

## Corporate Medical Policy

### Ambulatory Event Monitors

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<b>Origination:</b>	10/2000
<b>Last CAP Review:</b>	4/2011
<b>Next CAP Review:</b>	4/2012
<b>Last Review:</b>	12/2011

#### Description of Procedure or Service

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Ambulatory Holter electrocardiography (EKG) is a widely used noninvasive test in which EKG is continuously recorded over an extended period of time, typically 24 to 48 hours, to evaluate symptoms suggestive of cardiac arrhythmias, i.e., palpitations, dizziness, or syncope. However, Holter monitoring will be ineffective if a patient experiences infrequent symptoms. Ambulatory event monitors (AEMs) were developed to provide longer periods of monitoring. In this technique, the recording device is either worn continuously and activated only when the patient experiences symptoms, or carried by the patient and applied and activated when symptoms are present. The recorded EKGs are then stored for future analysis or transmitted by telephone to a receiving station, e.g., a doctor's office, hospital, or cardiac monitoring service, where the EKGs can then be analyzed. AEMs can be used for extended periods of time, typically up to a month until the patient experiences symptoms. Since the EKGs are recorded only during symptoms, there is good correlation with any underlying arrhythmia. Conversely, if no EKG abnormality is noted, a noncardiac etiology of the patient's symptoms can be sought.

**Several different types of Ambulatory Event Monitors are available:**

*Noncontinuous devices with memory:* These devices are carried by the patient and applied to the precordial area via nongel electrodes when the symptoms are occurring or, alternatively, a recording device may be worn on the wrist and then activated when symptoms are present. The limitation of these devices is that an arrhythmia of very short duration would be difficult to record. In addition, noncontinuous devices require reasonable dexterity on the part of the patient to apply the device correctly during a symptomatic period. This is a particular limitation if the patient is incapacitated during symptomatic periods.

*Continuous "memory loop" devices:* These sophisticated devices are able to continuously store a single channel of EKG data in a refreshed memory. If the patient activates the device, the EKG is then recorded from the memory loop for the preceding 30 to 90 seconds, and for the next minute or so. Therefore, these types of devices permit recording of the onset of arrhythmias and/or transient or incapacitating events. They obviously must be worn continuously. The Zio™ Event Card is a new ambulatory event monitor that can be worn up to 30 days.

*Implantable continuous "memory loop" devices:* An implantable loop recorder device is inserted just under the patient's skin in the chest area during an outpatient surgical procedure. When symptoms are felt, the patient places a hand-held activator over the recorder to activate the storage of cardiac rhythms. This device can be used for more than one year. The Reveal® Insertable Loop Recorder is an implantable memory loop device recently approved by the U.S. Food and Drug Administration (FDA).

*Auto-triggered devices:* All of the previously described devices require activation by the patient. More recently, auto-triggering technology has become available, which can be adapted to memory loop devices. For example, event monitors can be programmed to detect heart rates greater than 165 beats per minute, less than 40 beats per minute, or an asystole of greater than 3 seconds.

*Continuous devices with memory:* The Zio™ Patch is a new long term cardiac rhythm monitor that provides continuous monitoring for up-to-14 days. This device does not require patient activation and

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therefore is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, dizziness, light-headedness, pre-syncope and syncope, shortness of breath, anxiety and fatigue. The Zio™ ECG Utilization Service (ZEUS) system is a comprehensive system that processes and analyzes received ECG data captured by long-duration, single-lead, continuous recording diagnostic devices, such as the Zio™ Patch and Zio™ Event Card.

*Implantable continuous “memory loop” devices with autotrigger:* These devices combine the long-term monitoring available with implantable devices with the autotriggers seen on newer event monitors. These devices contain algorithms that are programmed to detect heart rates exceeding an upper or lower limit and asystole of greater than 3 seconds. They typically contain other autotriggers such as a variable R-R interval seen with atrial fibrillation.

### **Mobile Cardiac Outpatient Telemetry (MCOT):**

Ambulatory event monitors store the recorded data, which are ultimately transmitted either to a physician’s office or to a central recording station. In contrast, outpatient cardiac telemetry provides real-time monitoring and analysis. For example, CardioNet Inc. is a company that offers mobile cardiac outpatient telemetry. In this system, the patient wears a 3-lead sensor, which constantly communicates with the CardioNet monitor, a lightweight unit that can be carried in a pocket or purse. When an arrhythmia is detected according to preset parameters, the EKG is automatically transmitted to a central CardioNet service center, where the EKG is immediately interpreted, with results sent to the referring physician. The referring physician can request the level and timing of response, ranging from daily reports to stat results. Other systems for outpatient cardiac telemetry include the HEARTLink II system (Cardiac Telecom Corp.), the VST (Vital Signs Transmitter, Biowatch Medical), and the Lifestar ambulatory cardiac telemetry (ACT) system (Card Guard Scientific Survival Ltd). The CardioNet system has a built-in cellular telephone that automatically transmits signals when the patient is away from home.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## Policy

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**BCBSNC will provide coverage for Ambulatory Event Monitors when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

**Outpatient Cardiac Telemetry (also known as mobile cardiac outpatient telemetry or MCOT) is considered not medically necessary. BCBSNC does not cover services that are considered not medically necessary.**

## Benefits Application

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Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

## When Ambulatory Event Monitors are covered

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The use of patient-activated or auto-activated external ambulatory event monitors may be considered medically necessary as a diagnostic alternative to Holter monitoring in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope).

The use of implantable ambulatory event monitors, either patient activated or auto-activated, may be considered medically necessary only in the small subset of patients who experience recurrent symptoms so infrequently that a prior trial of Holter monitor and other external ambulatory event monitors has been unsuccessful.

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The use of auto-activated external ambulatory event monitors may be considered medically necessary in patients treated for atrial fibrillation to monitor for asymptomatic episodes in order to evaluate treatment response.

### When Ambulatory Event Monitors are not covered

Outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry or MCOT) is considered not medically necessary as a diagnostic alternative in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope).

The use of long-term ambulatory monitoring, i.e., Zio™ Patch, Zio™ Event Card and the Zeus ECG Utilization Service, is considered not medically necessary because the clinical (health) outcomes and cost effectiveness of extended monitoring have not been shown to be superior to other available approaches.

Other uses of ambulatory event monitors, including outpatient cardiac telemetry, are considered investigational, including but not limited to monitoring effectiveness of antiarrhythmic therapy and detection of myocardial ischemia by detecting ST segment changes.

### Policy Guidelines

A number of studies have indicated that auto-trigger event monitors detect additional episodes of arrhythmias compared to Holter monitoring or patient-triggered devices. This evidence has led to the acceptance of auto-trigger event monitors as the gold standard for detecting arrhythmias that occur infrequently. There is also evidence that auto-trigger devices can pick up asymptomatic episodes of atrial fibrillation in treated patients and that identifying asymptomatic episodes may lead to modifications in treatment.

MCOT is another option for long-term cardiac monitoring. The current evidence on MCOT establishes that it does record cardiac electric signals, without patient activation, for subsequent analysis. Currently, the literature does not provide any adequate comparative data for MCOT compared to the autotrigger device. One retrospective, uncontrolled study reported that only a small minority of events (1%) detected by MCOT were potentially emergent. None of the available studies have clearly shown an improvement in clinical utility as a result of using MCOT. Further study of MCOT is needed to compare MCOT with the autotrigger loop recorder in order to determine whether the faster response possible with real-time monitoring leads to improved outcomes.

### Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 93224, 93225, 93226, 93227, 93228, 93229, 93268, 93270, 93271, 93272, 33282, 33284, E0616, 0295T, 0296T, 0297T, 0298T*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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## Scientific Background and Reference Sources

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- BCBSNA Medical Policy Reference Manual, 2.02.08, 11/1/99.
- Specialty Matched Consultant Advisory Panel, 9/00
- Medical Policy Advisory Group - 10/00
- Specialty Matched Consultant Advisory Panel - 8/2002
- BCBSA Medical Policy Reference Manual, 2.02.08, 7/12/02
- BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.08, 04/29/03
- Specialty Matched Consultant Advisory Panel - 6/2004
- BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.08, 9/18/07
- Rothman SA, Laughlin JC, Seltzer J, et al. The diagnosis of cardiac arrhythmias: a prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. *J Cardiovasc Electrophysiol* 2007; 18(3):1-7.
- Olson JA, Fouts AM, Padanilam BJ, et al. Utility of mobile cardiac outpatient telemetry for the diagnosis of palpitation, presyncope, syncope, and the assessment of therapy efficacy. *J Cardiovasc Electrophysiol* 2007; 18:473-7.
- BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.08, 5/14/09
- Specialty Matched Consultant Advisory Panel – 3/2010
- BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.08, 9/16/10
- Kadish AH, Reiffel JA, Clauser J et al. Frequency of serious arrhythmias detected with ambulatory cardiac telemetry. *Am J Cardiol* 2010;105:1313-1316.
- Hindricks G, Pokushalov E, Urban L et al. Performance of a new leadless implantable cardiac monitor in detecting and quantifying atrial fibrillation: Results of the XPECT trial. *Circ Arrhythm Electrophysiol* 2010; 3:141-147.
- Hanke T, Charitos EI, Stierle U et al. Twenty-four-hour holter monitor follow-up does not provide accurate heart rhythm status after surgical atrial fibrillation ablation therapy: up to 12 months experience with a novel permanently implantable heart rhythm monitor device. *Circulation* 2009; 120:S177-S184.
- Specialty Matched Consultant Advisory Panel 4/2011
- BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.08, 10/4/11
- Medical Director review 12/2011

## Policy Implementation/Update Information

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| 9/00    | Specialty Matched Consultant Advisory Panel. Revised section, "When Ambulatory Event Monitors are not covered" to include routine monitoring for effectiveness of antiarrhythmic therapy and when used for asymptomatic patients. |
| 10/2000 | Original policy issued. Medical Policy Advisory Group - Approved.                                                                                                                                                                 |
| 9/02    | Specialty Matched Consultant Advisory Panel review. When Covered and When Not Covered sections clarified. Code 93232 added to policy. New sources added. No criteria change.                                                      |
| 12/03   | Benefits Application and Billing/Coding sections updated for consistency.                                                                                                                                                         |
| 7/29/04 | Specialty Matched Consultant Advisory Panel review 06/08/2004 with no changes made to criteria. HCPCS Codes G0004, G0005, G0006 and G0007 removed (deleted 2003) from                                                             |

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- Billing and Coding information. CPT codes 33282, 33284 and HCPCS E0616 added. References added.
- 3/30/06 Specialty Matched Consultant Advisory Panel review 2/27/06 with no changes made to coverage criteria. Added information regarding "Outpatient Cardiac Telemetry" to Description, Policy and Policy Guidelines sections to indicate that this technology is considered investigational. Added policy number to Key Words section. HCPCS codes effective 4/1/06 added to policy.
- 4/21/08 Description section extensively revised for clarity. Outpatient cardiac telemetry is considered investigational. Deleted statement from Policy Guidelines section regarding Telemedicine billed under the evaluation and management codes. Specialty Matched Consultant Advisory Panel review 3/12/08. No change to policy statement. (adn)
- 01/05/09 Added new CPT codes 93228 and 93229 to Billing/Coding section. (adn)
- 7/20/09 Description section revised. Policy statement changed to read, "Outpatient Cardiac Telemetry (also known as mobile cardiac outpatient telemetry or MCOT) is considered **not medically necessary**." Criteria in the When AEM is Covered section deleted and replaced with the following statements: The use of patient-activated or auto-activated external ambulatory event monitors may be considered medically necessary as a diagnostic alternative to Holter monitoring in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope). The use of implantable ambulatory event monitors, either patient activated or auto-activated, may be considered medically necessary only in the small subset of patients who experience recurrent symptoms so infrequently that a prior trial of Holter monitor and other external ambulatory event monitors has been unsuccessful. Information in the When AEM is Not Covered section deleted and replaced with the following statements: Outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry or MCOT) is considered not medically necessary as a diagnostic alternative in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope). Other uses of ambulatory event monitors, including outpatient cardiac telemetry, are considered investigational, including but not limited to monitoring effectiveness of antiarrhythmic therapy and detection of myocardial ischemia by detecting ST segment changes. Rationale in the Policy Guidelines section revised. References updated. (adn)
- 1/5/10 HCPCS Codes S0345, S0346, S0347 deleted.
- 4/27/10 Specialty Matched Consultant Advisory Panel review 3/24/2010. Removed Medical Policy number. No changes to policy (mco)
- 1/4/11 CPT codes 93230, 93231, 93233, 93235, 93236 and 93237 deleted from Billing/Coding section. (mco)
- 5/10/11 Specialty Matched Consultant Advisory Panel 4/2011. Added information to "Description" section regarding implantable continuous "memory loop" devices with autotrigger. References updated. (mco)
- 12/30/11 New product information added to "Description" section. New codes effective 1/1/2012: 0295T, 0296T, 0297T, 0298T added to "Billing/Coding" section. "When Covered" section revised to include the following statement: "The use of auto-activated external ambulatory event monitors may be considered medically necessary in patients treated for atrial fibrillation to monitor for asymptomatic episodes in order to evaluate treatment response." The "When not Covered" section revised to include the following statement: "The use of long-term ambulatory monitoring, i.e., Zio™ Patch, Zio™ Event Card and the Zeus ECG Utilization Service, is considered not medically necessary because the clinical (health) outcomes and cost effectiveness of extended monitoring have not been shown to be superior to other available approaches." Policy Guidelines updated. References updated. Medical Director review

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.