

Leadless Cardiac Pacemakers

Effective: December 1, 2020

Next Review: September 2021

Last Review: October 2020

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

Conventional pacemakers consist of two components: a pulse generator and electrodes (or leads). Although the efficacy and safety profile of conventional pacemakers are excellent, 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.

MEDICAL POLICY CRITERIA

Notes: See Policy Guidelines for contraindications for the Micra leadless pacemaker system.

- I. An FDA-approved leadless cardiac pacing system (e.g. the Micra transcatheter system) may be considered **medically necessary** in patients when both Criteria A. and B. below are met:
 - A. The patient has one or more of the following:
 1. Symptomatic paroxysmal or permanent high-grade arteriovenous block; or
 2. Symptomatic bradycardia-tachycardia syndrome; or

3. Sinus node dysfunction (sinus bradycardia or sinus pauses).
 - B. The patient has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads, including but not limited to a history or high risk of infection, limited venous access, or presence of a bioprosthetic tricuspid valve.
- II. A leadless cardiac pacing system is considered **investigational** for all other indications when Criterion I. is not met, including but not limited to the use of non-FDA-approved devices.

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

POLICY GUIDELINES

MICRA SYSTEM CONTRAINDICATIONS

Devices

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
- An implanted cardiac device providing active cardiac therapy which may interfere with the sensing performance of the Micra device

Conditions

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

Other Contraindications

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.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of symptoms, associated diagnoses and treatments
- Name of FDA-approved leadless device
- Documentation that supports contraindication of placement of conventional single-chamber ventricular pacemaker leads

CROSS REFERENCES

1. [Implantable Cardioverter Defibrillator](#), Surgery, Policy No. 17
2. [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.

Annually, approximately 200,000 pacemakers are implanted in the United States and one million worldwide.^[1] 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 has usually demonstrated acceptable pacing capture thresholds and sensing. Intermediate performance (90 days through more than five

years) has usually demonstrated the reliability of the pulse generator and lead technology. Chronic performance (5 to 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. These data are summarized in Table 1. It is important to recognize that valid comparison of complication rates is limited by differences in definitions of complications, which results in a wide variance of outcomes, as well as by the large variance in follow-up times, use of single-chamber or dual-chamber systems, and data reported over more than two decades.^[2] As such, the following data are contemporary and limited to single-chamber systems when reported separately.

In many cases when conventional pectoral approach is not possible, alternate approaches such as epicardial pacemaker implantation and trans-iliac approaches have been used^[3]. Cohen (2001) reported outcomes from a retrospective analysis of 123 patients who underwent 207 epicardial lead implantations^[4]. 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 one-, two-, and five-year lead survival was 96%, 90%, and 74%, respectively. Epicardial lead survival in those placed by a subxiphoid approach was 100% at one year and at 10 years, by the sternotomy approach (93.9% at one year and 75.9% at 10 years) and lateral thoracotomy approach (94.1% at one year and 62.4% at 10 years).

Doll (2008) reported results of a randomized trial comparing epicardial implantation to conventional pacemaker implantation in 80 patients with indications for cardiac resynchronization therapy.^[5] The authors reported that the conventional pacemaker group had 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 alternate to epicardial approach, 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 (2018) reported a retrospective analysis of five patients who underwent a transvenous iliac approach (median age 26.9 years)^[6]. 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 four 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 (2010) reported a case series of four 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 iliac vein approach was satisfactory and less invasive alternative to epicardial lead implantation. However, the authors reported 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.^[7]

Table 1. Reported Complication Rates with Conventional Pacemakers

Complications	Rates, %^{[8-10]a}
Traumatic complications	
RV perforation	0.2-0.8
RV perforation with tamponade	0.07-0.4
Pneumo(hemo)thorax	0.7-2.2
Pocket complications	
Including all hematomas, difficult to control bleeding, infection, discomfort, skin erosion	4.75
Including only those requiring invasive correction or reoperation	0.66-1.0
Lead-related complications	
Including lead fracture, dislodgement, insulation problem, infection, stimulation threshold problem, diaphragm or pocket stimulation, other	1.6-3.8
All system related infections requiring reoperation or extraction	0.5-0.7

Adapted from Food and Drug Administration executive summary memorandum (2016).^[11]

^a Rates are for new implants only and ventricular single-chamber devices when data were available. Some rates listed in this column are for single- and dual-chamber devices when data were not separated in the publication. Note that Micra transcatheter pacing system is a single-chamber device.

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.^[12]

Lead complications include lead failure, lead fracture, insulation defect, pneumothorax, infections requiring lead extractions and replacements that can result in a torn subclavian vein or 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.

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.^[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 FDA and commercially available in the United States. Multiple clinical studies of Nanostim have been published^[1 13-18] 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 two 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 two grams and uses a temperature-based rate response sensor.^[19]

REGULATORY STATUS

In April 2016, the Micra™ transcatheter pacing system (Medtronic) was approved by 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.

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).

VENTRICULAR PACING FOR INDIVIDUALS WHO ARE MEDICALLY ELIGIBLE FOR A CONVENTIONAL PACING SYSTEM

Nonrandomized Controlled Trials

Pivotal Trial

The pivotal investigational device exemption (IDE) trial was a prospective single cohort study enrolled 744 patients with a class I or II indications for implantation of a single-chamber ventricular pacemaker based on national guidelines. Details on the design^[20], and results of the IDE trial have been published.^[21-23] Trial characteristics and results at six months are summarized in Tables 2 and 3, respectively. System performance from the pivotal trial has been published,^[24] but results are not discussed further.

Of the 744 patients enrolled, implantation of the Micra transcatheter pacing system was successful in 719 (99.2%) of the 725 patients who underwent the procedure. The demographics of the trial population were typical for a single-chamber pacemaker study performed in the U. S., with 42% being female and the average age was 76 years. Sixty-four percent had a pacing indication associated with persistent or permanent atrial arrhythmias, 72.6% had any atrial fibrillation at baseline, and 27.4% did not have a history of atrial fibrillation. Among those 27.4% (n=199) without atrial fibrillation, 16.1% (n=32) had a primary indication of sinus bradycardia and 3.5% (n=7) had a primary indication of tachycardia-bradycardia.^[23]

The IDE trial had two primary endpoints related to safety and efficacy. The trial would meet its safety endpoint if the lower bound of the 95% confidence interval (CI) for the rate of freedom from major complications related to the Micra transcatheter pacing system or implantation procedure exceeded 83% at six months. Major complications were defined as those resulting in any of the following; death, permanent loss of device function due to mechanical or electrical dysfunction of the device (e.g., pacing function disabled, leaving device abandoned electrically), hospitalization, prolonged hospitalization by at least 48 hours, or system revision (reposition, replacement, explant).^[25] The trial would meet its efficacy endpoint if the lower bound of the 95% CI for the proportion of patients with adequate pacing capture thresholds (PCT) exceeded 80% at six months. PCT as an effectiveness objective is a common electrical measure of pacing efficacy and is consistent with recent studies. Pacing capture threshold measured in volts is defined as the minimum amount of energy needed to capture the myocardial tissue electrically. Unnecessary high pacing output adversely shortens the battery

life of the pacemaker and is influenced by physiologic and pharmacologic factors.^[25] As per the FDA, demonstrating that “PCT is less than 2 Volts for the vast majority of subjects will imply that the Micra system will have longevity similar to current pacing systems since Micra’s capture management feature will nominally set the safety margin to 0.5 Volts above the PCT with hourly confirmation of the PCT.”^[25]

Safety and efficacy results of the IDE trial are summarized in Table 3. At six months, the trial met both of its efficacy and safety primary endpoints including freedom from major complications related to the system or procedure in 96.0% of the patients (95% CI 93.9% to 97.3%), compared with a performance goal of 83%, and an adequate pacing capture threshold in 98.3% of the patients (95% CI 96.1% to 99.5%), compared with a performance goal of 80%.^[23]

Quality of life results of the IDE trial were published in 2018. At baseline and 12 months, 702 (98%) and 635 (88%) participants completed the 36-Item Short Form questionnaire, respectively.^[22] The mean 36-Item Short Form Physical Component Scale at baseline was 36.3 (standard deviation [SD] 9.0) and the mean 36-Item Short Form Mental Component Scale was 47.3 (SD 12.5); the general population mean for both scores is 50. Both the Physical Component Scale and Mental Component Scale improved at 12 months post-implant to a mean Physical Component Scale score of 38.6 (SD 9.4, $p < 0.001$) and a mean Mental Component Scale score of 50.7 (SD 12.2, $p < 0.001$) compared with baseline.

IDE trial results were compared post hoc with a historical cohort of 2,667 patients generated from six previous pacemaker studies, conducted between 2005 and 2012 by Medtronic, that evaluated the performance requirement at six months postimplant of right ventricle pacing leads (single-chamber rates obtained by excluding any adverse events only related to the right atrial lead from the analysis). The Micra device was associated with fewer complications than the historical control (4.0% vs 7.4%, hazard ratio [HR], 0.49, 95% CI 0.33 to 0.75, $p = 0.001$).^[23] Because there were differences in baseline patient characteristics between the two cohorts (patients in the historical cohort were younger and had a lower prevalence of coexisting conditions vs the IDE trial), an additional propensity-matched analysis was conducted. It showed similar results (HR 0.46, 95% CI 0.28 to 0.74). As per the FDA, the lower rate of major complications with the Micra device was driven by reductions in access site events (primarily implant site hematoma and implant site infections), pacing issues (primarily device capture and device pacing issues), and fixation events (there was no device or lead dislodgements in the Micra IDE trial).^[11]

While the overall rate of complications was low, the rate of major complications related to cardiac injury (i.e., pericardial effusion or perforation) was higher in the Micra IDE trial than in the six reference Medtronic pacemaker studies (1.6% vs 1.1%, $p = 0.288$).^[11] Thus, there appears to be a trade-off between types of adverse events with the Micra transcatheter pacing system and conventional pacemakers. While adverse events related to leads and pocket are eliminated or minimized with the Micra device, certain adverse events (e.g., groin vascular complications, vascular or cardiac bleeding) occur at a higher frequency or are additive (new events) compared with conventional pacemakers. Of these, procedural complications (e.g., acute cardiac perforations) that were severe enough to result in tamponade and emergency surgery were most concerning.^[11]

In addition to lack of adequate data on long-term safety, effectiveness, reliability, and incidence of late device failures and battery longevity, there is also inadequate clinical experience with

issues related to devices that have reached end-of-life, including whether to extract or leave the device in situ and possible device-device interactions.^[26] There are limited data on device-device interactions (both electrical and mechanical) that may occur when there is a deactivated Micra device alongside another leadless pacemaker or when a leadless pacemaker and transvenous device are both present. Even though there have only been few device retrievals and very limited experience with the time course of encapsulation of these devices in humans, it is highly likely that these devices will be fully encapsulated by the end of its typical battery life, and therefore device retrieval is unlikely.^[26] Current recommendations for end-of-device-life care for a Micra device may include the addition of a replacement device with or without explantation of the Micra device, which should be turned off.^[27]

Grubman (2017) reported on system revisions including patients from the IDE study (n=720) and the Micra Transcatheter Pacing System Continued Access Study (n=269).^[28] The Continued Access study was conducted to allow for continued access of the Micra in the same centers as the IDE study while the device was pending the FDA approval. The mean follow-up duration was 13 months (16 months in the IDE patients and two months in the continued access patients). There were 11 system revisions in 10 patients, corresponding to a 1.4% (95% CI 0.7% to 2.6%) actuarial rate of revisions through 24 months. Micra was disabled and left in situ in 7 of 11 revisions including five patients in which there was no retrieval attempt, one patient in which retrieval was aborted because of fluoroscopy failure, and one patient in which retrieval was unsuccessful because of inability to dislodge the device. There were three percutaneous retrievals and one retrieval during surgical valve replacement. There were no complications associated with retrievals. The report indicates that there when a transvenous system was implanted with a deactivated Micra, there were no reported interactions between the two systems, although it is not clear how often this occurred. In the historical controls from the IDE study, there were 123 revisions in 117 patients through 24 months (actuarial rate 5.3%, 95% CI 4.4% to 6.4%). Using propensity score matching, the reduction in system revisions for Micra compared to historical controls was significant (HR 0.27, 95% CI 0.14 to 0.54, p<0.001).

Postapproval Study

The FDA approval of the Micra transcatheter pacing system was contingent on multiple postapproval studies to provide reasonable assurance of continued safety and effectiveness of the device. Among these, the Micra Transcatheter Pacing System Post-Approval Study, a global, prospective, observational, multicenter study, enrolled 1,830 patients to collect data on 1,741 patients to estimate the acute complication rate within 30 days of the implant, 500 patients to estimate the nine-year complication-free survival rate, and a minimum of 200 patients with a Micra device revision for characterizing device end of service.^[25] As per the protocol, if a subsequent device is placed and the Micra is deactivated or explanted, Medtronic would contact the implanting center and request the patient's clinical data concerning the revision. All such data would be summarized, including the type of system revision, how the extraction was attempted, success rate, and any associated complications.^[26]

Study characteristics and results at one year (reported in the FDA documents and published) are summarized in Table 2 and 3, respectively. The postapproval study completed enrollment in early March 2018. The definition of a major complication in the postapproval study was the same as the Micra IDE trial. Although some patients who participated in the IDE study consented to also participate in the PAR study, the publication excludes those patients from analysis and therefore includes an independent population. Results summarized in Table 3

summarize the data at 30 days published by Roberts (2017)^[29] and El-Chami (2018),^[30 31] with a mean follow-up of 6.8 months for 1,817 patients, of whom 465 patients had a follow-up for more than one year.

At 30 days, the major complication rate was 1.51% (95% CI 0.78 to 2.62%). The major complication rate was lower in the postapproval study than in the IDE trial (odds ratio, 0.58, 95% CI 0.27 to 1.25) although this did not reach statistical difference. The lower rate of major complications was associated with a decrease in events that led to hospitalization, prolonged hospitalization, or loss of device function in the postapproval study compared with the IDE trial.^[29]

After a mean follow-up of 6.8 months, the estimated major complication rate at 12 months was 2.7% (95% CI 2.0% to 3.7%), corresponding to 46 major complications in 41 patients, the majority of which (89%) occurred within 30 days of implantation. The major complications included 14 device pacing issue events, 11 events at the groin puncture site, eight cardiac effusion/perforation events, three infections, one cardiac failure event, one cardiomyopathy event, and one pacemaker syndrome event. Authors compared these results with the same historical cohort of 2,667 patients used in the IDE trial and reported a 63% reduction in the risk for major complications through 12 months with the Micra transcatheter pacing system relative to conventional pacemakers (HR 0.37, 95% CI 0.27 to 0.52). Additionally, the risk for major complications was lower in the Micra postapproval study than in the IDE trial but it was a statistically significant difference (HR 0.71, 95% CI 0.44 to 1.1).^[30] The reduction in major complications compared to historical controls was primarily driven by a significant 74% (95% CI 54 to 85, p=0.0001) relative risk reduction in system revisions and 71% (95% CI 51 to 83, p=0.0001) relative risk reduction in hospitalizations. The reduction in risk compared to the IDE trial was driven by significantly lower pericardial effusion rates in the post-approval study.

Table 2. Summary of Key Nonrandomized Trial Characteristics

Study; Trial	Study; Type	Country	Dates	Participants	Treatment	Follow-Up, mo
Reynolds (2016) ^[23] NCT02004873	Prospective single cohort	19 countries in North America, Europe, Asia, Australia, and Africa	2013-2015	Patients who met a class I or II guidelines-based indication for pacing and suitable candidates for single-chamber ventricular demand pacing	Micra pacemaker (n=744)	6
Roberts (2017) ^[29] El-Chami (2018) ^[30 31] NCT02536118	Prospective single cohort (Micra Post-Approval Study)	23 countries in North America, Europe, Asia, Australia, and Africa	2016-2018	Any patient to be implanted with a Micra device	Micra pacemaker (n=795 ^a and 1830 ^b)	1.8 ^a 6.8 ^b

^a 30-day results reported by Roberts (2017).^[29]

^b Results after a mean follow-up of 6.8 months reported by El-Chami (2018)^[30 31]

Table 3. Summary of Key Nonrandomized Trial Results

Study	Freedom from System- or Procedure-Related Major Complications	Percentage of Patients with Adequate Pacing Capture Thresholds	Major Complications Criteria, n (%)	Major Complications, n (%)
IDE Trial				
	6 Months	6 Months	6 Months	6 Months
Reynolds (2016) ^[23]				
N	719 ^a ;300 ^b	719	725	725
Micra	96.0%	98.3% (≤ 2.0 V)	Death: 1 (0.1) Loss of device function: 1 (0.1) Hospitalization: 13 (2.3) Prolonged hospitalization (≥ 48 h): 16 (2.6) System revision: 3 (0.4)	TMCs: 28 in 25 patients (3.5%) <ul style="list-style-type: none"> • DVT: 1 (0.1) • Pulmonary TE: 1 (0.1) • Events at groin puncture site: 5 (0.7) • Cardiac perforation: 11 (1.6) • Pacing issues: 2 (0.3) • Others: 8 (1.7)
95% CI	93.9% to 97.3%	95.4% to 99.6%	NA	NA
	12 Months	12 Months	12 Months	12 Months
Duray (2017) ^[32]				
N	726	NA	726	726
Micra	96.0%	NR (93%)	Death: NR (0.1) Loss of device function: NR (0.1) Hospitalization: NR (2.3) Prolonged hospitalization (≥ 48 h): NR (2.2) System revision ^c : NR (0.7) Loss of device function: NR (0.3)	TMCs: 32 in 29 patients (4.0) <ul style="list-style-type: none"> • DVT: 1 (0.1) • Pulmonary TE: 1 (0.1) • Events at groin puncture site: 5 (0.7) • Cardiac perforation: 11 (1.6) • Pacing issues: 2 (0.3) • Others: 11 (1.7)
95% CI	94.2% to 97.2%	NA		
Micra Post-Approval Study				

Study	Freedom from System- or Procedure-Related Major Complications	Percentage of Patients with Adequate Pacing Capture Thresholds	Major Complications Criteria, n (%)	Major Complications, n (%)
	30 Days	30 Days	30 Days	30 Days
Roberts (2017) ^[29]				
N	795	NA	795	795
Micra	97.3% ^d	87.2% (≤ 1.0 V) 97.0% (≤ 2.0 V)	Death: 1 (0.13%) Hospitalization: 4 (0.50) Prolonged hospitalization (≥ 48 h): 9 (1.01) System revision ^c : 2 (0.25)	TMCs: 13 in 12 patients (1.51% [95% CI 0.78% to 2.62%]) <ul style="list-style-type: none">• DVT: 1 (0.13)• Events at groin puncture site: 6 (0.75)• Cardiac effusion/perforation: 1 (0.13)• Device dislodgement: 1 (0.13)• Pacing issues: 1 (0.13)• Others: 3 (0.38)
OR (95% CI)	0.58 (0.27 to 1.25) ^e	NA	NA	NA
	1 Year	1 Year	1 Year	1 Year
El-Chami (2018) ^[30 31]				
N	1,817	NA	NA	1,817
Micra	97.3% ^d	NA	NA	TMCs: 46 in 41 patients (2.7% [95% CI 2.0% to 3.6%]) <ul style="list-style-type: none">• Pericardial effusions: 8 (0.44)• Dislodgement: 1 (0.06)• Procedure-related infections: 3 (0.17)• Procedure-related deaths: 5 (0.28) As per FDA: Complications ^f : 61 in 53

Study	Freedom from System- or Procedure-Related Major Complications	Percentage of Patients with Adequate Pacing Capture Thresholds	Major Complications Criteria, n (%)	Major Complications, n (%)
				(deaths: 4 procedure-related; 3 unknown relatedness; 3 pending adjudication)
HR (95% CI)	0.71 (0.44 to 1.1) ^e 0.37 (0.27 to 0.52) ^g	NA	NA	NA

CI: confidence interval; DVT: deep vein thrombosis; FDA: Food and Drug Administration; HR: hazard ratio; IDE: investigational device exemption; OR: odds ratio; NA: not available; NR: not reported; TE: thromboembolism; TMC: Total major complication.

^a Total number of patients who received the implant successfully.

^b Number of patients for whom data were available for six-month evaluation.

^c Device explant, reposition, or replacement.

^d Calculations based on the major complication rate (2.7%, 95% CI 2.0 to 3.6%) reported by El-Chami (2018).

^e Major complication vs IDE trial.

^f Unclear if the complications met the definition of a major complication as events leading to death, hospitalization, prolonged hospitalization by 48 hours, system revision, or loss of device therapy.

^g Major complication vs historical controls.

Section Summary: Ventricular Pacing for Individuals Who Are Medically Eligible for a Conventional Pacing System

The evidence for use of the Micra transcatheter pacing system consists of a pivotal prospective cohort study and a postapproval prospective cohort study. Results at six months and one 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 complications 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 and one year (1.5% and 2.7%, respectively). In both studies, the point estimates of major complication were lower than the pooled estimates from six studies of conventional pacemakers used as a historical comparator. While the Micra transcatheter pacing system eliminates adverse events associated with lead and pocket issue, its use results in additional complications related to the femoral access site (groin hematomas, access site bleeding) and implantation and release of the device (traumatic cardiac injury). Considerable uncertainties and unknowns remain in terms of the durability of device and end-of-life device issues. Early and limited experience has suggested that retrieval of these devices is unlikely because in due course of time, the devices will be encapsulated. There are limited data on device-device interactions (both electrical and mechanical), which might occur when there is a deactivated Micra device alongside another leadless pacemaker or when a leadless pacemaker and transvenous device are both present.

VENTRICULAR PACING FOR INDIVIDUALS WHO ARE MEDICALLY INELIGIBLE FOR A CONVENTIONAL PACING SYSTEM

Nonrandomized Controlled Trials

No studies that exclusively enrolled patients who were medically ineligible to receive a conventional pacing system were identified.

In the IDE trial, 6.2% or 45 patients received the Micra Transcatheter Pacing System because they were medically ineligible for a conventional pacing system due to compromised venous access, the need to preserve veins for hemodialysis, thrombosis, a history of infection, or the need for an indwelling venous catheter. A stratified analysis of these 45 patients was not presented in the published paper^[23] or the FDA documents.^[11 19 25 26]

In the postapproval registry as an abstract, the authors reported stratified results for 105 of 1,820 patients who had previous cardiac implantable electronic device (CIED) infection.^[30 33] Of these, 83 patients (79%) were classified as medically ineligible to receive a conventional pacemaker in the opinion of the physician. A stratified analysis of these 83 patients was not presented in the publication. Trial characteristics and results are summarized in Tables 4 and 5, respectively. In this cohort of patients with CIED infection, the Micra device was implanted successfully in 104 patients and the previous CIED was explanted the same day as the Micra device was implanted in 37% of patients. Major complications were reported in 3.8% of patients with an average follow-up of 8.5 months. Ten deaths were reported (14% at 12 months) but none were related to the Micra transcatheter pacing system or the implantation procedure.

Table 4. Summary of Key Nonrandomized Trial Characteristics in Patients Ineligible for a Conventional Pacing System and/or Previous CIED Infection

Study; Trial	Study Type	Country	Dates	Participants	Treatment	Follow-Up, mo
El-Chami (2018) ^[30 33]	Prospective single cohort (Micra Post-Approval Registry)	23 countries in North America, Europe, Asia, Australia, and Africa	2016-2018	Any patient to be implanted with a Micra with a CIED infection	Micra pacemaker (n=105)	8.5 (range 0 to 28.5)

CIED: cardiac implantable electronic device.

Table 5. Summary of Key Nonrandomized Trial Results in Patients Ineligible for a Conventional Pacing System and/or Previous Cardiac Implantable Electronic Device Infection

Study	No. of Patients With System- or Procedure-Related Major Complications at One Year	Average Pacing Threshold at One Year	Major Complications at 1 Year
El-Chami (2018) ^[30 33]			
N	105	82	105
Micra	4 (4/105)	0.6 V	Total major complications: 6 in 4 patients (patient 1: effusion requiring pericardiocentesis; patient 2: elevated thresholds, complication of device removal [IVC filter entanglement], and

Study	No. of Patients With System- or Procedure-Related Major Complications at One Year	Average Pacing Threshold at One Year	Major Complications at 1 Year
			subsequent abdominal wall infection, patients 3 and 4: pacemaker syndrome)

IVC: in cava filter.

Garg (2020) performed a stratified analysis of data from the Micra clinical trials (Micra Post-Approval Registry, Micra Continued Access Study, Micra Transcatheter Pacing Study, Medtronic Product Surveillance Registry) based on whether the patient was deemed to be ineligible to receive a conventional pacemaker by the implanter.^[34] Of the 2,817 patients that underwent an attempted implantation of a Micra device, 546 (19%) were considered to be precluded from receiving a transvenous permanent pacemaker, for reasons that included venous access issues or previous device infections. Compared with individuals that were not precluded from a transvenous device, the precluded patients had significantly higher acute mortality and total mortality at 36 months (2.75% vs 1.32%, $p=0.022$; and 38.1% vs 20.6%, $p<0.001$; respectively). The major complication rate was not significantly different between the groups.

Section Summary: Ventricular Pacing for Individuals Who Are Medically Ineligible for a Conventional Pacing System

No studies that exclusively enrolled patients who were medically ineligible for a conventional pacing system were identified. However, a subgroup of patients in whom the use of conventional pacemakers was precluded was enrolled in the pivotal and the postapproval trials. Information on the outcomes in these subgroups of patients from the postapproval study showed that Micra 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 may outweigh the risks in the context of the life-saving potential of pacing systems in patients that are ineligible for conventional pacing systems.

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.^[35]

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.^[36] 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 did not include recommendations on leadless cardiac pacemakers.^[37]

SUMMARY

There is enough research to show that an FDA-approved leadless pacing system may improve health outcomes for patients with a guidelines-based indication for a ventricular pacing system who are medically ineligible for a conventional pacing system. Although evidence is limited and long-term effectiveness and safety are unknown, the short-term benefits may outweigh the risks, in the context of the life-saving potential of pacing systems for patients who are ineligible for conventional pacing systems. Therefore, a leadless pacemaker system may be considered medically necessary in patients who meet the policy criteria.

There is not enough research to show that a leadless pacing system can improve health outcomes for patients who do not meet medical necessity criteria, including the use of a non-FDA-approved system, or in patients who are eligible for a conventional pacing system. There is little evidence regarding the durability of devices, device end-of-life issues, and device-device interactions (both electrical and mechanical), which may occur when there is a deactivated leadless device alongside another leadless pacemaker or when a leadless pacemaker and transvenous device are both present. Therefore, a leadless pacemaker is considered investigational when criteria are not met.

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CODES

Codes	Number	Description
CPT	33274	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 (new eff 1/1/19)
	33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed
HCPCS	None	

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