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.
<table>
<thead>
<tr>
<th>Device</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micra™ transcatheter pacing system</td>
<td>The Micra™ transcatheter pacing system may be considered medically necessary when BOTH of the following conditions are met:</td>
</tr>
<tr>
<td></td>
<td>- The patient has ONE of the following conditions:</td>
</tr>
<tr>
<td></td>
<td>- Symptomatic paroxysmal arteriovenous block</td>
</tr>
<tr>
<td></td>
<td>- Permanent high-grade arteriovenous block</td>
</tr>
<tr>
<td></td>
<td>- Symptomatic bradycardia-tachycardia syndrome</td>
</tr>
<tr>
<td></td>
<td>- Sinus node dysfunction (sinus bradycardia or sinus pauses).</td>
</tr>
<tr>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td>- The patient has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as ANY of the following:</td>
</tr>
<tr>
<td></td>
<td>- History of an endovascular or cardiovascular implantable electronic device (CIED) infection or who are at high risk for infection</td>
</tr>
<tr>
<td></td>
<td>- 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</td>
</tr>
<tr>
<td></td>
<td>- Presence of a bioprosthetic tricuspid valve</td>
</tr>
</tbody>
</table>

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

**Contraindications**

As per the 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
Contraindications

- 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 medical contrast 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 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).

Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Documentation that patient has: symptomatic paroxysmal or permanent high-grade arteriovenous block, or symptomatic bradycardia-tachycardia syndrome, or sinus node dysfunction (sinus bradycardia or sinus pauses)
Documentation Requirements

AND

- Documentation that the patient has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker such as: an endovascular or cardiovascular implantable electronic device, limited access for transvenous pacing due to venous anomaly, occlusion of axillary veins, or an AV fistula for hemodialysis, or the patient has a biprosthetic tricuspid valve

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed</td>
</tr>
</tbody>
</table>

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Related Information

N/A

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 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™ transcatheter pacing system is the only commercially available leadless pacemaker in the U. S. approved by the Food and Drug Administration.

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 (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 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. 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 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 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. 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. 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 a randomized controlled trial comparing epicardial implantation vs conventional pacemaker implantation in 80 patients with indications for cardiac resynchronization therapy. 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.

Harakee et al (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. 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 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.
Table 1. Reported Complication Rates with Conventional Pacemakers

<table>
<thead>
<tr>
<th>Complications</th>
<th>Rates, %&lt;sup&gt;8,9,10,a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Traumatic complications</strong></td>
<td></td>
</tr>
<tr>
<td>RV perforation</td>
<td>0.2-0.8</td>
</tr>
<tr>
<td>RV perforation with tamponade</td>
<td>0.07-0.4</td>
</tr>
<tr>
<td>Pneumo(hemo)thorax</td>
<td>0.7-2.2</td>
</tr>
<tr>
<td><strong>Pocket complications</strong></td>
<td></td>
</tr>
<tr>
<td>Including all hematomas, difficult to control bleeding, infection, discomfort, skin erosion</td>
<td>4.75</td>
</tr>
<tr>
<td>Including only those requiring invasive correction or reoperation</td>
<td>0.66-1.0</td>
</tr>
<tr>
<td><strong>Lead-related complications</strong></td>
<td></td>
</tr>
<tr>
<td>Including lead fracture, dislodgement, insulation problem, infection, stimulation threshold problem, diaphragm or pocket stimulation, other</td>
<td>1.6-3.8</td>
</tr>
<tr>
<td>All system-related infections requiring reoperation or extraction</td>
<td>0.5-0.7</td>
</tr>
</tbody>
</table>

Adapted from Food and Drug Administration executive summary memorandum (2016).<sup>11</sup>

<sup>a</sup> 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.

**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.<sup>12</sup>

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 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 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 Nanostim leadless pacemaker (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 Nanostim device, there is a screw-in helix that penetrates about 1 mm into the myocardium, with nylon tines that provide secondary fixation. 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 transcatheter pacing system is approved by the FDA and commercially available in the U. S. Multiple clinical studies of Nanostim have been published\textsuperscript{1,13,14,15,16,17} but trials have been halted due to the migration of the docking button in the device. Evidence on Nanostim is not reviewed further because the device is not yet FDA approved.

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 2 grams and has an accelerometer-based rate response.

Nanostim is about 40 mm in length and introduced using an 18 French catheter to the right ventricle. It also weighs about 2 grams and uses a temperature-based rate response sensor.\textsuperscript{18}

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 Micra™ transcatheter pacing system, the evidence includes a pivotal prospective cohort study and a postapproval prospective cohort study. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Results at 6 months and 1 year for the 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 complication did not increase substantially from six months (3.5% at six months vs 4% at one year). Results of the postapproval study were consistent with a 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). Considerable uncertainties and unknowns remain in terms of the durability of device and device end-of-life issues. Early and limited experience has suggested that retrieval of these devices is unlikely because in due course, the devices 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. While the current evidence is encouraging, overall benefit with the broad use of Micra transcatheter pacing system compared with conventional pacemakers has not been shown. The evidence is insufficient to determine the effects of technology on health outcomes.

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, the evidence includes subgroup analysis of a pivotal prospective cohort study and a postapproval prospective cohort study. The 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% 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 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 sufficient to determine the effects of technology on health outcomes.

**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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT03039712</td>
<td>Longitudinal Coverage With Evidence Development Study on Micra Leadless Pacemakers (Micra CED)</td>
<td>37,000</td>
<td>Jun 2021</td>
</tr>
<tr>
<td>NCT02610673a</td>
<td>WiCS-LV Post Market Surveillance Registry</td>
<td>100</td>
<td>Nov 2021</td>
</tr>
<tr>
<td>NCT02051972a</td>
<td>Nanostim Study for a Leadless Cardiac Pacemaker System</td>
<td>1000</td>
<td>Mar 2024</td>
</tr>
<tr>
<td>NCT02536118a</td>
<td>Micra Transcatheter Pacing System Post-Approval Registry</td>
<td>3100</td>
<td>Aug 2026</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

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

2019

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 2 respondents, including 1 specialty society-level response and 1 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 patients when both conditions below are met:

- 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).
- The patient 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**

**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. 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.'

**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 postapproval 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?"34

The following two studies are currently approved by CMS:

- 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 details).
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 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.

References


33. Blomstrom-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. Apr 01 2020; 22(4): 515-549. PMID 31702000

**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.

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  - Information written in other languages

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Italian (Italian):

Deutsche (German):

Hmooob (Hmong):

Iloko (Ilocano):
Daytoy a Pakdaara ket naglaon iti Napateg nga Impomarsa. Daytoy a pakdaara mabalin nga adda ket naglaon iti napateg nga impomarsa maianggep iti aplikasyonyo wenu coverage babaen ti Premera Blue Cross. Daytoy kel mabalin dagiti importante a pelsa iti daytoy a pakdaara. Mabalin nga adda rumbeng na aramideng nga addag sakkay dagiti particular a naituding nga aldaw tapno mapagtalainedyo ti coverage ti salun-ayyo wenu tulong kadagit gastos. Adda karbenganyo a mangala iti daytoy nga impomarsa ken tulong iti bukodyo a pagasao nga awan ti bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要的日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).
Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれています。この通知に記載されている情報は重要な日付をご確認ください。健康保険や無料サービスを維持するには、特定の期限までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357) までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어있습니다. 즉 이 통지서는 귀하의 신청에
관하여 그리고 Premera Blue Cross 를 통해 커버리지에 관한 정보를
포함하고 있습니다. 본 통지서에는 백신이 되는 난페디가 있을 수
있습니다. 귀하의 권한가 있는 커버리지를 계속 유지하거나 비용을 절감하기
위해서 일정한 마감까지 조치를 취해야 할 필요가 있을 수 있습니다.
귀하의 이러한 정보와 동등한 권한이 되는 배당이 없을 수 있는
권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

ロシア語 (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):

Romāņu valoda (Latvian):
Vieta, kādas vērtības informācija var būt svarīga jūsu apjomam. Šī informācija var ietvert jutīgās datu datumi, ko jāievieš atbilstoši konkrētiem termiņiem lai saglabātu savu kārtēju un spētu saņemt nepieciešamo palīdzību. Lūdzu, sazinieties ar mieru, ja jums ir jāievieš jaunas datumi. Lai sasniegtu informāciju un palīdzību, lūdzu, sazinieties pie kārtēju telefonā 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อมูลสำคัญเกี่ยวกับการส่งข้อมูลส่วนบุคคลของคุณผ่าน Premera Blue Cross และการมีส่วนร่วมในการได้รับการช่วยเหลือเรื่องการส่งข้อมูลส่วนบุคคลของคุณที่มีการใช้จ่าย คุณมีสิทธิ์ที่จะได้รับข้อมูลและการช่วยเหลือในสถานการณ์ดังกล่าวได้ โดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357).

Українська (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути визначені у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретній ситуації для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):