This document is intended to provide clear, factual, and balanced information that may be pertinent to physicians and patients in cases for Micra™ Transcatheter Pacing System (TPS) 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 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.

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

DOCUMENT & VERIFY

- 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 Micra TPS.

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

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 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 Longitudinal Coverage With Evidence Development Study on Micra Leadless Pacemakers (Micra CED) meets this definition, is approved by CMS for purposes of coverage under the CED, and is posted on CMS’ CED website as such. 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, 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.

**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>
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</tbody>
</table>

**FDA-APPROVED INDICATIONS FOR MICRA TPS**

Micra TPS is currently the only FDA-approved leadless pacing device and is FDA-approved for patients who have experienced one or more of the following conditions:

- Symptomatic paroxysmal or permanent high-grade AV block in the presence of atrial fibrillation (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
CONSIDERATIONS FOR USE OF MICRA TPS

The Micra TPS device is a fully capable VVI pacemaker with the same advanced pacing features available in traditional VVI pacing systems, including comparable longevity, capture threshold automaticity, rate response, and MRI conditional operation. By design, it is expected that the therapy delivered by Micra TPS and the therapy delivered by a transvenous VVI pacemaker are clinically equivalent.

Given the equivalence of basic pacing therapy, the primary benefits that Micra TPS offers above traditional pacemakers are:

- **Reduced complications**
  - Approximately one in eight patients experience pacemaker complications related to traditional pacemakers, 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.
  - Micra TPS by design eliminates the need for a lead and for a subcutaneous pocket.
  - Results from the Medtronic Post-approval Registry, presented at the Heart Rhythm Society (HRS) in May 2018, showed the Micra TPS was successfully implanted in 99.1% of patients and that the system met its safety and effectiveness end points at 12 months follow-up with wide margins. The risk of major complications at 12 months for Micra TPS patients was low at 2.7%, 63% lower than 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 Micra TPS 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 MICRA TPS

The following CPT codes are associated with Micra TPS for hospital outpatient and physician procedures, effective January 1, 2019:\(^\text{13}\):

- **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

The following ICD-10 procedure codes are associated with Micra TPS for hospital outpatient and physician procedures, effective January 1, 2019:

- **02HK3N2**: Insertion of intracardiac pacemaker into right ventricle, percutaneous approach

- **02PA3N2**: Removal of intracardiac pacemaker from heart, percutaneous approach, for the removal of the leadless pacemaker

- **02WA3N2**: Revision of intracardiac pacemaker in heart, percutaneous approach, for the repositioning of the leadless pacemaker

The NCT number assigned to this study is NCT03039712. 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.\(^\text{17,18}\))

FURTHER INFORMATION

Additional billing and coding information can be found on our CRHF Reimbursement Services website. For questions or for more information, please contact Medtronic CRHF Reimbursement Services at 1-866-877-4102 (8:00 a.m. to 5:00 p.m. CT, Monday-Friday) or rs.healthcareeconomics@medtronic.com.

References

1. Medicare Managed Care Coverage Manual – Chapter 4 section 10.7.1 and 10.7.3.
7. El-Chami, MF, et al. Leadless Pacemaker Implant in Patients with Pre-Existing Infections: Results from the Micra Post-Approval Registry. Presented at HRS 2018; Boston, MA.
15. CPT® 2018 American Medical Association. All Rights Reserved. CPT® is a registered trademark of the American Medical Association.
a clinician who has expertise in the removal of implanted leads. If removal of the device is required, it is recommended that the removal be performed by a physician. Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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**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 conditions: femoral venous anatomy unable to accommodate a 7.8 mm (23 Fr) 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 tolerated.

Contraindications include the addition of a replacement device with or without explantation of the Micra device, which should be turned off. 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.

**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.

**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.