

Coverage and prior authorization information

Micra™ Transcatheter Pacing System



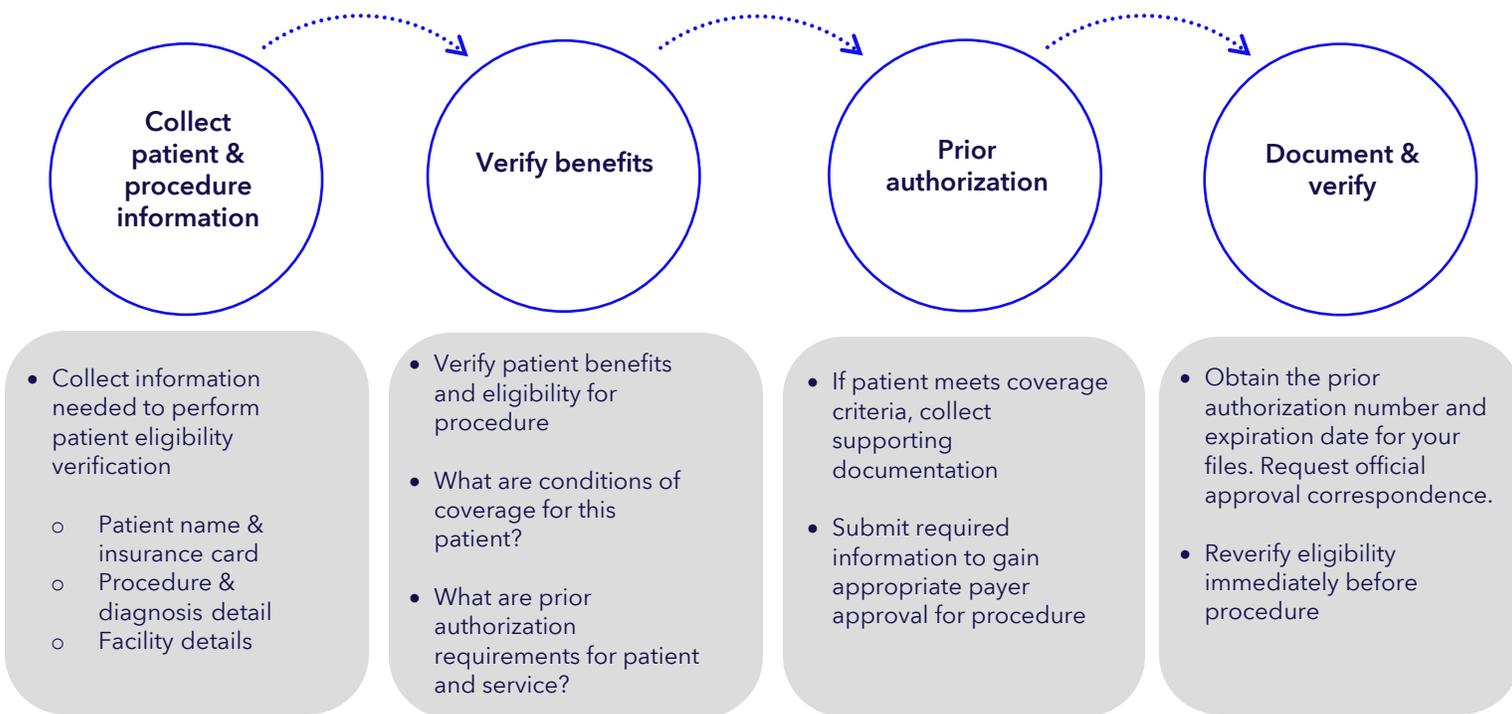
Overview

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. 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.

*The single chamber Micra Transcatheter Pacing System (TPS) 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.

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.



Prior authorization procedures can vary by payer plan and 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. [Prior authorization does not guarantee coverage.](#)

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 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.¹ The National Coverage Determination for Leadless Pacemakers (20.8.4) defining this coverage applies to both traditional Medicare and Medicare Advantage Plans² 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.¹

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.³

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 Medicare Advantage plans. The Medicare Managed Care Manual establishes that Medicare Advantage plans are subject to the same coverage requirements as traditional Medicare for NCD requiring CED², such as the Micra CED studies as described above. [Prior authorization for Micra TPS insertion procedures is not required for traditional Medicare, however, may be required from some insurers](#) that manage Medicare Advantage plans to determine the applicability of covered benefits for a specific patient case.

Summary of coverage/prior authorization for leadless pacemaker insertion by payer type

	Medicare	Medicare Advantage	Private/commercial insurer
Coverage: leadless pacemaker insertion	Yes, covered. ¹⁻³		Depends; check with plan for specific policy.
Prior authorization requirements	None.	Depends; check with plan for specific requirements.	

FDA-approved indications for Micra TPS

The Micra VR and AV devices are 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 labeling⁴ 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 potential 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.⁵ 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.⁶
- 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 VR was successfully implanted in 99.1% of patients. The rate of major complications through 12 months for Micra VR patients was low at 2.7%. The risk of major complications for Micra VR patients was 63% lower than that for patients with traditional pacemakers (hazard ratio 0.37; 95% CI: 0.27–0.52, $P < 0.001$).⁷
- The Medicare Micra Coverage with Evidence Study showed a significant 38% reduction in the adjusted rate of reintervention at two years, a 31% reduction in the adjusted rate of chronic complications at two years, and no significant difference in adjusted two-year all-cause mortality, between patients receiving Micra VR and TV-VVI.⁸

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 potential 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.⁹⁻¹⁵ 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

CPT® code	Description
The following CPT® codes are associated with leadless pacemakers for hospital outpatient and physician procedures ¹⁶ :	
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 inpatient procedures ¹⁷ :	
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

There are two National Clinical Trial (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.^{18,19})

Device	Model #	Study Name	NCT #
Micra VR System	MC1VR01	Micra CED Study	03039712
Micra AV System	MC1AVR1	Micra AV CED Study	04235491

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.healthcareconomics@medtronic.com.

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References

- ¹CMS.gov. National Coverage Determination (NCD) for Leadless Pacemakers (20.8.4). Available at: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=370>. Accessed November 30, 2021.
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- ³CMS.gov. Coverage with Evidence Development. Available at: <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Leadless-Pacemakers>. Accessed November 30, 2021.
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- ¹⁵Solis LD, Toquero J, Castro V. Leadless Pacemaker Due to Bilateral Subclavian Stenosis. *Rev Esp Cardiol (Engl Ed)*. April 2017;70(4):294.
- ¹⁶CPT codes and descriptions only are copyright ©2021 American Medical Association. All rights reserved. No fee schedules are included in CPT. The American Medical Association assumes no liability for data contained or not contained herein.

¹⁷CMS.gov. ICD-10-CM/PCS MS-DRG v39.0 Definitions Manual. Available at: <https://www.cms.gov/medicare/icd-10/2022-icd-10-pcs> Updated October 19, 2021. Accessed November 23, 2021

¹⁸Medicare Learning Network. MLN Matters Number: MM10117: National Coverage Determination (NCD 20.8.4): Leadless Pacemakers. Available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/mm10117.pdf>. Accessed November 30, 2021.

¹⁹CMS.gov. Medicare Claims Processing Manual 100-04, Transmittal 3815. National Coverage Determination (NCD20.8.4): Leadless Pacemakers. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3815CP.pdf>. Accessed November 30, 2021.

Brief Statement

Indications

Micra devices, Micra Model MC1VR01 and Micra AV Model MC1AVR1, are indicated for use in patients who have experienced one or more of the following conditions:

- 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

Micra AV Model MC1AVR1 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.

Contraindications

Micra Model MC1VR01 and Micra AV Model MC1AVR1 are 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 Instruction for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated, or if the steroid dose from this device 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. For Micra Model MC1VR01, 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.

For Micra AV Model MC1AVR1, patient activities and environments which present mechanical vibrations to the patient can interfere with the mechanical sensing of atrial contractions. This can result in a loss of AV synchrony.

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.

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