This document is intended to provide information that may be pertinent to physicians and patients in cases for leadless pacemaker systems, including both Micra™ VR devices and Micra™ AV* devices, requiring prior authorization with private insurers, when used in accordance with FDA-approved labeling. The document is not intended as a guide through prior authorization; instead, it is a resource to depict a simplified version of the prior authorization process and provide an overview of evidence available about leadless pacemakers, including both Micra VR and Micra AV systems, Micra TPS that providers may consider in patient cases involving prior authorization. Check with the payer regarding their specific prior authorization requirements and processes.

This document highlights general steps in the prior authorization process, which may be required by private payers, and provides an overview of Medicare coverage for leadless pacemakers, which applies to Medicare Advantage plans administered by private payers.

GENERALIZED OVERVIEW OF THE PRIOR AUTHORIZATION PROCESS

The information below depicts the basic process for obtaining prior authorization from a payer for a medical procedure. In general, requirements include providing patient- and case-specific information along with any supporting evidence for the clinical course of action, as well as verifying benefits and eligibility.

*The single chamber Micra Transcatheter Pacing System is being described herein as Micra VR in order to distinguish it from the Micra AV product. When information in this document relates to both Micra AV and VR, “Micra Transcatheter Pacing Systems” is used to represent the portfolio of devices.

COLLECT PATIENT & PROCEDURE INFORMATION

- Collect information needed to perform patient eligibility verification
  - Patient name and insurance card
  - Procedure and diagnosis detail
  - Facility details

BENEFIT VERIFICATION

- Verify patient benefits and eligibility for procedure
- What are conditions of coverage for this patient?
- What are prior authorization requirements for patient and service?

PRIOR AUTHORIZATION

- If patient meets coverage criteria, collect supporting documentation
- Submit required information to gain appropriate payer approval for procedure
- Obtain the prior authorization number and expiration date for your files. Request official approval correspondence.
- Reverify eligibility immediately before procedure

Prior authorization procedures can vary by payer plan and also within a payer based on an individual patient’s coverage policy. Providers should contact the health plan for specific steps and requirements regarding advance notification and approval processes specific to your patient.
The information contained in this document may be helpful as providers consider evidence and supporting information available to support prior authorization requests in specific cases. Relevant information providers may consider including as supporting information for prior authorization includes, though is not limited to, the information provided below detailing CMS coverage information, FDA-approved indications, conditions for use, and relevant procedure codes for the Micra AV and Micra VR Transcatheter Pacing Systems.

**MEDICARE COVERS LEADLESS PACEMAKERS UNDER BOTH TRADITIONAL AND MEDICARE ADVANTAGE PLANS**

Medicare has a National Coverage Determination (NCD) designating coverage for leadless pacemakers. This NCD applies to all leadless pacemaker systems, including both Micra AV and Micra VR devices and can be found in Section 20.8.4 of the Medicare NCD Manual. The National Coverage Determination for Leadless Pacemakers (20.8.4) defining this coverage applies to both traditional Medicare and Medicare Advantage Plans 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. The CED studies for both the Micra AV and the Micra VR devices meet this definition, are approved by CMS for purposes of coverage under the CED, and are posted on CMS' CED website as such.

Medicare coverage for leadless pacemaker procedures performed as part of the Micra CED studies apply 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, such as the Micra CED studies 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.

### Summary of Coverage/Prior Authorization for Leadless Pacemaker Insertion by Payer Type

<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>Coverage: Leadless Pacemaker Insertion</td>
<td>Yes, covered.</td>
<td>Depends; check with plan for specific policy.</td>
<td>Depends; check with plan for specific requirements.</td>
</tr>
<tr>
<td>Prior Authorization Requirements</td>
<td>None.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**FDA-APPROVED INDICATIONS FOR MICRA TPS**

The Micra VR TPS is FDA approved for patients who have experienced one or more of the following conditions. Not every Micra TPS model is approved for all indications; please see the product labeling for indication details:

- Paroxysmal or permanent high-grade AV block in the presence of AF
- Paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when a dual-chamber transvenous pacing system 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 a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy

The Micra AV device is also indicated for VDD pacing in patients with adequate sinus rates who may benefit from maintenance of AV synchrony. The Micra AV device provides AV synchronous ventricular pacing similar to a transvenous VDD system. The implanted device depends on the appropriate sensing of atrial mechanical signals to achieve AV synchrony. The level of AV synchrony may vary in individual patients and may not be predictable prior to implant.

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity. The device is designed to be used only in the right ventricle.
CONSIDERATIONS FOR USE OF MICRA TPS

The original Micra pacing system, referred to in this document as the Micra VR device, is a single-chamber ventricular pacemaker. The Micra AV device extends leadless pacing to patients with high-degree AV block in the absence of AF, including a portion of patients who may have traditionally received a dual-chamber transvenous pacing system. This technology has the unique ability to sense mechanical atrial activity, allowing the device to provide AV synchronous ventricular pacing to indicated patients. The Micra AV device is the same size and maintains the same streamlined implant procedure as the Micra VR device.

Given the equivalence of basic pacing therapy, leadless pacing offers benefits that patients with transvenous pacemakers may not receive, such as:

- **Reduced complications**
  - Approximately one in eight patients implanted with traditional pacemakers experience complications, frequently related to the lead or subcutaneous pocket. Complications include problems with the subcutaneous pocket, such as hematomas and infections; lead-insertion problems, such as pneumothorax and hemothorax; lead dislodgements and integrity problems; infections including septicemia and endocarditis; vascular obstructions; and reduced vascular access. Pacemaker infections have a high mortality risk: 31–66% of cardiac device-related endocarditis cases result in death if the device is not extracted while up to 18% die even after device removal and antibiotic treatment.
  - The Micra TPS by design eliminates the need for a lead and for a subcutaneous pocket.
  - Results from the Medtronic Post-approval Registry, published in *Heart Rhythm Journal* in December 2018, showed the Micra TPS was successfully implanted in 99.1% of patients. The rate of major complications through 12 months for Micra TPS patients was low at 2.7%. The risk of major complications for Micra TPS patients was 63% lower than that for patients with traditional pacemakers (hazard ratio 0.37; 95% CI: 0.27–0.52, P < 0.001).

Because the implant technique also differs from traditional pacemakers, patients considered for leadless pacemakers should be those who can reasonably accommodate a large-sized femoral sheath for implant.

CONSIDERATIONS FOR USE OF MICRA TPS IN “DIFFICULT” OR “HIGH-RISK POPULATIONS”

The second and third elements of the FDA-approved labeling refer to conditions where Micra TPS is an “alternative” to atrial or dual chamber pacing in patients without AV block and no AF and in patients with sinus node dysfunction. This is to be considered “when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy.” Patients in this category will derive the same benefits that are described in the previous section related to reduction in complications and improved patient satisfaction. These patients are considered difficult and high-risk for transvenous pacing with respect to access and complications related to traditional pacing leads and subcutaneous pockets. Therefore, Micra TPS represents an alternative that can increase access to pacing therapy.

Case studies/series give insights into the conditions that might put a patient into the “difficult” or “high-risk” category. From these publications, patients with one or more of the following conditions may be considered:

- **High risk of infection**
  - End-stage renal disease with hemodialysis
  - Previous bilaterally infected pectoral tissue
  - Previous pacemaker pocket/lead infections or erosion
- **Patients with pacemaker lead failures where lead extraction is difficult or risky**
- **Venous access**
  - Subclavian vein occlusion/stenosis due to previous IPG implantations/revisions
  - Total vena cava occlusion
- **Bioprosthetic tricuspid valve replacement**
CODING FOR IMPLANTATION OF LEADLESS PACEMAKERS

The following CPT® codes are associated with leadless pacemakers for hospital outpatient and physician procedures, effective January 1, 2019:

- **33274**: Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed
- **33275**: Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed

The following ICD-10 procedure codes are associated with leadless pacemakers for hospital outpatient and physician procedures:

- **02HK3NZ**: Insertion of intracardiac pacemaker into right ventricle, percutaneous approach
- **02PA3NZ**: Removal of intracardiac pacemaker from heart, percutaneous approach, for the removal of the leadless pacemaker
- **02WA3NZ**: Revision of intracardiac pacemaker in heart, percutaneous approach, for the repositioning of the leadless pacemaker

References

2. Medicare Managed Care Coverage Manual — Chapter 4 section 10.7.1 and 10.7.3.

There are two NCT numbers that apply because there are two different Medicare CED studies that pertain — one for the Micra AV leadless pacemaker and one for the Micra VR leadless pacemaker. See table below for information relating to each device. Medicare Advantage plans may have specific instructions requiring the specification of the NCT for proper billing; please check with a patient’s plan for applicable instructions. (Medicare has published CED claims instructions via Medicare Claims Processing Transmittal 3815, which instructs billing staff on how to properly submit claims under NCD 20.8.4)

<table>
<thead>
<tr>
<th>Device</th>
<th>Model #</th>
<th>Study Name</th>
<th>NCT #</th>
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<tr>
<td>Micra VR System</td>
<td>MC1VR01</td>
<td>Micra CED Study</td>
<td>03039712</td>
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<tr>
<td>Micra AV System</td>
<td>MC1AVR1</td>
<td>Micra AV CED Study</td>
<td>04235491</td>
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</tbody>
</table>

FURTHER INFORMATION

If you have additional questions on leadless pacemaker reimbursement, please visit our website at www.medtronic.com/MicraReimbursement, call us at 1-866-877-4102, Monday–Friday from 8 a.m. to 5 p.m. CST, or email us at: rs.healthcareeconomics@medtronic.com.

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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 removing the device. If 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.

Potential Complications

Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, pacemaker syndrome, cardiac arrest, acceleration of tachycardia, necrosis, myocardial infarction and surgical complications such as cardiac perforation, pericardial effusion, cardiac tamponade, device embolization, hematoma, AV fistula, vessel dissection, infection, cardiac 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.