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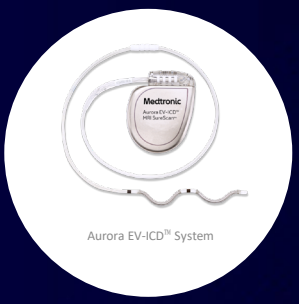

Aurora EV-ICD™ System

Prior authorization resources

Aurora EV-ICD™ System

December 2023

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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

Aurora EV-ICD™ System

Overview

This document outlines resources available to support your efforts in obtaining prior authorization for the Aurora EV-ICD™ system. 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 — Aurora EV-ICD FDA approval letter

Click here — Aurora EV-ICD product brochure

Click here — Reimbursement guide

Click here — Product summary overview

Click here — Medicare Advantage: coverage requirement information*

*Note: While the link provides a complete overview of Medicare Advantage coverage requirements for managing organizations, part (a) and (b)(1) outline the need for compliance with CMS coverage determinations

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

Aurora EV-ICD™ System

Overview

This document is a sample pre-service appeal letter to assist providers in obtaining a prior authorization for an extravascular implantable cardioverter defibrillator (EV ICD) 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 *red 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

Click here To open the sample prior authorization letter in Microsoft Word

Provider Letterhead – Please include organization name and address

Date
Payer Name
Attn: Utilization Management/Prior Authorization Department

RE: Prior authorization for extravascular implantable cardioverter defibrillator system implant

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 an extravascular implantable cardioverter defibrillator, which has been deemed medically necessary to *[insert statement of medical necessity]*.

The *Aurora EV-ICD™ system* is an FDA-approved, implantable cardioverter implantable defibrillator and is indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias through the delivery of antitachycardia pacing, cardioversion, and defibrillation therapies. Medical conditions that may indicate a patient for an EV-ICD for primary or secondary prevention of sudden cardiac death due to life-threatening ventricular tachyarrhythmias include previous ventricular tachyarrhythmias, coronary disease with left ventricular dysfunction, cardiomyopathy, inherited primary arrhythmia syndromes, and congenital heart.

Explain the clinical rationale leading to the decision to recommend an extravascular implantable cardioverter defibrillator. You may require one or more paragraphs to address the following:

- *Patient's relevant medical history*
    - *Diagnosis, date of diagnosis, and any diagnostic tests*
    - *Current clinical presentation: symptoms, severity, impact on quality of life and activities of daily living, etc.*
    - *Any significant risk factors, comorbidities, or other relevant history (e.g., hospitalizations, compliance with other therapies or treatments)*
- *Outcomes and limitations of previous treatments (e.g., surgeries, interventions)*
- *If the patient is a Medicare Advantage (MA) beneficiary, and a Medicare National Coverage Determination (NCD) applies, reminder that MA plans are required to follow Medicare NCDs. Consider including a link to the Medicare NCD for ICDs (found in our EV-ICD Reimbursement Guide) and link to the requirement of MA plans to honor these. Please see Product Links & Support Information in this guide*

In closing, I have determined that an extravascular implantable cardioverter defibrillator 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 device 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

Aurora EV-ICD™ System

Overview

This document includes recommendations on how to write a pre-service appeal letter to assist providers in appealing a prior authorization denial for the Aurora EV-ICD™ system 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.

Click here

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

Provider Letterhead – Please include organization name and address

Date
Payer Name
Attn: Utilization Management/Prior Authorization Department

RE: Appeal for extravascular implantable cardioverter defibrillator – *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 extravascular implantable cardioverter defibrillator, 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.

The *Aurora EV-ICD™ system* is an FDA-approved, implantable cardioverter implantable defibrillator and is indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias through the delivery of antitachycardia pacing, cardioversion, and defibrillation therapies. Medical conditions that may indicate a patient for an EV-ICD for primary or secondary prevention of sudden cardiac death due to life-threatening ventricular tachyarrhythmias include previous ventricular tachyarrhythmias, coronary disease with left ventricular dysfunction, cardiomyopathy, inherited primary arrhythmia syndromes, and congenital heart.

Explain the clinical rationale leading to the decision to recommend an extravascular implantable cardioverter defibrillator. 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*
    - *Diagnosis, date of diagnosis, and any diagnostic tests*
    - *Current clinical presentation: symptoms, severity, impact on quality of life and activities of daily living, etc.*
    - *Any significant risk factors, comorbidities, or other relevant history (e.g., hospitalizations, compliance with other therapies or treatments)*
- *Outcomes and limitations of previous treatments (e.g., surgeries, interventions)*
- *Goal/Clinical benefit of extravascular implantable cardioverter defibrillator for this patient*
- *Your experience with extravascular implantable cardioverter defibrillator outcomes*
- *Other key factors supporting your request (e.g., guidelines, medical policy, clinical studies, payers that cover extravascular implantable cardioverter defibrillators)*

In closing, I have determined that an extravascular implantable cardioverter defibrillator 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 device 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)

Aurora EV-ICD™ System

Overview

The Aurora EV-ICD™ system is approved for patients with varying indications. This evidence compendium outlines published evidentiary resources related to the Aurora EV-ICD system. This is not a comprehensive list; additional evidentiary resources may be available to support your needs.

Click here — Guidelines

Click here — Outcomes

Guidelines

2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: Executive Summary
AHA Circulation. 2018 Aug; 138: e210-e271. doi: 10.1161/CIR.0000000000000548
Sana M. Al-Khatib, William G. Stevenson, Michael J. Ackerman, William J. Bryant, David J. Callans, Anne B. Curtis, Barbara J. Deal, Timm Dickfeld, Michael E. Field, Gregg C. Fonarow, Anne M. Gillis, Christopher B. Granger, Stephen C. Hammill, Mark A. Hlatky, José A. Joglar, G. Neal Kay, Daniel D. Matlock, Robert J. Myerburg and Richard L. Page

2012 ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities
Journal of the American College of Cardiology. 2013 Nov; 61(3):e8-e75
doi: 10.1016/j.jacc.2012.11.007
Cynthia M. Tracy MD, FACC, FAHA; Andrew E. Epstein, MD, FACC, FAHA, FHRS, John P. DiMarco, MD, PHD, FACC, FHRS; Kenneth A. Ellenbogen. MD, FACC, FAHA, FHRS; N.A. Mark Estes III, MD, FACC, FAHA, FHRS; Roger A. Freedman, MD, FACC, FHRS; Leonard S. Gettes, MD, FACC, FAHA; Marc Gillinov, MD, FACC, FAHA; Gabriel Gregoratos, MD, FACC, FAHA; Stephen C. Hammill, MD, FACC, FHRS; David L. Hayes, MD, FACC, FAHA, FHRS; Mark A. Hlatky, MD, FACC, FAHA; L. Kristin Newby, MD, FACC, FAHA; Richard L. Page, MD, FACC, FAHA, FHRS; Mark H. Schoenfeld, MD, FACC, FAHA, FHRS; Michael J. Silka, MD, FACC; Lynne Warner Stevenson, MD, FACC; Michael O. Sweeney, MD, FACC

2013 HRS/ACC/AHA Expert Consensus Statement on the Use of Implantable Cardioverter-Defibrillator Therapy in Patients Who Are Not Included or Not Well Represented in Clinical Trials
Hearth Rhythm Journal. 2014 Jul; 11(7): P1270-1303
doi:10.1016/j.hrthm.2014.03.041
Fred M. Kusumoto, MD, FHRS, Hugh Calkins, MD, FHRS, John Boehmer MD, Alfred E. Buxton MD, Mina K. Chung MD FHRS, Michael R. Gold, MD PhD FHRS, Stefan H. Hohnloser MD FHRS, Julia Indik MD PhD FHRS, Richard Lee MD MBA, Mandeep R. Mehra MD, Venu Menon MD, Richard L. Page MD FHRS, Win-Kuang Shen MD, David J. Slotwiner MD, Lynne Warner Stevenson MD, Paul D. Varosy MD FHRS, Lisa Welikovitch, MD

Outcomes

EV ICD Pivotal Trial: Efficacy and Safety of an Extravascular Implantable Cardioverter–Defibrillator
N Engl J Med 2022;387:1292-302. DOI: 10.1056/NEJMoa2206485
P. Friedman, F. Murgatroyd, L.V.A. Boersma, J. Manlucu, D. O'Donnell, B.P. Knight, N. Clémenty, C. Leclercq, A. Amin, B.P. Merkely, U.M. Birgersdotter-Green, J.Y.S. Chan, M. Biffi, R.E. Knops, G. Engel, I. Muñoz Carvajal, L.M. Epstein, V. Sagi, J.B. Johansen, M. Sterliński, C. Steinwender, T. Hounshell, R. Abben, A.E. Thompson, C. Wiggenhorn, S. Willey, I. Crozier

The clinical and economic impact of extended battery longevity of a substernal extravascular implantable cardioverter defibrillator
Journal of Cardiovascular Electrophysiology. 2023; 1045-3873. doi:10.1111/jce.16150
Bradley P. Knight MD, Nicolas Clémenty MD, PhD, Anish Amin MD, Ulrika M. Birgersdotter-Green MD, Henri Roukoz MD, Reece Holbrook MBA, Jaimie Manlucu MD

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Indications

Device: The Aurora EV-ICD™ MRI SureScan™ Model DVEA3E4 device is indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias through the delivery of antitachycardia pacing, cardioversion, and defibrillation therapies. Medical conditions that may indicate a patient for an EV-ICD for primary or secondary prevention of sudden cardiac death due to life-threatening ventricular tachyarrhythmias include: previous ventricular tachyarrhythmias, coronary disease with left ventricular dysfunction, cardiomyopathy, inherited primary arrhythmia syndromes, and congenital heart disease.

Note: For patient-specific recommendations regarding indications for primary and secondary prevention of sudden cardiac death, refer to current clinical guidelines from the European Society of Cardiology (ESC), American Heart Association (AHA), American College of Cardiology (ACC), and Heart Rhythm Society (HRS).

Lead: The Epsila EV™ MRI SureScan™ Model EV2401 extravascular lead is indicated for use in the anterior mediastinum for pacing therapies, cardioversion, and defibrillation when an extravascular implantable cardioverter defibrillator is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias.

Tunneling Tools: The Epsila EV™ Model EAZ101 sternal tunneling tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

The Epsila EV™ Model EAZ201 transverse tunneling tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

MR Conditions for Use

The Aurora EV-ICD MRI SureScan system is MR Conditional and, as such, is designed to allow patients to be safely scanned by an MRI machine when used according to the specified MR conditions for use. A complete SureScan system is required for use in the MR environment. Before performing an MR scan, refer to the MRI technical manual for MRI-specific warnings and precautions. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned. A complete SureScan system includes a SureScan extravascular ICD device (Model DVEA3E4) with a SureScan extravascular lead (Model EV2401). To verify that components are part of a SureScan system, visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan.

Contraindications

The Aurora EV-ICD MRI SureScan Model DVEA3E4 device is contraindicated for use in the following situations:
If implanted with a unipolar pacemaker, a device delivering dual-chamber or triple-chamber pacing, and/or a device delivering antitachyarrhythmia therapies
If incessant ventricular tachycardia (VT) or ventricular fibrillation (VF) exists
If the patient's primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF
If symptomatic bradycardia exists
If tachyarrhythmias with transient or reversible causes exist
The Epsila EV MRI SureScan Model EV2401 lead is contraindicated for any application that is not specified in the Indications.
The Epsila EV Model EAZ101 sternal tunneling tool is contraindicated for use in patients with a prior sternotomy.
The Epsila EV Model EAZ201 transverse tunneling tool is contraindicated for any application that is not specified in the Indications.

Warnings and Precautions

Device and Lead: It is important to read the Aurora EV-ICD MRI Technical Manual before conducting an MRI scan on a patient with an implanted SureScan system. The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine. When programmed to On, MRI SureScan operation disables arrhythmia detection and all user-defined diagnostics. Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode On may result in patient harm or damage to the SureScan system.

Patients and their implanted systems must be screened to meet the following requirements for MRI: no implanted lead extenders, lead adaptors or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; and the Sure Scan device must be operating within the projected service life; the device does not provide pacing therapy when SureScan mode is programmed On. Do not scan pacemaker-dependent patients. MRI scans during the lead maturation period have not been prospectively studied by Medtronic and are not recommended. If scanning a patient with multiple devices, ensure all devices meet the MRI labeling conditions.

Use only the Epsila EV MRI SureScan Model EV2401 extravascular lead with a Medtronic EV4 implantable cardioverter defibrillator system. The known potential adverse consequences of using any other combination may include undersensing of cardiac activity, failure to deliver necessary therapy, or an intermittent electrical connection. All can present serious risks for adverse events to the patient. The EV4 connector is a Medtronic proprietary design, not an industry standard. No claims of safety and efficacy can be made with regard to devices that are not labeled as EV4 by Medtronic.

Pre-implant consideration for concomitant implant with a neurostimulator and cardiac device implants: Some patients have medical conditions that require the implant of both a neurostimulator and a cardiac device (for example, a pacemaker, a defibrillator, or a monitor). In this case, physicians involved with either device should contact Medtronic Technical Services or their Medtronic representative before implanting the patient with the second device. Based on the particular devices that the physicians have prescribed, Medtronic can provide the necessary precautions and warnings related to the implant procedure.

Use of the DVEA3E4 device has not been evaluated in patients who have undergone a prior sternotomy.
The DVEA3E4 device has not been tested specifically for pediatric use.
Use of the EV2401 lead has not been evaluated in patients who have undergone a prior sternotomy.
Performing a sternotomy on a patient with an implanted lead has not been evaluated.
Do not implant the EV2401 lead using any tools other than the Medtronic tunneling tools designed for implanting the extravascular ICD system.
Tunneling Tools: The tunneling tools have not been tested for use with non-Medtronic products or for pediatric use.
Use of the EAZ201 transverse tunneling tool have not been evaluated in patients who have undergone a prior sternotomy

Potential Adverse Events

Implant and usage of this system may result in adverse events, which may lead to injury, death, or other serious adverse reactions. Potential adverse events include, but are not limited to acute tissue trauma, allergic reaction, bradyarrhythmia, cardiac arrest, cardiac inflammation, cardiac perforation, cardiac tamponade, death, device migration, discomfort, dizziness, dyspnea, erosion, extracardiac stimulation, fever, hematoma, hemorrhage, hemothorax, hiccups, hospitalization, inappropriate shock, infection, insulation failure, lead abrasion, lead fracture, lead migration or dislodgement, lethargy, mental anguish, organ damage (liver, mammary arteries, diaphragmatic arteries), pain, palpitations, pericardial effusion, pericarditis, pneumothorax, return of cardiac symptoms, seroma, syncope, tachyarrhythmia, toxic reaction, and wound dehiscence.

Potential MRI adverse events include the following: lead electrode heating resulting in tissue damage near the lead electrodes or patient discomfort or both; spontaneous tachyarrhythmia occurring during the scan that is not detected and treated because tachyarrhythmia detection is suspended while MRI SureScan mode is programmed to On; device heating resulting in tissue damage in the implant pocket or patient discomfort or both; MR-induced muscle stimulation resulting in patient discomfort; damage to the device or lead causing the system to fail to detect or treat irregular heartbeats or causing the system to treat the patient's condition incorrectly; damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer; and movement or vibration of the device or leads resulting in dislodgment.

See the Aurora EV-ICD MRI SureScan technical manual before performing an MRI Scan, and the device, lead and tunneling tools manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. Refer to the Medtronic Manual Library website www.medtronic.com/manuals. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com or www.mrisurescan.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:

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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