Leadless Cardiac Pacemakers

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 brady-arrhythmias. 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.

OBJECTIVE

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

The Micra 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 in the presence of atrial fibrillation OR paroxysmal or permanent high-grade arteriovenous block in the absence of atrial fibrillation OR symptomatic bradyarrhythmia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses).

2. The patient has a significant contraindication precluding placement of conventional ventricular pacemaker leads such as any of the following:
   - History of an endovascular or cardiovascular implantable electronic device (CIED) infection or who are at high risk for infection
   - 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

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

POLICY GUIDELINES

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

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 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.

RATIONALITY

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 post approval 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 post approval study were consistent with a pivotal study and showed a lower incidence of major complications up to 30 days post implantation as well as 1 year (1.5% and 2.7%, respectively). In both studies, the point estimates of major complications were lower than the pooled estimates from 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. Clinical input suggests that some individuals who are eligible for conventional pacing but are concerned about the long-term risk of lead-related issues may prefer initial use of a leadless pacemaker after considering the balance of benefits and harms using shared decision making. 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 post approval 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 post approval 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. Clinical input supplements and informs the interpretation of the published evidence. Clinical input supports the use of leadless pacemakers in individuals who are ineligible for conventional pacing. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Cardiology Foundation et al

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.34.

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.35.

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 the 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?"36.

The following 2 studies are currently approved by CMS: (1) The Micra CED Study (NCT03039712); CMS approval date: 03/09/17; and (2) Micra Transcatheter Pacing System Post-Approval Registry (NCT02536118); CMS approval date: 02/09/17.

REFERENCES


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

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<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>September 2019</td>
<td>New Policy</td>
<td>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.</td>
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