Medtronic

Engineering the extraordinary

Prior authorization resources

LINQ Family of ICMs

October 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.

Medtronic

Product links & supporting documentation

LINQ™ family of insertable cardiac monitors

Overview

This document outlines resources available to support your efforts in obtaining prior authorization for subcutaneous cardiac rhythm monitors. 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 — Reveal LINQ™ ICM FDA clearance letter

Click here — Reveal LINQ™ ICM product brochure

Click here — LINQ II™ ICM FDA clearance letter

Click here — LINQ II™ ICM product brochure

Click here — Product summary overview

Click here — Reimbursement guide

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.

Medtronic

Sample prior authorization letter

LINQ™ family of insertable cardiac monitors

Overview

This document provides a sample pre-service appeal letter to assist providers in obtaining a prior authorization for a subcutaneous cardiac rhythm monitor 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

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 subcutaneous cardiac rhythm monitor

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 subcutaneous cardiac rhythm monitor, which has been deemed medically necessary to *[insert statement of medical necessity]*.

The *Reveal LINQ™/LINQ II™* ICM is an implantable patient-activated and automatically activated monitoring system that records subcutaneous ECG and is indicated for patients with clinical syndromes or situations at increased risk of cardiac arrhythmias or patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain, which may suggest a cardiac arrhythmia. *LINQ II™ insertable cardiac monitor (ICM) is indicated in adult patients and is the only subcutaneous cardiac rhythm monitor indicated for pediatric patients who are at least 2 years old [do not include this disclaimer when Reveal LINQ™ ICM is used.].*

Explain the clinical rationale leading to the decision to recommend a subcutaneous cardiac rhythm monitor. 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)*
- *Reasons for procedure including why short-term monitoring did not work or would not be successful*
- *If the patient is a Medicare beneficiary, reminder that Medicare Advantage is required to follow Medicare NCDs*

In closing, I have determined that a subcutaneous cardiac rhythm monitor 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)*

Medtronic

Pre-service appeal letter

LINQ™ family of insertable cardiac monitors

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 subcutaneous cardiac rhythm monitor 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

Date
Payer Name
Attn: Utilization Management/Prior Authorization Department

RE: Appeal for subcutaneous cardiac rhythm monitor – *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 subcutaneous cardiac rhythm monitor, 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 *Reveal LINQ™/LINQ II™* ICM is an implantable patient-activated and automatically activated monitoring system that records subcutaneous ECG and is indicated for patients with clinical syndromes or situations at increased risk of cardiac arrhythmias or patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain, which may suggest a cardiac arrhythmia. *LINQ II™ insertable cardiac monitor (ICM) is indicated in adult patients and is the only subcutaneous cardiac rhythm monitor indicated for pediatric patients who are at least 2 years old [do not include this disclaimer when Reveal LINQ™ ICM is used.].*

Explain the clinical rationale leading to the decision to recommend a subcutaneous cardiac rhythm monitor. 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)*
- *Reasons for procedure including why short-term monitoring did not work or would not be successful*
- *Goal/Clinical benefit of subcutaneous cardiac rhythm monitor for this patient*
- *Your experience with subcutaneous cardiac rhythm monitor outcomes*
- *Other key factors supporting your request (e.g., guidelines, medical policy, clinical studies, payers that cover subcutaneous cardiac rhythm monitors)*

In closing, I have determined that a subcutaneous cardiac rhythm monitor 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)*

Medtronic

Supportive evidence (bibliography)

LINQ™ family of insertable cardiac monitors

Overview

The LINQ™ family of insertable cardiac monitors (ICM) are approved for patients with varying indications. This evidence compendium outlines published evidentiary resources related to subcutaneous cardiac rhythm monitors. This is not a comprehensive list; additional evidentiary resources may be available to support your needs.

Stroke resources

Click here Guidelines	Click here Outcomes	Click here Stroke care pathways
Click here AF detection & treatment	Click here Patient considerations	Click here Economic

Syncope resources

Click here Guidelines	Click here Etiology and outcomes	Click here Cost savings
Click here Pathways benefits	Click here Superior diagnostic yield	Click here Economic

Atrial fibrillation resources

Click here Guidelines	Click here AF burden	Click here ICM as the 'gold standard
Click here Asymptomatic AF post ablation	Click here OAC management	Click here Economic

Guidelines

Neurology guidelines

2021 Guideline for the prevention of stroke in patients with stroke and transient ischemic attack: A guideline from the American Heart Association/American Stroke Association
Stroke. 2021; 52(7):e364-e467. doi: 10.1161/STR.0000000000000375
Kleindorfer DO, Towfighi A, Chaturvedi S, Cockroft KM, Gutierrez J, Lombardi-Hill D, Kamel H, Kernan WN, Klittner SJ, Ceira EC, Lennon O, Meschia JF, Nguyen TN, Pollak PM, Santangeli P, Sharrief AZ, Smith Jr. SC, Turan TN, Williams LS

European Stoke Organization (ESO) guideline on screening for subclinical atrial fibrillation after stroke or transient ischaemic attack of undetermined origin
European Stroke Journal. 2022; 7(3). doi: 10.1177/23969873221099478
Rubiera M, Aires A, Antonenko K, Lemeret S, Nolte CH, Putaala J, Schnabel RB, Tuladhar AM, Werring DJ, Zeraatkar D, Paciaroni M

Cardiology Guidelines

2019 AHA/ACC/RHS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines and the Heart Rhythm Society in collaboration with the Society of Thoracic Surgeons
AHA Circulation. 2019 Jan; 140: e125-e151. doi: 10.1161/CIR.0000000000000665
January CT, Wann S, Calkins H, Chen LY, Cigarrao JE, Cleveland Jr. JC, Ellinor PT, Ezekowitz MD, Field ME, Furie KL, Heidenreich Pa, Murray KT, Shea JB, Tracy CM, Yancy CW

2020 ESC guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): The task force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC
European Stroke Journal. 2021 Feb; 42(5):373-498. doi: 10.1093/eurheartj/ehaa612
Hindricks G, Potpara T, Dagres N, Arbelo E, Bax JJ, Blomstrom-Lundqvist C, Boriani G, Castella M, Dan G-A, Dilaveris PE, Fauchier L, Filippatos G, Kalman JM, La Meir M, Lane DA, Lebeau J-P, LEttino M, Lip GYH, Pinto FJ, Thomas GN, Valgimigli M, Van Gelder IC, Van Putte BP, Watkins CL, ESC Scientific Document Group

AF detection and treatment

Cryptogenic stroke and underlying atrial fibrillation
New England Journal of Medicine. 2014; 370:2478-2486. doi:10.1056/nejmoa1313600.
Sanna T, Diener HC, Passman RS, Di Lazzaro V, Bernstein RA, Morillo CA, Mollman Rymer M, Thijs V, Rogers T, Beckers F, Lindborg K, Brachmann J, for the CRYSTAL-AF Investigators

Long-term detection of atrial fibrillation with insertable cardiac monitors in a real-world cryptogenic stroke population
International Journal of Cardiology. 2017; 244: 175-179. doi:10.1016/j.ijcard.2017.06.039
Ziegler PD, Rogers JD, Ferreira SW, Nichols AJ, Richards M, Koehler JL, Sarkar S

Rivaroxaban for stroke prevention after embolic stroke of undetermined source
New England Journal of Medicine. 2018; 378:2191-2201. doi: 10.1056/NEJMoa1802686
Hart RG, Sharma M, Mundl H, Kasner SE, Bangdiwala SI, Berkowitz SD, Swaminathan B, Lavados P, Wang Y, Wang, Y, Davalos A, Shamalov N, et al.

Dabigatran for prevention of stroke after embolic stroke of undetermined source
New England Journal of Medicine. 2019; 380:1906-1917. doi: 10.1056/NEJMoa1813959
Diener HC, Sacco RL, Easton D, Granger CB, Bernstein RA, Uchiyama S, Kreuzer J, Cronin L, Cotton D, Grauer C, Brueckmann M, Chernyatina M, for the RE-SPECT ESUS Steering Committee and Investigators

Effect of long-term continuous cardiac monitoring vs usual care on detection of atrial fibrillation in patients with stroke attributed to large- or small-vessel disease: the STROKE AF randomized clinical trial
JAMA. 2021; 325(21):2169-2177. doi:10.1001/jama.2021.6470
Bernstein RA, Kamel H, Granger CB, Piccini JP, Sethi PP, Katz JM, Alfaro Vives C, Ziegler PD, Franco NC, Schwamm LH, for the STROKE-AF investigators

Effect of implantable vs prolonged external electrocardiographic monitoring on atrial fibrillation detection in patients with ischemic stroke. The PER DIEM randomized clinical trial
JAMA. 2021;325(21):2160-2168. doi:10.1001/jama.2021.6128
Buck BH, Hill MD, Quinn R, butcher KS, Menon BK, Gulamhusein S, Siddiqui M, Coutts SB, Jeerakathil T, Smith EE, Khan K, Barber PA, Jickling G, Reyes L, Save S, Fairall P, Piquette L, Kamal N, Chew DS, Demchuk AM, Shuaib A, Exner DV

Outcomes

Prolonged cardiac rhythm monitoring and secondary stroke prevention in patients with cryptogenic cerebral ischemia
Stroke. 2019;50(8):2175-2180. Doi:10.1161/STROKEAHA.119.025169
Tsivgoulis G, Katsanos AH, Mac Grory B, Köhrmann M, Ricci BA, Tsioufis K, Cutting S, Krogias C, Schellinger PD, Rodriguez Campello A, Cuadrado-Godia E, Gladstone DJ, Sanna T, Wachter R, Furie K, Alexandrov AV, Yaghi S

Longitudinal outcomes in cryptogenic stroke patients with and without long-term cardiac monitoring for atrial fibrillation
Heart Rhythm 02. 2022;3(3):223-230. doi: 10.1016/j.hroo.2022.02.006
Yaghi S, Ryan MP, Gunnarsson CL, Irish W, Rosemas SC, Neisen K, Ziegler PD, Reynolds MR.

Patient considerations

Pilot randomized trial of outpatient cardiac monitoring after cryptogenic stroke
Stroke. 2012;44(2):528-530. Doi:10.1161/STROKEAHA.112.679100
Kamel H, Navi BB, Elijovich L, Josephson SA, Yee AH, Fung G, Claiborne Johnston S, Smith WS

Stroke care pathways

Atrial fibrillation incidence in the first month after a cryptogenic stroke as detected with an implantable cardiac monitor
AHA Circulation. 2018;138(1):A13051.
Milstein NS, Allred J, Seiler Am Pimienta J, Bhatt A, Preminger M, Sichrovsky T, Shaw RE, Mittal S, Musat D

Cardiovascular care of patients with stroke and high risk of stroke: The need for interdisciplinary action: A consensus report from the European Society of Cardiology Cardiovascular round table
European Journal of Preventive Cardiology. 2020; 27(7):682-692.
doi: 10.1177/2047487319873460
Doehner W, Mazighi M, Hofmann BM, Lautsch D, Hindricks G, Bohula EA, Byrne RA, Camm AJ, Casadei B, Caso V, Cognard C, Diener HC, Ednres M, Goldstein P, Halliday A, Hopewell JC, Jovanovic DR, Kobayashi A, Kostrubiec M, Krajina A, Landmesser U, Markus HS, Ntaios G, Pezzela FR, Ribo M, Rosano GMC, Rubiera M, Sharma M, Touyz RM, Widimsky P

Economic

A cost comparison of atrial fibrillation monitoring strategies after embolic stroke of undetermined source
American Heart Journal Plus: Cardiology Research and Practice. 2022;21:100195.
Chalfoun N, Pierobon J, Rosemas SC, Fox J, Albano A, Banno J, Brunner M, Corner K, Dahu M, Dandamudi S, Davis AT, Elmouchi D, Jawad W, Khan M, Min J, Rai V, Rosema S, Sagorski R, Gauri A

Cost-effectiveness of an insertable cardiac monitor to detect atrial fibrillation in patients with cryptogenic stroke
Journal of Comparative Effectiveness Research. 2021; 10(2):127-141.
doi: 10.2217/cer-2020-0224
Sawyer LM, Witte KK, Reynolds MR, Mittal S, Grimsey Jones FW, Rosemas SC, Ziegler PD, Kaplon RE, Yaghi S

Burden of oral anticoagulation in embolic stroke of undetermined source without atrial fibrillation
BMC Cardiovascular Disorders. 2021; 21(1):160. doi: 10.1186/s12872-021-01967-x
Witte KK, Tsivgoulis G, Reynolds MR, Tsintzos SI, Eggington SI, Ismyrloglou E, Huynh M, Egea M, de Brouwer B, Ziegler PD, Franco N, Joglekar R, Rosemas SC, et al

Atrial fibrillation diagnosis timing, ambulatory ECG monitoring utilization, and risk of recurrent stroke
AHA Circulation: Cardiovascular Quality and Outcomes. 2017; 10(1):e002864.
doi: 10.1161/CIRCOUTCOMES.116.002864
Lip GY, Hunter TD, Quiroz ME, Ziegler PD, Turakhia MP

Cost-effectiveness of an insertable cardiac monitor to detect atrial fibrillation in patients with cryptogenic stroke
International Journal of Stroke. 2016;11(3):302-312. doi: 10.1177/1747493015620803
Diamantopoulos A, Sawyer LM, Lip GYH, Witte KK, Reynolds MR, Fauchier L, Thijs V, Brown B, Quiroz Angulo ME, Diener HC

Individual and combined risk factors for incident atrial fibrillation and incident stroke: an analysis of 3 million at-risk US patients
Journal of the American Heart Association. 2015;4:e001723 doi: 10.1161/JAHA.114.001723
Chyou JY, Hunter TD, Mollenkopf SA, Turakhia MP, Reynolds MR

Economic (continued)

Use of insertable cardiac monitors for the detection of atrial fibrillation in patients with cryptogenic stroke in the United States is cost-effective
Journal of Medical Economics. 2019; 22(11):1221-1234.
doi: 10.1080/13696998.2019.1663355
Maervoet J, Bossers N, Borge Jr. RP, Thompson Hilpert S, van Engen A, Smala A

Implantable cardiac monitors to detect atrial fibrillation after cryptogenic stroke – diagnostic guidance
National Institute for Health and Care Excellence (NICE). 2020. MIB141.
https://www.nice.org.uk/guidance/dg41

Economic evaluation of extended electrocardiogram monitoring for atrial fibrillation in patients with cryptogenic stroke
Sage Journals. 2020; 16(7). doi: 10.1177/1747493020974561
Chew DS, Rennert-May E, Russell Quin, F, Buck B, Hill MD, Spackman E, Manns BJ, Exner DV

Implantable cardiac monitors to detect atrial fibrillation after cryptogenic stroke: a systematic review and economic evaluation
Health Technology Assessment. 2020; 24(5):1-184. doi: 10.3110/hta24050
Edwards SJ, Wakefield V, Jhita T, Kew K, Cain P, Marceniuk G

Cost-effectiveness of insertable cardiac monitors for diagnosis of atrial fibrillation in cryptogenic stroke in Australia
Journal of Arrhythmia. 2021; 37(4):1077-1085. doi: 10.1002/joa3.12586
Thijs V, Witte KK, Guarnieri C, Makino K, MCom, Tilden D, Gillespie J, Huynh M

Guidelines

ESC guidelines for the diagnosis and management of syncope
European Heart Journal. 2018 Jun;39(21):1883-1948. doi: 10.1093.eurheartj/ehy037
Brignole M, Moya A, de Lange FJ, et. al.

2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: A report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines, and the Heart Rhythm Society
Journal of the American College of Cardiology. 2017 Aug;70(5):e39-e110.
doi: 10.1016/j.jacc.2017.03.003
Shen WK, Sheldon RS, Benditt DG, et. al.

Pathways benefit

The benefit of a remotely monitored implantable loop recorder as a first line investigation in unexplained syncope: The EaSyAS II trial
EP Europace. 2016 Jun;18(6):912-8. doi: 10.1093/europace/euv228
Sulke N, Sugihara C, Hong P, Patel N, Freemantle N

Etiology and outcomes

The diagnostic yield of implantable loop recorders in unexplained syncope: A systematic review and meta-analysis
International Journal of Cardiology. 2017 Mar 15; 231:170-176. doi: 10.1016/j.ijard.2016.12.128
Solbaiti M, Casazza G, Diapaola F, Barbic F, Caldato M, Montano N, Furlan R, Sheldon RS, Costantino G

The clinical impact of implantable loop recorders in patients with syncope
European Heart Journal. 2006 Feb; 27(3):351-6. doi: 10.1093/eurheartj/ehi602
Farwell DJ, Freemandle N, Sulke N

Effectiveness and safety of implantable loop recorder and clinical utility of remote monitoring in patients with unexplained, recurrent, traumatic syncope
Expert Review of Medical Devices. 2023 Jan;20(1):45-54. doi: 10.1080/17434440.2023.2168189
Palmisano P, Guerra F, Aspromonte V, Dell'Era G, Pellegrino PL, Laffi M, Uran C, De Bonis S, Accogli M, Dello Russo A, Patti G, Santoro F, Torriglia A, Nigro G, Bisignani A, Coluccia G, Stronati G, Russo V, Ammendola E

Superior diagnostic yield

Clinical impact of the implantable loop recorder in patients with isolated syncope, bundle branch block and negative workup: A randomized multicentre prospective study
Archives of Cardiovascular Diseases. 2013 Mar;106(3):146.54. doi: 10.1016/j.acvd.2012.12.002
Da Costa A, Defaye P, Romeyer-Bouchard C, Roche F, Dauphinot V, Deharo JC, Jacon P, Lamaison D, Bathélemy JC, Isaaz K, Lauren G

Early use of an implantable loop recorder in syncope evaluation: A randomized study in the context of the French healthcare system (FRESH study)
Archives of Cardiovascular Diseases. 2014 Oct;107(10):546-52. doi: 10.1016/j.acvd.2014.05.009
Podoleanu C, DaCosta A, Defaye P, Taieb J, Galley D, Bru P, Maury P, Mabo P, Boveda S, Cellarier G, Anselme F, Kouakam C, Delarche N, Deharo JC, FRESH investigators

Cost-savings

Randomized assessment of syncope trial: Conventional diagnostic testing versus a prolonged monitoring strategy
AHA Circulation. 2001 Jul 3; 104(1):46-51. doi 10.1161/01.cir.104.1.46
Krahn AD, Klein GJ, Yee R, Skanes AC

Economic value of insertable cardiac monitors in unexplained syncope in the United States
Open Heart. 2021;8(1): e001263. doi: 10.1136/openhrt-2020-001263
Sutton BS, Bermingham SL, Diamantopoulos A, Rosemas SC, Tsintzos SI, Xia Y, Reynolds MR

Financial impact of adopting implantable loop recorder diagnostic for unexplained syncope compared with conventional diagnostic pathways in Portugal
BMC Cardiovascular Disorders. 2014;14(63). doi: 10.1186/1471-2261-14-63
Providencia R, Morais C, Reis H, Elvas L, Sanfins V, Farinha S, Eggington S, Tsintzos S.

Use of implantable loop recorders in the diagnosis and management of syncope
European Heart Journal. 2004;25(14): 1257-1263. doi: 10.1016/j.ehj.2004.03.010
Farwell DJ, Freemantle N, Sulke AN

Economic (continued)

Costs of unstructured investigation of unexplained syncope: insights from a micro-costing analysis of the observational PICTURE registry
EP Europace. 2015 July;17(7):1141-1148. doi: 10.1093/europace/euu412
Edvardsson N, Wolff C, Tsintzos S, Rieger G, Linker NJ

Syncope recurrence and downstream diagnostic testing after insertable cardiac monitor placement for syncope
Diagnostics (Basel). 2022;12(8):1977. doi: 10.3390/diagnostics12081977
Frazier-Mills CG, Johnson LC, Xia Y, Rosemas SC, Franco NC, Pokorney SD

Diagnostic sensitivity and cost per diagnosis of ambulatory cardiac monitoring strategies in unexplained syncope patients
PLoS One. 2022;17(6): e0270398. doi: 10.1371/journal.pone.0270398
Rogers JD, Higuera L, Rosemas SC, Cheng YJ, Ziegler PD

Atrial fibrillation

Guidelines

2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines and the Heart Rhythm Society in collaboration with the Society of Thoracic Surgeons
AHA Journal. 2019; 140(2):e125-e151. doi: 10.1161/CIR.0000000000000665
January CT, Wann S, Calkins H, Chen LY, Cigarrao JE, Cleveland Jr. JC, Ellinor PT, Ezekowitz MD, Field ME, Furie KL, Heidenreich PA, Murray KT, Shea JB, Tracy CM, Yancy CW

2020 ESC guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC
European Heart Journal. 2020; 42(5): 373-498. doi: 10.1063/eurheartj/ehaa612
Hindricks G, Potpara T, Dagres N, Arbelo E, Bax JJ, Blomström-Lundqvist C, Boriani G, Castella M, Dan GA, Dilaveris PE, Fauchier L, Filippatos G, Kalman JM, La Meir M, Lane DA, Lebeau JP, Lettino M, Lip GYH, Pinto FJ, Thomas GN, Valgimigli M, Van Gelder IC, Van Putte BP, Watkins CL, ESC Scientific Document Group

Asymptomatic AF post ablation

Cryoballoon or radiofrequency ablation for atrial fibrillation assessed by continuous monitoring: A randomized clinical trial
AHA Circulation. 2019 Oct 21;140(22):1779-1788. doi: 10.1161/CIRCULATIONAHA.119.042622
Andrade JG, Champagne J, Dubuc M, Deyell MW, Verma A, Macle L, Leong-Sit P, Novak P, Badra-Verdu M, Sapp J, Mangat I, Khoo C, Steinberg C, Bennett MT, Tang ASL, Khairy P, for the CIRCA-DOSE study investigators

Clinical assessment of AF pattern is poorly correlated with AF burden and post ablation outcomes: A CIRCA-DOSE sub-study
Journal of Electrocardiology. 2020 Mar 21; 60:159-164. doi: 10.1016/j.jelectrocard.2020.03.008
Andrade JG, Yao RRJ, Deyell MW, Hawkins NM, Rizhallah J, Jolly U, Khoo C, Raymond JM, McKinney J, Cheung C, Steinberg C, Ha A, Ramanathan K, Luong C, Glover B, Verma A, Macle L, Khairy, CIRCA-DOSE study investigators

Quality of life and health care utilization in the CIRCA-DOSE study
JACC: Clinical Electrophysiology. 2020 Aug;6(8):935-944. doi: 10.1016/j.jacep.2020.04.017
Andrade JG, Macle L, Verma A, Deyell MW, Champagne J, Dubuc M, Leong-Sit P, Novak P, Roux JF, Sapp J, Khoo C, Rizkallah J, Levesque S, Tang ASL, Khairy P, CIRCA-DOSE study investigators

Atrial fibrillation

Atrial fibrillation (AF) burden

Influence of monitoring strategy on assessment of ablation success and post-ablation atrial fibrillation burden assessment: Implications for practice and clinical trial design
AHA Circulation. 2022 Jan;145(1):21-30. doi: 10.1161/CIRCULATIONAHA.121.056109
Aguilar M, Macle L, Deyell MW, Yao R, Hawkins NM, Khairy P, Andrade JG

Cryoballoon or radiofrequency ablation for atrial fibrillation assessed by continuous monitoring: A randomized clinical trial
AHA Circulation. 2019 Oct;140(22):1779-1788. doi: 10.1161/CIRCULATIONAHA.119.042622
Andrade JG, Champagne J, Dubuc M, Deyell MW, Verma A, Macle L, Leong-Sit P, Novak P, Badra-Verdu M, Sapp J, Mangat I, Khoo C, Steinberg C, Bennett MT, S.L. Tang A, Khairy P, for the CIRCA-DOS study investigators

Oral anticoagulation (OAC) management

Continuous rhythm monitoring-guided anticoagulation after atrial fibrillation ablation
Journal of Cardiovascular Electrophysiology. 2021 Feb;32(2):345-353. doi: 10.1111/jce.14864.
Pothineni NVK, Amankwah N, Santangeli P, Schaller RD, Supple GE, Deo R, Nazarian S, Garcia FC, Dixit S, Callans DJ, Marchlinski FE, Frankel DS

Continuous rhythm monitoring-guided anticoagulation after atrial fibrillation ablation
J Cardiovasc Electrophysiol. February 2021;32(2):345-353. doi: 10.1111/jce.14864
Pothineni NVK, Amankwah N, Santangeli P, schaller RD, Supple GE, Deo R, Nazarian S, Garcia FC, Dixit S, Callans DJ, Marchlinski FE, Frankel DS

Anticoagulation after catheter ablation of atrial fibrillation guided by implantable cardiac monitors
PACE; 2015 38:688-693. doi: 10.1111/pace.12625
Zuern CS, Kilias A, Berlitz P, Seizer P, Gramlich M, Müller K, Duckheim M, Gawaz Meinrad, Schreieck J

Targeted anticoagulation for atrial fibrillation guided by continuous rhythm assessment with an insertable cardiac monitor: the rhythm evaluation for anticoagulation with continuous monitoring (REACT.COM) pilot study
PACE 2016; 27:264-70. doi: 10.1111/jce.12864
Passman R, Leong-Sit P, Andrei AC, Huskin A, Tomson TT, Bernstein R, Ellis E, Waks JW, Zimetbaum P

Role of insertable cardiac monitors in anticoagulation therapy in patients with atrial fibrillation at high risk of bleeding
Europace 2016; 18:799-806. doi: 10.1093/europace/euv350
Mascarenhas DAN, Faroow MU, Ziegler PD, Kantharia BK

ICM as the 'gold standard'

Continuous monitoring after atrial fibrillation ablation: The LINQ AF study
EP Europace. 2018 Nov 1; 20(FI_3):f312-f320. doi: 10.1093/europace/euy038.
Wechselberger S, Kronborg M, Huo Y, Piorkowski J, Neudeck S, Päßler S, El-Armouche A, Richter U, Mayer J, Ulbrich S, Pu L, Kirstein B, Gaspar T, Piorkowski C

Economic

Healthcare utilization and clinical outcomes after ablation of atrial fibrillation in patients with and without insertable cardiac monitoring
Heart Rhythm O2. 2022 Jan 7;3(1):79-90. doi:10.1016/j.hroo.2021.12.005
Mansour MC, Gillen EM, Garman A, Rosemas SC, Franco N, Ziegler PD, Pines JM+

Cost-effectiveness of an insertable cardiac monitor in a high-risk population in the UK
Open Heart 2019; 20;6(1):e001037. doi: 10.1136/openhrt-2019-001037
Rinciog CI, Sawyer LM, Diamantopoulos A, Elkind MSV, Reynolds M, Tsintzos SI, Ziegler PD, Quiroz ME, Wolff C, Witte KK

Cost-effectiveness of an insertable cardiac monitor in a high-risk population in the US
BMC Cardiovascular Disorders 2023. 23(45):1-14. doi: 10.1186/s12872-023-03073-6
Elkind MSV, Witte KK, Kasner SE, et al.

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.

Brief Statement for LINQ Family of Insertable Cardiac Monitors (ICMs) Systems and Accessories

Indications

The Reveal LINQ ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia

This device has not been tested specifically for pediatric use.

The LINQ II ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in adult patients, and in pediatric patients who are at least 2 years old, in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia

Contraindications

There are no known contraindications for the insertion of the LINQ Family ICM's or their accessories. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

Warnings and Precautions

Patients with a LINQ Family ICM should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the Medical procedure and EMI Warnings, Precautions and Guidance Manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the LINQ II or Reveal LINQ ICM MRI Technical Manual.

Wireless accessories available for use with a LINQ Family ICM may experience connectivity or performance issues. See product manuals for details and troubleshooting instructions.

Potential Adverse Events

Potential adverse events from the LINQ Family ICM include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

There are no known adverse events associated with the use of any LINQ Family ICM wireless accessories.

See the device manuals for detailed information regarding the implant procedure, indications/intended use, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at (800) 328-2518 (Technical Services), (800) 551-5544 (Patient Services), and/or consult Medtronic's website at www.medtronic.com.

Caution: Federal law (USA) restricts prescription 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

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

UC202313900a EN ©2023
Medtronic. Minneapolis, MN.
All Rights Reserved.
Printed in USA. 10/2023

Medtronic and the Medtronic logo are trademarks of Medtronic.™ Third party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company.

Medtronic