. However, patients receiving the Micra leadless pacemaker experienced significantly more other complications, driven by higher rates of pericarditis (adjusted, 1.6% vs. 0.8%;  $p<.0001$ ). It is also unclear whether all patients were considered medically eligible for a conventional pacing system. 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. Incidence of major complications was comparable to rates observed in the Micra pivotal trial (4.0%). 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, clinical experience with device retrieval has not yet been reported. 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 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 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 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. 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.

## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

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

#### National Institute for Health and Care Excellence

In 2018, the National Institute for Health and Care Excellence (NICE) issued evidence-based recommendations on leadless cardiac pacemaker implantation for adults with bradyarrhythmias.<sup>45</sup> The guidance states that the evidence "on the safety of leadless cardiac pacemaker implantation for bradyarrhythmias shows that there are serious but well-recognised 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 scheduled for review in August 2021. An update has not been released as of April 2022.

## 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.<sup>46</sup> 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 [cardiovascular implantable electronic device] infection and after extraction of infected leads.'

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## 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 U.S. Food and Drug Administration (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?"<sup>47</sup>,

The following 4 studies are currently approved by CMS:<sup>48</sup>.

1. Effectiveness of the EMPOWER™ Modular Pacing System and EMBLEM™ Subcutaneous ICD to Communicate Antitachycardia Pacing (NCT04798768); CMS approval date: 1/20/22;
2. The LEADLESS II IDE Study (Phase II): A Safety and Effectiveness Trial for a Leadless Pacemaker System (NCT04559945); CMS approval date: 3/16/21;
3. Longitudinal Coverage with Evidence Development Study on Micra AV Leadless Pacemakers (Micra AV CED) (NCT04235491); CMS approval date: 2/5/2020;
4. The Micra CED Study (NCT03039712); CMS approval date: 03/09/17; and
5. Micra Transcatheter Pacing System Post-Approval Registry (NCT02536118); CMS approval date: 02/09/17 (see Table 10 for details).

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2019	New Policy	Policy created with literature review through May 15, 2019. The Micra transcatheter pacing system may be considered medically necessary as a second line treatment in patients who not eligible for conventional pacemakers when all of the specified conditions are met.
September 2020	Replace policy	Policy updated with literature review through May 29, 2020; references added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through April 2, 2021; no references added. Policy statements unchanged.
September 2022	Replace policy	Policy updated with literature review through April 22, 2022; references added. Investigational policy statement added for the Aveir transcatheter pacing system for all indications.

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