Most commercial payers in the United States do not have a positive coverage policy for Micra transcatheter pacing system (TPS). Many of these payers have expressed no opinion on Micra TPS and have no active policy. Of those that do have an active policy, most have designated Micra TPS as “experimental and investigational.” Micra TPS also has been assigned a Category III CPT® code, which some payers exclude from coverage by general policy. Because of these considerations, Micra TPS is likely to be denied at first request for prior authorization.

Even though it may be denied on prior authorization, there is a path to possible approval through the appeal process. Every commercial health plan has a method by which denials can be appealed by a process documented in the plan’s Provider Manual.

This document is intended to provide clear, factual and balanced information that may be pertinent to the process by which physicians and patients make an appeal to a U.S. private payer for coverage for Micra TPS when used in accordance with FDA-approved labeling. This is not a “one size fits all” justification for all patients — instead it is a resource to quickly understand what evidence is available about Micra TPS. Any prior authorization or appeal would need to include all of the patient-specific characteristics that lead to the conclusion that Micra TPS would be the right choice for that patient. Once that patient-specific case is laid out, corresponding evidence from this document could be used to strengthen the justification.

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What is the FDA-approved labeling for Micra TPS?
Micra TPS is currently the only FDA-approved leadless pacing device. The FDA-approved labeling for Micra TPS is as follows:

The Micra TPS single chamber ventricular system is indicated for 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

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

Micra TPS 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 TPS device in the judgment of the implanting physician
- An implanted inferior vena cava filter
- A mechanical tricuspid valve
- An implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra TPS device

The device 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)
- Known intolerance to the following materials: titanium, titanium nitride, parylene C, primer for parylene C, PEEK, siloxane, nitinol, platinum, iridium, liquid silicone rubber, and silicone medical adhesive 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 dexamethasone acetate cannot be tolerated.

For the MRI contraindications for patients with a Micra TPS MRI device, refer to the Medtronic MRI Technical Manual.

What are the considerations for Micra TPS vs. transvenous VVI for patients with AV block and atrial fibrillation (AF)?
The first element of the FDA-approved labeling refers to patients with “high grade AV block in the presence of atrial fibrillation.” In simple terms, this is referring to cases where the atrial fibrillation is such that there is minimal value to sensing or pacing in the atrium, and the therapy choice has come down to single chamber ventricular pacing instead of dual chamber pacing.

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.
  - Primary results from the Medtronic Micra TPS Global Clinical Trial, published November 2015 in the New England Journal of Medicine, showed the Micra TPS was successfully implanted in 99.2 percent of patients by 94 physicians around the world and that the system met its safety and effectiveness end points at 6 months follow-up with wide margins. Long-term results from the Micra TPS Trial, published November 2016 in Heart Rhythm, reinforced these data, showing the risk of major complications at 12 months for Micra TPS patients was low at 4 percent, 48 percent lower than for patients with traditional pacemakers (hazard ratio: 0.52, 95% CI: 0.35-0.77, P = 0.001).
Improved patient satisfaction
– Because the entire pacing system is implanted in the patient’s right ventricle, leadless pacing may increase patient satisfaction by eliminating chest scarring and bulging that may occur with transvenous pacemaker systems. Leadless pacing may also reduce post-implant movement restrictions as a result of the less invasive implant procedure.⁷

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.

What are the considerations for the 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. Since these patients are considered difficult and high risk with relation to access and complications related to traditional pacing leads and subcutaneous pockets, Micra TPS presents 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 these 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

In addition to the conditions supported by case studies listed above, Micra TPS may also be considered in young patients for whom preservation of superior veins is desired, patients with poorly managed diabetes, and immunosuppressed patients.

In the above cases, patients are considered poor candidates for transvenous pacemaker lead implantation. The alternatives are limited to choices such as epicardial lead placement (delivered via thoracotomy with attendant risk of complications and mortality), or in extreme cases, heart transplant.

The standard Micra TPS contraindications still apply to patients in this category.

What are the considerations for the use of Micra TPS in patients where atrial or dual chamber pacing is not deemed necessary for effective therapy?

This is likely a reference to a recent HRS/ACCF consensus statement on pacemaker device and mode selection. This states as a class I recommendation for patients with AV Node Disease:

*Single-chamber ventricular pacing is recommended as an acceptable alternative to dual-chamber pacing in patients with AV block who have specific clinical situations that limit the benefits of dual-chamber pacing. These include, but are not limited to, sedentary patients, those with significant medical comorbidities likely to impact clinical outcomes, and those in whom technical issues, such as vascular access limitations, preclude or increase the risk of placing an atrial lead (Level of Evidence: B).*

The standard Micra TPS contraindications still apply to patients in this category.
**Does Medicare pay for Micra TPS?**

Yes, Micra TPS is covered for all Medicare patients. The coverage is under “Coverage with Evidence Development,” meaning that a condition of being paid by Medicare is that the patient is enrolled in a CMS approved study. The currently approved studies are the FDA post-approval study for Micra TPS (Clinicaltrials.gov NCT02536118), and a claims analysis based study developed specifically for CMS (Clinicaltrials.gov NCT03039712). The claims analysis based study essentially allows Medicare to use its own billing records to effectively gather data on any Medicare patient who receives a Micra TPS device, and does not require any additional action on the part of the hospital other than what is required for billing purposes.

The following codes are associated with Micra TPS:

- For hospital outpatient and physician procedures, the Category III CPT codes are:
  - 0387T — Transcatheter insertion or replacement of permanent leadless pacemaker, ventricular
  - 0388T — Transcatheter removal of permanent leadless pacemaker, ventricular
  - 0389T — Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report, leadless pacemaker system
  - 0390T — Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure or test with analysis, review and report, leadless pacemaker system
  - 0391T — Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, leadless pacemaker system

- For hospital inpatient procedures, the ICD-10 procedure codes are:
  - 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

**Whom should I contact if a payer continues to deny a prior authorization/pre-determination or a Micra TPS implant?**

Each commercial payer has a multiple level appeals process. If you have a legitimate clinical case for why the patient should receive Micra TPS as opposed to standard transvenous pacing, continue to follow the defined escalation process for your payer.
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 antiagulant 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 elimination 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.