FREQUENTLY ASKED QUESTIONS

May 2017

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.1 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.

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

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.
General Questions: Coverage timeline, training, and Micra access

Q1. When will the studies be approved and coverage be effective?

A1. Medicare beneficiaries enrolled in the PAS are considered covered under the new Leadless Pacemaker Coverage Decision. CMS has approved the Micra PAS study as meeting the eligibility requirements for the Leadless Pacemaker CED, making coverage for Medicare beneficiaries under the PAS trial effective as of Feb. 9, 2017.

Effective Mar. 10, 2017, Medicare has approved coverage for beneficiaries enrolled in the prospective longitudinal study, hereafter known as the Micra CED study.

Since both the PAS and the Micra CED study have each received approval by CMS, all U.S. sites that implant Micra according to FDA indications in a Medicare patient should be considered covered. The CMS approval for the PAS and the Micra CED study are available on the CED website at: cms.gov/Medicare/Coverage-with-Evidence-Development/index.html. Micra procedures performed according to FDA indications are eligible for Medicare coverage and reimbursement.

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. Please refer to the Billing section of this document for specific billing instructions.

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

A3. The hospital does not need IRB (Institutional Review Board) 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 March 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. Have the participants of the Post Approval Study (PAS) been finalized?

A4. Yes, the list of hospitals participating in the Micra PAS has been finalized. If you have questions about PAS participation, please contact CRHF Reimbursement and Economics. Please refer to the contact information located at the end of this document.

Q5. After implanting the allotted number of patients in the PAS, would the hospital and physician automatically qualify for the Micra CED study?

A5. Yes, providers from the PAS that have implanted their allotted number of patients will become part of the Micra CED study.

Q6. How can I become a Micra implanting site?

A6. 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, or the Micra Program Team (see contact information below).

Q7. Are commercial (private) payers covering Micra? How is Medtronic approaching commercial (private) payers to support coverage?

A7. Currently, we are not aware of any private payers who provide coverage for Micra. Medtronic will be working to address Micra coverage from private payers. In the interim, until existing private payer policies are changed, 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. This will initiate the commercial (private) payer case review for possible coverage and policy exemption. Any denials should be brought to the attention of Medtronic by sending an email to: rs.healthcareeconomics@medtronic.com.
Q8. What are the covered indications for Micra?
A8. 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

Billing

Q9. What is the C code for the device?

Q10. What are the CPT® and ICD-10 codes associated with the implant and follow-up of Micra?

Q11. Can you explain what I need to add to my claim to identify it as complying with the CED requirements?
A11. CMS has not yet issued specific claim reporting instructions. However, in our approval letters CMS indicated sites are expected to include the CMS approved study NCT number on their hospital and physician claims. These NCT numbers are listed in the table below and are posted on the CMS website at: cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/.


<table>
<thead>
<tr>
<th>Claims Identifying Information to Signify Patient is Participating in a Study</th>
<th>PAS Study</th>
<th>CED Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Clinical Trial (NCT) number (secured from clinicaltrials.gov)</td>
<td>NCT02536118</td>
<td>NCT03039712</td>
</tr>
<tr>
<td>Modifier to Category III* CPT Implant code</td>
<td>-Q0</td>
<td>-Q0</td>
</tr>
<tr>
<td>Investigational clinical service provided in a clinical research study that is in an approved clinical research study.</td>
<td></td>
<td>Investigational clinical service provided in a clinical research study that is in an approved clinical research study.</td>
</tr>
<tr>
<td>Secondary Diagnosis Code†</td>
<td>Z00.6</td>
<td>Z00.6</td>
</tr>
<tr>
<td>Encounter for examination for normal comparison and control in clinical research program</td>
<td>Encounter for examination for normal comparison and control in clinical research program</td>
<td></td>
</tr>
<tr>
<td>Condition Code</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Qualifying clinical trial</td>
<td>Qualifying clinical trial</td>
<td></td>
</tr>
</tbody>
</table>

*Category III Codes are a set of temporary codes that allow data collection for emerging technology, services, and procedures.
†While CMS regulation allows for the Z00.6 to be coded in the primary (principal) or secondary position, FDA labeled indications are typically listed as a primary (principal) diagnosis.
Q12. I understand the Micra physician codes are Category III CPT codes that have no assigned Medicare RVUs (Relative Value Units) for the calculation of Medicare physician payment. How then does a physician get paid?

A12. Physicians submitting a Medicare claim for the Micra implant are advised to reference an existing service or procedure that is comparable to the Micra procedure in both costs and resources. Potential reference procedures* may include:

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33207</td>
<td>Insertion of new or replacement of permanent pacemaker with transvenous electrode(s), ventricular</td>
</tr>
<tr>
<td>33216</td>
<td>Insertion of a single transvenous electrode, permanent pacemaker or cardioverter-defibrillator</td>
</tr>
<tr>
<td>93580</td>
<td>Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant</td>
</tr>
<tr>
<td>93581</td>
<td>Percutaneous transcatheter closure of a congenital ventricular septal defect with implant</td>
</tr>
</tbody>
</table>

*One or more of these comparisons might be provided in claims submission to help determine appropriate reimbursement for this implant procedure. Each provider must determine the most appropriate reference code. These are examples only, not an exhaustive or definitive list.

Q13. Are payments established?

A13. Medicare Hospital payment for both the inpatient and outpatient settings is established. Inpatient MS-DRG assignments have been established for the Micra ICD-10 PCS coding, and outpatient APC/C-APC groupings have been assigned for the Micra Category III CPT codes. However, physician payment is contractor priced (subject to MAC discretion), as Micra is a novel technology with Category III codes, enabling physician payment but without assigned RVUs or national Medicare physician payment rates. Please see Question and Answer 12 on how you might support physician payment until Category I CPT codes, with assigned RVUs and payment rates, are established. Medtronic is working with the societies to establish Category I CPT codes and establish physician payment for leadless pacemakers.

Q14. Are Medicare Advantage plans required to provide coverage for Micra?

A14. Medicare requires Medicare Advantage (MA) plans to follow CMS’ national coverage decisions. Therefore, Medicare Advantage patients should not be treated differently. We do find some MA plans do not necessarily understand this requirement and services may be denied initially. Any denials should be brought to the attention of Medtronic by sending an email to: rs.healthcareeconomics@medtronic.com

Q15. Does Micra follow the same CMS National Coverage Determination (NCD) Cardiac Pacemaker Evaluation Services* guidelines?

A15. 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.

Q16. There is not a code for remote monitoring of the leadless pacemaker. What code(s) should I report?

A16. There are two possible options as shown in the table below. The ultimate responsibility for correct coding lies with the provider of services.

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1</td>
<td></td>
</tr>
<tr>
<td>93799</td>
<td>Unlisted cardiovascular service or procedure</td>
</tr>
<tr>
<td>Option 2</td>
<td></td>
</tr>
<tr>
<td>93294</td>
<td>Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional</td>
</tr>
<tr>
<td>93296</td>
<td>Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system or implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results</td>
</tr>
</tbody>
</table>
Q17. Are CMS NCDs binding on all MACs?
A17. Yes. CMS NCD decisions are binding on all Medicare contractors, and local Medicare policies cannot be more restrictive than the NCD.

Q18. My account has received denials with other new technology medical devices even though there is CMS coverage. Why is that?
A18. While CMS covers the Micra (PAS and CED), there may be initial denials that need to be appealed and coverage advocated. In part, Category III codes such as 0387T are considered emerging technologies and MACs have placed these procedures on a non-covered list. Any denials should be brought to the attention of Medtronic by sending an email to: rs.healthcareeconomics@medtronic.com.

Q19. Does the CMS Medicare coverage decision for both the PAS and CED apply to State Medicaid patients?
A19. No. We suggest that a patient’s physician contact Medicaid to request coverage 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.

Micra Coverage, Coding and Payment Questions
Send an email to:
rs.healthcareeconomics@medtronic.com
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
2. CPT copyright 2016 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to government use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for the data contained or not contained herein.
3. Waiver of consent information is at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/

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 when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.

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 implanted 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.