MICRA™ TRANSCATHETER PACING SYSTEM (TPS) REIMBURSEMENT OVERVIEW

MARCH 20, 2017
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- Note: CPT® code descriptions may be abbreviated and not listed in their entirety in all cases in this presentation. For full descriptions, please refer to your 2017 CPT code book.
AGENDA

- Micra Overview
- Leadless Pacemaker Coverage Decision
- Micra Coding Overview
- Reimbursement Overview
- Micra – Frequently Asked Questions
CARDIAC PACING MILESTONES

External Pacemaker

Implantable Pacemaker

Rate Responsive Pacemaker

MRI Conditional Pacemaker

Leadless Pacemaker

1958

1960

1986

2011

Today
**LEADLESS PACEMAKERS**

- Leadless (intracardiac) pacemakers deliver the same therapy as a conventional single chamber pacemaker, with fewer complications.¹
  - Leadless pacemakers are an advanced technology in which the generator and the electrode are combined into a single device implanted entirely within the heart chamber.
    - A subcutaneous pocket for the generator is not used.
    - Subcutaneous tunneling for the lead is also not used.
  - Lack of subcutaneous components eliminates a significant source of potential complications such as pocket infection, skin erosion, and lead fractures.

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Note: Codes and payment rates are already established for leadless pacemakers. See following slides for additional details.
## MICRA COVERAGE
### INFORMATION FOR MICRA IMPLANTS

<table>
<thead>
<tr>
<th>Medicare</th>
<th>Private Payer</th>
</tr>
</thead>
<tbody>
<tr>
<td>• CMS released the final NCD for Leadless Pacemakers on January 18, 2017 requiring Coverage with Evidence Development (CED).&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Varies by Payer Policy</td>
</tr>
<tr>
<td>• CMS has approved both studies required under the CED to provide coverage for all Medicare beneficiaries indicated for Micra.</td>
<td>• We encourage physicians to address with private payers on an individual patient basis.</td>
</tr>
</tbody>
</table>

The effective dates of each study are listed below:

- **Micra FDA Post Approval Study**: February 9, 2017<sup>2</sup>
  - The Micra PAS Study will enroll a subset of Medicare Micra patients through a traditional clinical research design

- **Micra Prospective Longitudinal Study**: March 10, 2017<sup>2</sup>
  - The prospective longitudinal study, also known as the Micra CED Study, will encompass all Medicare beneficiaries who receive Micra under an innovative new approach to CED

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### MICRA CODING
**PROCEDURE INFORMATION FOR MICRA IMPLANTS**

<table>
<thead>
<tr>
<th></th>
<th>Implant Codes&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Follow-up Codes&lt;sup&gt;1&lt;/sup&gt; (In person)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physician</strong></td>
<td>Category III Code: 0387T&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Category III Code: 0389T&lt;sup&gt;2&lt;/sup&gt; (Programming) 0391T&lt;sup&gt;2&lt;/sup&gt; (Interrogation)</td>
</tr>
<tr>
<td><strong>Hospital Inpatient&lt;sup&gt;3&lt;/sup&gt;</strong></td>
<td>ICD-10-PCS Procedure Code: 02HK3NZ&lt;sup&gt;3&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td><strong>Hospital Outpatient</strong></td>
<td>Category III Code: 0387T&lt;sup&gt;2&lt;/sup&gt;</td>
<td></td>
</tr>
</tbody>
</table>

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<sup>1</sup> 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.

<sup>2</sup> Current Procedural Terminology (CPT<sup>®</sup>) 2016 American Medical Association. All rights reserved.

<sup>3</sup> CMS-1655-F Final Rule Inpatient Prospective Payment System (IPPS) Fiscal Year 2017 released on August 2, 2016. The above ICD-10-PCS code reflects the assignment to Intracardiac Pacemaker into right ventricle, percutaneous approach.
Medicare claims in a qualified clinical trial require additional codes and modifiers^{1}

| National Clinical Trial (NCT) Identifier Number | • FDA Post Approval Study (NCT02536118), OR  
|                                  | • Prospective, Longitudinal Study (NCT03039712) |
| Diagnosis Code | Z00.6 – Encounter for examination for normal comparison and control in clinical research program  
(While CMS regulation allows for the Z00.6 to be coded in the primary (principal) or secondary position, FDA labeled indications are generally most appropriately listed as a primary (principal) diagnosis.) |
| Modifier | Q0 (zero) – Participation in a qualifying registry or qualified clinical study  
(outpatient hospital and physician claims only) |
| Condition Code | 30 – Qualified clinical trial  
(facility hospital claims only) |

## Micra Reimbursement Overview

### Medicare National Payment Rates*  

<table>
<thead>
<tr>
<th></th>
<th>Micra</th>
<th>Traditional IPG</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physician Payment</strong></td>
<td>Contractor Priced</td>
<td>$491</td>
</tr>
<tr>
<td><strong>Hospital Inpatient</strong></td>
<td>DRG 228 (w MCC): $41,414</td>
<td>DRG 242 (w MCC): $21,626</td>
</tr>
<tr>
<td></td>
<td>DRG 229 (w/o MCC): $27,733</td>
<td>DRG 243 (w CC): $15,392</td>
</tr>
<tr>
<td><strong>Hospital Outpatient</strong></td>
<td>C - APC 5194 $14,487</td>
<td>C - APC 5223 $9,225</td>
</tr>
<tr>
<td></td>
<td>C - APC 5223 $14,487</td>
<td>C - APC 5223 $9,225</td>
</tr>
</tbody>
</table>

*All rates include a 2% sequestration adjustment.

**MCC:** Major complication or comorbidity  
**CC:** Complication or comorbidity

The above payment information is presented to give healthcare providers facts only. Treatment decisions and procedure location is the sole decision of the healthcare provider.

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2. CMS-1655-F Final Rule Inpatient Prospective Payment System (IPPS) Fiscal Year 2017 released on August 2, 2016. These rates reflect the FY 2017 national payment amounts for MS-DRG 228 and 229. The FY 2017 traditional IPG national payment amounts reflect the highest and the lowest MS-DRGs 242-244 rates.  
3. DRG 228 and 229 are the most likely DRG assignments for a Micra when a patient presents with a cardiac diagnosis. If a patient is admitted for another reason and receives a Micra, the possibility exists to be assigned to DRG 981, 982, or 983.  
ADDITIONAL BILLING RESOURCE CAN BE FOUND ON THE MEDTRONIC WEBSITE

Q. Does Micra follow the same CMS National Coverage Determination (NCD)\(^1\) Cardiac Pacemaker Evaluation Services guidelines?
   A. 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.

Q. There is not a code for remote monitoring of the leadless pacemaker. What code(s) should I report?
   A. 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(^{\circ})</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Option 1</strong></td>
<td></td>
</tr>
<tr>
<td>93799</td>
<td>Unlisted cardiovascular service or procedure</td>
</tr>
<tr>
<td><strong>Option 2</strong></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>

Q. I understand the Micra physician codes are Category III CPT\(^1\) codes that have no assigned Medicare RVUs for the calculation of Medicare physician payment. How then does a physician get paid?

A. 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.

\(^1\) Current Procedural Terminology (CPT®) 2016 American Medical Association. All rights reserved.
THANK YOU!

ANY QUESTIONS?

PLEASE SEND FUTURE QUESTIONS VIA EMAIL TO:

 RS.HEALTHCAREECONOMICS@MEDTRONIC.COM

VISIT MEDTRONIC’S REIMBURSEMENT WEBSITE AT:

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 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.
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 Instruction for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated, or where a single dose of 1.0 mg dexamethasone acetate may be contraindicated.
Precautions should be taken before administering anticoagulant agents, antiplatelet agents, or contrast media in patients with known hypersensitivity to these agents.
The following may be contraindications to Micra VVIR pacing. Rate-responsive mode may be contraindicated for patients who cannot tolerate pacing rates above the programmed Lower Rate. Asynchronous VVIR pacing with sinus rhythm may be contraindicated 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.
**BRIEF STATEMENT:**

MICRA TRANSCATHETER PACING SYSTEM
VVIR SINGLE CHAMBER WITH SURESCAN™ MRI

**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.

**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 Medtronic’s website at [www.medtronic.com](http://www.medtronic.com).

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

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