



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 05/26/15
LAST REVIEW DATE: 06/05/18
LAST CRITERIA REVISION DATE: 10/31/17
ARCHIVE DATE:

MOBILE CARDIAC OUTPATIENT TELEMETRY (MCOT)

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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MOBILE CARDIAC OUTPATIENT TELEMETRY (MCOT) (cont.)

Description:

Mobile Cardiac Outpatient Telemetry (MCOT):

An automatic electrocardiogram, arrhythmia detection and alarm system to provide cardiac monitoring and transmit real-time analysis from a low-risk individual's home to a central monitoring facility.

Systems include, *but are not limited to*:

- CardioNet MCOT™
- HEARTLink II™
- LifeStar™ Mobile Cardiac Telemetry
- SEEQ™ Mobile Cardiac Telemetry
- VectraplexECG™ System
- Vital Signs Transmitter (VST™)

Continuous Monitoring Devices With Longer Recording Periods:

Continuous monitors that are similar to traditional Holter monitoring in concept, with the ability to monitor for longer periods of time.

Systems include, *but are not limited to*:

- BodyGuardian® Remote Monitoring System™
- Zio® Patch

Self-Monitoring ECG Device:

The Kardia™ Mobile (AliveCor, Inc.) is a smartphone-enabled, non-continuous ECG event monitor. Two stainless steel electrodes attached to a smartphone are activated by touch. The system also includes a smartphone application. The Kardia Mobile, previously the AliveCor™ Heart Monitor, is available without a prescription.

Criteria:

Mobile Cardiac Outpatient Telemetry (MCOT):

- Mobile cardiac outpatient telemetry (MCOT) for the evaluation of syncope, near syncope or palpitations is considered **medically necessary** with documentation of **ALL** of the following:
 1. Non-diagnostic Holter monitoring fails to establish a definite diagnosis because symptoms occur so infrequently or unpredictably that prolonged testing is necessary
 2. Non-diagnostic Holter monitoring must have been within 60 days prior to consideration of the use of MCOT
 3. A non-life-threatening cardiac arrhythmia is suspected as the cause of the above symptoms
 4. Individual has never demonstrated evidence of sustained ventricular tachycardia or ventricular fibrillation



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MOBILE CARDIAC OUTPATIENT TELEMETRY (MCOT) (cont.)

Criteria: (cont.)

Mobile Cardiac Outpatient Telemetry (MCOT): (cont.)

- MCOT for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Continuous Monitoring Devices With Longer Recording Periods:

- Continuous ambulatory monitors that record and store information for periods longer than 48 hours are considered **medically necessary** as a diagnostic alternative to Holter monitoring or individual-activated or auto-activated external ambulatory event monitors with documentation of **ANY** of the following:
 1. Infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (e.g., palpitations, dizziness, presyncope, or syncope)
 2. Atrial fibrillation treated with catheter ablation and discontinuation of systemic anticoagulation is being considered
 3. History of a cryptogenic stroke with a negative standard work-up for atrial fibrillation including a 24-hour Holter monitor
 4. Evaluation of atrial fibrillation after an ablation procedure when it would change medical management.
- Continuous ambulatory monitors that record and store information for periods longer than 48 hours for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.



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Criteria: (cont.)

Self-Monitoring ECG Device:

- Self-monitoring ECG devices available over the counter, with or without a prescription, are considered **a benefit plan exclusion and not eligible for coverage.**

Devices include, *but are not limited to:*

- AliveCor Kardia Mobile

- Self-monitoring ECG devices available over the counter, with or without a prescription, connection and interpretation of data are considered **experimental or investigational** based upon:

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Devices include, *but are not limited to:*

- AliveCor Kardia Mobile

Resources:

Literature reviewed 06/05/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 2.02.08 BCBS Association Medical Policy Reference Manual. Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry. Re-issue date 05/04/2018, issue date 07/10/1998.
2. Chan NY, Choy CC. Screening for atrial fibrillation in 13 122 Hong Kong citizens with smartphone electrocardiogram. *Heart (British Cardiac Society)*. Jan 01 2017;103(1):24-31.
3. Crawford MH, Bernstein SJ, Deedwania PC, et al. ACC/AHA guidelines for ambulatory electrocardiography: executive summary and recommendations. A report of the American College of Cardiology/American Heart Association task force on practice guidelines (committee to revise the guidelines for ambulatory electrocardiography). *Circulation*. 1999 Aug 24 1999;100(8):886-893.



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Resources: (cont.)

4. Evans GF, Shirk A, Muturi P, Soliman EZ. Feasibility of Using Mobile ECG Recording Technology to Detect Atrial Fibrillation in Low-Resource Settings. *Global heart*. Mar 13 2017.
5. Garabelli P, Stavrakis S, Po S. Smartphone-based arrhythmia monitoring. *Current opinion in cardiology*. Jan 2017;32(1):53-57.
6. Guhl EN, Schlusser CL, Henault LE, et al. Rationale and design of the Atrial Fibrillation health Literacy Information Technology Trial: (AF-LITT). *Contemporary clinical trials*. Nov 2017;62:153-158.
7. Halcox JPJ, Wareham K, Cardew A, et al. Assessment of Remote Heart Rhythm Sampling Using the AliveCor Heart Monitor to Screen for Atrial Fibrillation: The REHEARSE-AF Study. *Circulation*. Aug 28 2017.
8. Hickey KT, Hauser NR, Valente LE, et al. A single-center randomized, controlled trial investigating the efficacy of a mHealth ECG technology intervention to improve the detection of atrial fibrillation: the iHEART study protocol. *BMC cardiovascular disorders*. Jul 16 2016;16:152.
9. Naccarelli GV. Ambulatory electrocardiographic monitoring: has mobile cardiac outpatient telemetry changed the playing field? *J Cardiovasc Electrophysiol*. 2007 Mar 2007;18(3):248-249.
10. Olson JA, Fouts AM, Padanilam BJ, Prystowsky EN. Utility of mobile cardiac outpatient telemetry for the diagnosis of palpitations, presyncope, syncope, and the assessment of therapy efficacy. *J Cardiovasc Electrophysiol*. 2007 May 2007;18(5):473-477.
11. Park SB, Platia EV, Lyons K, Langer AA. Features: Cardiac Surveillance at Home. *EP Lab Digest*. 11/2002;2(6).
12. Treskes RW, Gielen W, Wermer MJ, et al. Mobile phones in cryptogenic stroke patients Bringing single Lead ECGs for Atrial Fibrillation detection (MOBILE-AF): study protocol for a randomised controlled trial. *Trials*. Aug 29 2017;18(1):402.
13. Tsang JP, Mohan S. Benefits of monitoring patients with mobile cardiac telemetry (MCT) compared with the Event or Holter monitors. *Med Devices (Auckl)*. 2013;7:1-5.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

