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Engineering the extraordinary

Prior authorization resources

Micra™ leadless pacemakers

December 2023

Disclaimer

Medtronic provides Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules and regulations. The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists and/or legal counsel for interpretation of coding, coverage and payment policies. This document provides assistance for FDA approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA cleared or approved labeling (e.g., instructions for use, operator's manual or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service.

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Product links & supporting documentation

Micra™ leadless pacemakers

Overview

This document outlines resources available to support your efforts in obtaining prior authorization for Micra leadless pacemakers. A prior authorization should include two areas of focus: patient-specific information and supportive clinical evidence. Click on the blue buttons below to access resources within this document as well as links to external resources.

Prior authorization resources

Click here — Sample prior authorization letter

Click here — Sample prior authorization appeal letter

Click here — Supportive evidence (bibliography)

Additional resources

Click here — Micra VR FDA approval letter

Click here — Micra AV FDA approval letter

Click here — Micra AV2/VR2 FDA approval letter

Click here — Product summary overview

Click here — Reimbursement guide

Click here — Medicare billing instructions for Micra leadless pacemakers

Contact

For additional information, contact the Medtronic Reimbursement Customer Support team by phone at 866-877-4102 or by email at: rs.healthcareeconomics@medtronic.com.

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Sample prior authorization letter

Micra™ leadless pacemakers

Overview

This document is a sample pre-service appeal letter to assist providers in obtaining a prior authorization for a Micra leadless pacemaker and must be customized to the patient and payer. It is for your consideration and may not include all the information necessary to support your request. The requesting provider is responsible for ensuring accuracy and adequacy of all information provided. Use of this letter does not guarantee authorization or eventual payment.

Instructions

- Please do not include this instruction page to avoid misinterpretation of your prior authorization request as a form letter.
- It is recommended that providers use their business letterhead as appropriate.
- Please customize the sections in *blue italics* using information pertinent to you, your patient, and their condition/procedure. The remaining letter content can also be edited.
- This letter is not intended to replace any professional judgement; it is merely to assist with the appeal request. Providers are encouraged to include their professional expertise and experience with this procedure.
- It is important to contact the patient's insurance for prior authorization timeline(s), submission process, and requirements.
- For a list of supplemental resources that are available to accompany your appeal request, please refer to the additional resources in the Table of Contents

Considerations for Medicare Advantage beneficiaries

- Medicare Advantage plans are subject to the same coverage requirements as traditional Medicare but may require prior authorization.
- Medicare covers leadless pacemakers under a National Coverage Determination (NCD) specifying coverage with evidence development (CED). When a Micra procedure claim is submitted to Medicare, the patient is automatically enrolled in a CED study.
- Medicare Advantage plans may require the Micra CED National Clinical Trial (NCT) as part of Micra prior authorization to confirm coverage eligibility.
- Refer to Micra Reimbursement Guide & Micra Medicare Billing Instructions for details

Click here

To open the sample prior authorization letter in Microsoft Word

Provider Letterhead

Date
Payer Name
Attn: Utilization Management/Prior Authorization Department
RE: Prior authorization for Micra leadless pacemaker

Patient name: *Patient name*
Date of birth: *Date of birth*
Policy ID number: *Policy ID number*

Procedure code(s): *Procedure code(s)*
Diagnosis code(s): *Diagnosis code(s)*
Date(s) of service: *Date(s) of service*

To Whom it May Concern:

On behalf of my patient, *patient name*, I am writing to request a prior authorization for a leadless pacemaker, which has been deemed medically necessary to *[insert statement of medical necessity]*.

Micra™ leadless pacemakers are implantable devices that deliver the same pacing benefits as conventional transvenous pacemakers while eliminating the complications associated with transvenous pacing leads and generator pockets. Micra leadless pacemakers have been approved by the US Food & Drug Administration since 2016.

Explain the clinical rationale leading to the decision to recommend a Micra leadless pacemaker for this patient. You may require one or more paragraphs to address the following:

- *Patient's relevant medical history (e.g. diagnosis, clinical presentation)*
- *Outcomes and limitations of previous treatments (e.g. previous pacemaker pocket or lead-related complications)*
- *Any significant risk factors, comorbidities, or other relevant history (e.g. infection risk, vascular preservation, upper extremity vascular challenges, cognitive impairment, lifestyle or occupational considerations)*
- *Reasons for procedure including why transvenous pacing would not deliver acceptable outcomes*

If patient is Medicare Advantage beneficiary, consider including information related to Medicare coverage:

Medicare covers leadless pacemakers under an NCD specifying coverage with evidence development (CED). This NCD can be found in Section 20.8.4 of the Medicare NCD Manual. Beneficiaries enrolled in the Micra CED studies are approved for coverage within the CED requirements.

Patient name will be automatically enrolled in a Micra CED study (NCT#03039712 if request for Micra VR or NCT# 04235491 if request for Micra AV) when the procedure claim is submitted to Medicare.

In closing, I have determined that a Micra leadless pacemaker is medically necessary for my patient and provided the above and enclosed information to support this request. As such, I respectfully request prior authorization for coverage and reimbursement of all charges associated with this procedure, including physician professional fees, facility costs, device/supply charges, fees for follow-up care, and long-term monitoring.

Thank you for your review and consideration of coverage. If you have any questions, please contact me at *phone number*.

Sincerely,
Provider name
Provider NPI/Tax ID

Enclosed: *List of enclosures (e.g., prescriptions, copies of pertinent medical records along with any other relevant information you believe would make a persuasive argument for coverage such as clinical evidence)*

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Pre-service appeal letter

Micra™ leadless pacemakers

Overview

This document includes recommendations on how to write a pre-service appeal letter to assist providers in appealing a prior authorization denial for a leadless pacemaker and must be customized to the patient and payer. It is for your consideration and may not include all the information necessary to support your request. The requesting provider is responsible for ensuring accuracy and adequacy of all information provided. Use of these recommendations does not guarantee authorization or eventual payment. Each payer has their own pre-service appeal process. Please contact the patient's payer for exact steps.

Instructions

- It is recommended that providers use their business letterhead as appropriate.
- Please customize the sections in the sections of your letter using information pertinent to you, your patient, and their condition/procedure.
- These recommendations are not intended to replace any professional judgement; it is merely to assist with the appeal request. Providers are encouraged to include their professional expertise and experience with this procedure.
- It is important to contact the patient's insurance for appeal timeline(s), submission process, and requirements.
- For a list of supplemental resources that are available to accompany your appeal request, please refer to the Resource Table of Contents.

Considerations for Medicare Advantage beneficiaries

- Medicare Advantage plans are subject to the same coverage requirements as traditional Medicare but may require prior authorization.
- Medicare covers leadless pacemakers under an NCD specifying coverage with evidence development (CED). When a Micra procedure claim is submitted to Medicare, the patient is automatically enrolled in a CED study.
- Medicare Advantage plans may require the Micra CED National Clinical Trial (NCT) as part of Micra prior authorization to confirm coverage eligibility.
- Refer to Micra Reimbursement Guide & Micra Medicare Billing Instructions for details.

Click here

To open the sample pre-service appeal letter in Microsoft Word

Provider Letterhead

Date
Payer Name

Attn: Utilization Management/Prior Authorization Department

RE: Appeal for Micra leadless pacemaker – *Prior authorization/reference number (if available)*

Patient name: *Patient name*
Date of birth: *Date of birth*
Policy ID number: *Policy ID number*

Procedure code(s): *Procedure code(s)*
Diagnosis code(s): *Diagnosis code(s)*
Date(s) of service: *Date(s) of service*

To Whom it May Concern:

I am the treating physician for *patient name* and am writing to appeal the prior authorization denial for a Micra leadless pacemaker, which has been deemed medically necessary to *[insert statement of medical necessity]*. The denial cites *[insert rationale from denial letter (e.g., experimental/investigational, not medically necessary)]*. Additionally, I am requesting review of the denial and enclosed clinical documentation by a physician with similar medical specialty.

Micra leadless pacemakers are implantable devices that deliver the same pacing benefits as conventional transvenous pacemakers while eliminating the complications associated with transvenous pacing leads and generator pockets. Micra leadless pacemakers have been approved by the US Food & Drug Administration since 2016.

Explain the clinical rationale leading to the decision to recommend a Micra leadless pacemaker. You may require one or more paragraphs to address the following:

- *Denial reasons and why you disagree (Note: Even if the denial is a result of a payer's non-coverage policy, the goal for the appeal is to request a one-time patient exception for coverage based on medical necessity.)*
- *Patient's relevant medical history (e.g. diagnosis, clinical presentation)*
- *Outcomes and limitations of previous treatments (e.g. previous pacemaker pocket or lead-related complications)*
- *Any significant risk factors, comorbidities, or other relevant history (e.g. infection risk, vascular preservation, upper extremity vascular challenges, cognitive impairment, lifestyle or occupational considerations)*
- *Reasons for procedure including why transvenous pacing would not deliver acceptable outcomes*
- *Goal/Clinical benefit of subcutaneous cardiac rhythm monitor for this patient*
- *Your experience with Micra leadless pacemaker outcomes*
- *Other key factors supporting your request (e.g., guidelines, medical policy, clinical studies, payers that cover Micra leadless pacemakers)*

If patient is Medicare Advantage beneficiary, consider including information related to Medicare coverage, such as:

Medicare covers leadless pacemakers under an NCD specifying coverage with evidence development (CED). This NCD can be found in Section 20.8.4 of the Medicare NCD Manual. Beneficiaries enrolled in the Micra CED studies are approved for coverage within the CED requirements.

Patient name will be automatically enrolled in a Micra CED study (NCT#03039712 if request for Micra VR or NCT# 04235491 if request for Micra AV) when the procedure claim is submitted to Medicare.

In closing, I have determined that a Micra leadless pacemaker is medically necessary for my patient and provided the above and enclosed information to support this request. As such, I respectfully request reconsideration for coverage and reimbursement of all charges associated with this procedure, including physician professional fees, facility costs, device/supply charges, fees for follow-up care, and long-term monitoring.

Thank you for your prompt review. If you have any questions, please contact me at *phone number*.

Sincerely,

Provider name
Provider NPI/Tax ID

Enclosed: *List of enclosures (e.g., prescriptions, copies of pertinent medical records along with any other relevant information you believe would make a persuasive argument for coverage such as clinical evidence)*

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Supportive evidence (bibliography)

Micra™ leadless pacemakers

Overview

This evidence compendium outlines published evidentiary resources related to Micra leadless pacemakers. This is not a comprehensive list; additional evidentiary resources may be available to support your needs.

Leadless Pacemaker resources

Click here	Safety and patient outcomes	Click here	High-risk subpopulations
Click here	Quality of life	Click here	Procedural safety
Click here	AV synchrony	Click here	Guidelines

Supportive evidence

Safety and patient outcomes

Crossley, G., Longacre, C., Higuera, L., et al. (2023). Outcomes of Patients Implanted with an Atrioventricular Synchronous Leadless Ventricular Pacemaker in the Medicare Population. *Heart rhythm*, S1547-5271(23)02759-5. Advance online publication. https://doi.org/10.1016/j.hrthm.2023.09.017

Crossley, G. H., Piccini, J. P., Longacre, et al. (2023). Leadless versus transvenous single-chamber ventricular pacemakers: 3 year follow-up of the Micra CED study. *Journal of cardiovascular electrophysiology*, 34(4), 1015–1023. https://doi.org/10.1111/jce.15863

Duray, G. Z., Ritter, P., El-Chami, et al. (2017). Long-term performance of a transcatheter pacing system: 12-Month results from the Micra Transcatheter Pacing Study. *Heart rhythm*, 14(5), 702–709. https://doi.org/10.1016/j.hrthm.2017.01.035

El-Chami, M. F., Al-Samadi, F., Clementy, et al. (2018). Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control. *Heart rhythm*, 15(12), 1800–1807. https://doi.org/10.1016/j.hrthm.2018.08.005

Ngo, L., Nour, D., Denman, R. A., et al. (2021). Safety and Efficacy of Leadless Pacemakers: A Systematic Review and Meta-Analysis. *Journal of the American Heart Association*, 10(13), e019212. https://doi.org/10.1161/JAHA.120.019212

Piccini, J. P., El-Chami, M., Wherry, K., et al. (2021). Contemporaneous Comparison of Outcomes Among Patients Implanted With a Leadless vs Transvenous Single-Chamber Ventricular Pacemaker. *JAMA cardiology*, 6(10), 1187–1195. https://doi.org/10.1001/jamacardio.2021.2621

Reynolds, D., Duray, G. Z., Omar, R., et al. (2016). A Leadless Intracardiac Transcatheter Pacing System. *The New England journal of medicine*, 374(6), 533–541. https://doi.org/10.1056/NEJMoa1511643

High-risk subpopulations

Boveda, S., Higuera, L., Longacre, C., et al. (2023). Two-year outcomes of leadless vs. transvenous single-chamber ventricular pacemaker in high-risk subgroups. *Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology*, 25(3), 1041–1050. https://doi.org/10.1093/europace/euad016

Supportive evidence

High-risk subpopulations (continued)

El-Chami, M. F., Johansen, J. B., Zaidi, A., et al. (2019). Leadless pacemaker implant in patients with pre-existing infections: Results from the Micra postapproval registry. *Journal of cardiovascular electrophysiology*, 30(4), 569–574. https://doi.org/10.1111/jce.13851

Garg, A., Koneru, J. N., Fagan, D. H., et al. (2020). Morbidity and mortality in patients precluded for transvenous pacemaker implantation: Experience with a leadless pacemaker. *Heart rhythm*, 17(12), 2056–2063. https://doi.org/10.1016/j.hrthm.2020.07.035

Quality of life

Cabanas-Grandío, P., García Campo, E., Bisbal, F., et al. (2020). Quality of life of patients undergoing conventional vs leadless pacemaker implantation: A multicenter observational study. *Journal of cardiovascular electrophysiology*, 31(1), 330–336. https://doi.org/10.1111/jce.14322

Palmisano, P., Guido, A., Panico, V., et al. (2021). Leadless pacemaker versus transvenous single-chamber pacemaker therapy: peri-procedural aspects, utilization of medical resources and patient acceptance. *Expert review of medical devices*, 18(5), 483–491. https://doi.org/10.1080/17434440.2021.1921573

Tjong, F. V. Y., Beurskens, N. E. G., de Groot, et al. (2018). Health-related quality of life impact of a transcatheter pacing system. *Journal of cardiovascular electrophysiology*, 29(12), 1697–1704. https://doi.org/10.1111/jce.13726

Procedural safety

Piccini, J. P., Cunnane, R., Steffel, J., et al. (2022). Development and validation of a risk score for predicting pericardial effusion in patients undergoing leadless pacemaker implantation: experience with the Micra transcatheter pacemaker. *Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology*, 24(7), 1119–1126. https://doi.org/10.1093/europace/euab315

Supportive evidence

AV synchrony

Chinitz, L. A., El-Chami, M. F., Sagi, V., et al. (2023). Ambulatory atrioventricular synchronous pacing over time using a leadless ventricular pacemaker: Primary results from the AccelAV study. *Heart rhythm*, 20(1), 46–54. https://doi.org/10.1016/j.hrthm.2022.08.033

Guidelines

Glikson, M., Nielsen, J. C., Kronborg, M. B., et al. (2021). 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. *European heart journal*, 42(35), 3427–3520. https://doi.org/10.1093/eurheartj/ehab364

Roberts, P. R., ElRefai, M., Foley, et al. (2022). UK Expert Consensus Statement for the Optimal Use and Clinical Utility of Leadless Pacing Systems on Behalf of the British Heart Rhythm Society. *Arrhythmia & electrophysiology review*, 11, e19. https://doi.org/10.15420/aer.2022.17

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Indications

Micra Model MC1VR01, Micra VR2 Model MC2VR01, 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.

Micra AV2 Model MC2AVR1 is indicated for VDD pacing in patients when a dual chamber transvenous pacing system is considered a poor option or not deemed necessary for effective therapy, and when a right ventricular transcatheter pacing system promoting AV synchrony at rest is acceptable. Conditions when a patient is considered a poor candidate for transvenous pacing may include, but are not limited to, tortuous anatomy, a need to preserve venous access, or increased risk of infection. The device provides AV synchrony at rest and rate responsive (VVIR) pacing during periods of high patient activity.

Device-mediated AV synchrony can vary depending on patient condition and activity levels, and it can be limited at high sinus rates. During periods of intermittent AV synchrony, the device will provide ventricular pacing support with an increased potential for pacing rate variability. Micra AV2 is indicated for use in patients who have experienced one of the following:

- Paroxysmal or permanent high-grade AV block in the absence of AF
- Paroxysmal or permanent high-grade AV block in the presence of paroxysmal AF
- Paroxysmal or permanent high-grade AV block in the presence of persistent AF when attempts at restoring sinus rhythm are still planned
- The device is designed to be used only in the right ventricle.

Contraindications

Micra Model MC1VR01, Micra AV Model MC1AVR1, Micra VR2 Model MC2VR01 and Micra AV2 Model MC2AVR1 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. 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 explanation of the Micra device, which should be turned off.

For Micra AV Model MC1AVR1 and Micra AV2 Model MC2AVR1, 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 Adverse Events

Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, pacemaker syndrome, cardiac arrest, 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 Medtronic's website at www.medtronic.com.

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

Contact

For additional information, contact the Medtronic Reimbursement Customer Support team.
Operating hours: M-F, 8 a.m. to 5 p.m. CT

By email at rs.healthcareeconomics@medtronic.com.

By phone at 866-877-4102

Or visit our reimbursement website at
www.Medtronic.com/crhfreimbursement

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