FREQUENTLY ASKED QUESTIONS

Medicare Coverage for Leadless Pacemakers
June 2019

Brief Background

Micra™ Transcatheter Pacing System is the world’s smallest pacemaker, delivered percutaneously via a minimally invasive approach, directly into the right ventricle without the use of leads. Leadless pacemakers, also known as intracardiac or transcatheter pacemakers, are the first and only pacemakers in which the components are combined into a single device implanted directly within the heart, without any subcutaneous pocket or tunneling. This is in contrast to traditional transvenous pacemakers that require a subcutaneous generator plus transvenous/epicardial lead(s).

On Jan. 18, 2017, the Centers for Medicare & Medicaid Services (CMS) released the coverage decision for the leadless pacemaker. The CMS will cover leadless pacemakers that are used according to the FDA-labeled indications for the device through Coverage with Evidence Development (CED) as outlined below.

This document highlights frequently asked questions regarding Medicare coverage requirements for leadless pacemaker procedures. For non-Medicare payers, it is recommended to check with your specific payer for individual coverage requirements.

Nationally Covered Indications

CMS will provide coverage for leadless pacemakers when procedures are performed:

- In an FDA-approved post-approval study (PAS) such as the Micra Transcatheter Pacing System Post-Approval Study (PAS); or
- In a prospective longitudinal study for leadless pacemakers that have either:
  - An associated ongoing FDA-approved PAS; or
  - Completed an FDA PAS

Each study must be approved by CMS and listed on the CMS website before coverage is effective and payment can be made.

Disclaimer

Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules, and regulations. The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists, and/or legal counsel for interpretation of coding, coverage, and payment policies. This document provides assistance for FDA-approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA-cleared or approved labeling (e.g., instructions for use, operator’s manual, or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service.
Q1. When were the studies approved and when was coverage effective?

A1. CMS approved the Micra PAS study as meeting the eligibility requirements for the leadless pacemaker CED, effective on Feb. 9, 2017.

Effective Mar. 9, 2019, Medicare approved coverage for beneficiaries enrolled in the prospective longitudinal study, hereafter known as the Micra CED study.

All sites that were enrolled in the PAS study (enrollment now closed) are now being enrolled in the continuing Micra CED study. All U.S. sites that implant Micra according to FDA indications in a Medicare patient should be considered covered. Micra procedures performed according to FDA indications are eligible for Medicare coverage and reimbursement. Please see https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Leadless-Pacemakers.html for more information.

Q2. My hospital already has physicians who have been trained on Micra via the Medtronic Micra Academy Training program. How does my site enroll in the Micra CED study to be reimbursed for procedures?

A2. Hospitals do not need to take any action in order to enroll in the Micra CED study. As a claims-based study, enrollment will occur through regular claims submission. Similar to other clinical studies, hospitals and physicians need to follow specific claims submission instructions to identify study participation in order to ensure proper claims adjudication and payment.

Q3. What does the hospital need to do to approve the Micra CED study?

A3. The hospital does not need Institutional Review Board (IRB) approval for the Micra CED study. Version 1.0 of the study protocol was approved on Feb. 6, 2017 and Version 2.0 was approved on Mar. 8, 2017 by Western Institutional Review Board (WIRB). WIRB found this research meets the requirements for a waiver of consent under 45 CFR 46.116(d).

Q4. After implanting the allotted number of patients in the PAS (enrollment is now closed), would the hospital and physician automatically qualify for the Micra CED study?

A4. Yes, providers from the PAS (enrollment is now closed) that have implanted their allotted number of patients will become part of the Micra CED study.

Q5. How can I become a Micra implanting site?

A5. At this time, due to the novel nature of the technology there are extensive training requirements to become a Micra implanting site. For further information, please contact your local Medtronic sales representative.

Q6. Are commercial (private) payers covering Micra? How is Medtronic approaching commercial (private) payers to support coverage?

A6. Currently, we are not aware of many private payers who provide coverage for Micra. We suggest that a patient’s physician contact the insurer (commercial/private payer) to request coverage for the specific patient, providing supporting documentation as to why a Micra is the optimal option for that patient. Prior authorization for Micra TPS insertion procedures may be required from some commercial insurers to determine the applicability of covered benefits for a specific patient case.

Q7. What are the covered indications for Micra?

A7. CMS reinforces use in accordance with FDA-approved label indications as a condition for coverage. The coverage policy specifically stipulates that coverage under CED studies requires leadless pacemakers to be “used according to the FDA-labeled indications for the device...” As a reminder, the labeled indications for Micra include the following:

- Symptomatic paroxysmal or permanent high-grade AV block in the presence of AF
- Symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, 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
Q8. Are Medicare Advantage plans required to provide coverage for Micra?
A8. Medicare covers leadless pacemakers through coverage with evidence development (CED). The National Coverage Determination (NCD) for Leadless Pacemakers (20.8.4) defining this coverage applies to both traditional Medicare and Medicare Advantage plans\(^3\) and specifies coverage for procedures performed as part of an ongoing, CMS-approved study and used according to the FDA-labeled indications for the device.\(^4\) The Longitudinal Coverage With Evidence Development Study on Micra Leadless Pacemakers (Micra CED)\(^5\) meets this definition, is approved by CMS for purposes of coverage under the CED, and is posted on CMS’ CED website as such.\(^6\)

Medicare coverage for leadless pacemaker procedures performed as part of the Micra CED applies to all Medicare plans, whether administered directly by CMS or by commercial Medicare Advantage (MA) plans. The Medicare Managed Care Coverage Manual establishes that MA plans are subject to the same coverage requirements as traditional Medicare for NCD requiring CED, \(^1\) such as the Micra CED as described above. Prior authorization for Micra TPS insertion procedures may be required from some commercial insurers to determine the applicability of covered benefits for a specific patient case.

<table>
<thead>
<tr>
<th>Coverage: Leadless Pacemaker Insertion</th>
<th>Medicare</th>
<th>Medicare Advantage</th>
<th>Private/Commercial Insurer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, covered(^1,4,6)</td>
<td></td>
<td></td>
<td>Depends; check with plan for specific policy.</td>
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<tr>
<td>Prior Authorization Requirements</td>
<td>None</td>
<td>Depends; check with plan for specific requirements.</td>
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Q9. Does Micra follow the same CMS National Coverage Determination (NCD) Cardiac Pacemaker Evaluation Services\(^7\) guidelines?
A9. Yes, Micra is a single chamber pacemaker device that we believe falls under these guidelines. You should check with your Medicare Administrative Contractor (MAC) for further guidance.

Q10. Are CMS NCDs binding on all MACs?
A10. Yes. CMS NCD decisions are binding on all Medicare contractors, and local Medicare policies cannot be more restrictive than the NCD.

Q11. Does the CMS Medicare coverage decision for the CED apply to state Medicaid patients?
A11. No. We suggest that a patient’s physician contact Medicaid to request pre-authorization for specific patients, providing supporting documentation as to why a Micra is the optimal option for each patient. Any denials should be brought to the attention of Medtronic by sending an email to: rs.healthcareeconomics@medtronic.com.

Q12. Where can I get more information?
A12. If you have additional questions, please visit our website at medtronic.com/crhfreimbursement, call us at 866-877-4102, Monday-Friday from 8 a.m. to 5 p.m. CST, or email us at rs.crdmhealthcareeconomics@medtronic.com (24-hour turnaround).
These coding suggestions do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third party payers as to the correct form of billing or the amount that will be paid to providers of service.

References
3 Medicare Managed Care Coverage Manual—Chapter 4 sections 10.7.1 and 10.7.3.

Brief Statement
Micra™ Transcatheter Pacing System VVIR Single Chamber with SureScan™ MRI

Indications
Micra Model MC1VR01 is indicated for patients with:
- Symptomatic paroxysmal or permanent high grade AV block in the presence of AF
- Symptomatic paroxysmal or permanent high grade AV block in the absence of AF, 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/sinus pauses), as an alternative to atrial or dual chamber pacing

Contraindications
Micra Model MC1VR01 is contraindicated for patients who have the following types of medical 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, or an implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra device.

The device is 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 implantation device from obtaining telemetry communication within ≤ 12.5 cm (4.9 in), or known intolerance to the materials listed in the Instructions for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated.

Steroid use — Do not use in patients for whom a single dose of 1.0 mg of dexamethasone acetate cannot be tolerated.

Warnings and Precautions
End of Service (EOS) — When the EOS condition is met, the clinician has the option of permanently programming the device to Off and leaving it in the heart, or retrieving the device, provided the device has not yet become encapsulated. Removal of the Micra device after it has become encapsulated may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician who has expertise in the removal of implanted leads.

MRI conditions for use — Before an MRI scan is performed on a patient implanted with the Micra device, the cardiology and radiology professionals involved in this procedure must understand the requirements specific to their tasks as defined in the device manuals.

Rate-responsive mode may not be appropriate for patients who cannot tolerate pacing rates above the programmed Lower Rate. Asynchronous VVIR pacing with sinus rhythm may not be appropriate when competitive pacing is considered undesirable or causes symptoms of pacemaker syndrome. The patient’s age and medical condition should be considered by physicians and patients as they select the pacing system, mode of operation, and implant technique best suited to the individual.

Precautions should be taken before administering anticoagulant agents, antiplatelet agents, or contrast media in patients with known hypersensitivity to these agents.

The use of deactivated Micra devices in situ and an active Micra device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant. Bench testing supports that implantation of an active Micra device, or an active transvenous pacemaker or defibrillator, next to an inactivated Micra device is unlikely to cause EMI or physical interaction. Post-approval studies are planned to characterize risks of co-implanted, deactivated Micra devices. Currently recommended 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.

Potential Complications
Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, acceleration of tachycardia, myocardial infarction and surgical complications such as cardiac perforation, pericardial effusion, cardiac tamponade, death, device embolization, access site hematoma and AV fistulae, vessel spasm, infection, inflammation, and thrombosis.

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, MRI conditions for use, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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