Ambulatory Event Monitors

Description of Procedure or Service

There are a wide variety of devices available for outpatient cardiac rhythm monitoring. The primary purpose of these devices is the evaluation of suspected arrhythmias that have not been detected by office or hospital-based monitoring. These devices differ in the types of monitoring leads used, the duration and continuity of monitoring, the ability to detect arrhythmias without patient intervention, and the mechanism of delivery of the information from patient to clinician. These devices may be used to evaluate symptoms suggestive of arrhythmias (e.g., syncope, palpitations), and may be used to detect atrial fibrillation (AF) in patients who have undergone cardiac ablation of AF or who have a history of cryptogenic stroke.

Ambulatory cardiac monitoring with a variety of devices allows for the evaluation of cardiac electrical activity over time, in contrast to a static electrocardiogram (ECG), which only permits the detection of abnormalities in cardiac electrical activity at a single point in time. Cardiac monitoring is routinely used in the inpatient setting for the purpose of detecting acute changes in heart rate or rhythm that may need urgent response. For some clinical conditions, a more prolonged period of monitoring in the ambulatory setting is needed to detect heart rate or rhythm abnormalities that may occur infrequently. These cases may include the diagnosis of arrhythmias in patients with signs and symptoms suggestive of arrhythmias. In addition, ambulatory cardiac monitoring may be used for evaluation of paroxysmal atrial fibrillation (AF).

Arrhythmia Detection in Patients With Signs/Symptoms of Arrhythmia

Cardiac arrhythmias may be suspected because of symptoms suggestive of arrhythmias, including palpitations, dizziness, or syncope or presyncope, or because of abnormal heart rate or rhythm noted on exam. A full discussion of the differential diagnosis and evaluation of each of these symptoms is beyond the scope of this review, but some general principles on the use of ambulatory monitoring are discussed.

Arrhythmias are an important potential cause of syncope or near-syncope, which may in some cases be described as dizziness. An ECG is generally indicated whenever there is suspicion of a cardiac cause of syncope. Some arrhythmic causes will be apparent on ECG. However, in patients in whom an ECG is not diagnostic, longer monitoring may be indicated. The 2009 guidelines from the European Society of Cardiology suggest that in individuals with clinical or ECG features suggesting an arrhythmic syncope, ECG monitoring is indicated; they also state that the “duration (and technology) of monitoring should be selected according to the risk and the predicted recurrence rate of syncope.” Similarly, guidelines from the National Institute for Health and Care Excellence on the evaluation of transient loss of consciousness, published in 2010 and updated in 2014, recommends the use of an ambulatory ECG in individuals with a suspected arrhythmic cause of syncope, with the type and duration of monitoring chosen based on the individual’s history.

Similar to syncope, the evaluation and management of palpitations is patient-specific, but in cases where the initial history, examination, and ECG findings are suggestive of an arrhythmia, some form of
Ambulatory Event Monitors

Ambulatory ECG monitoring is indicated. A 2011 position paper from the European Heart Rhythm Association indicates that for individuals with palpitations of unknown origin who have clinical features suggestive of arrhythmia, referral for specialized evaluation with consideration for ambulatory ECG monitoring is indicated.

**Atrial Fibrillation (AF) Detection**

AF is the most common arrhythmia in adults. It may be asymptomatic or be associated with a broad range of symptoms, including lightheadedness, palpitations, dyspnea, and a variety of more nonspecific symptoms (eg, fatigue, malaise). It is classified as paroxysmal, persistent, or permanent based on symptom duration. Diagnosed AF may be treated with antiarrhythmic medications with the goal of rate or rhythm control, direct cardioversion, catheter-based radiofrequency- or cryo-energy-based ablation, or one of several surgical techniques, depending on the patient’s comorbidities and associated symptoms.

AF is associated with the development of thrombi in the atria, often the left atrial appendage. Patients with AF are at risk for ischemic stroke due to the risk of embolism of the thrombus. Multiple clinical trials have demonstrated that anticoagulation reduces the ischemic stroke risk in patients at moderate or high risk of thromboembolic events. Oral anticoagulation in patients with AF reduces the risk of subsequent stroke and is recommended by American Heart Association and American College of Cardiology guidelines for patients with a history of stroke or transient ischemic attack.

Ambulatory ECG monitoring may play a role in several situations in the detection of AF. In patients who have undergone ablative treatment for AF, if ongoing AF can be excluded with reasonable certainty, including paroxysmal AF which may not be apparent on ECG during an office visit, anticoagulation therapy could potentially be stopped.

Patients with cryptogenic stroke are often monitored for the presence of AF, because AF is estimated to be the cause of cryptogenic stroke in more than 10% of patients, and AF increases the risk of stroke. Paroxysmal AF confers an elevated risk of stroke, just as persistent and permanent AF. In individuals with a high risk of stroke, particularly those with a history of ischemic stroke that is unexplained by other causes, prolonged monitoring to identify paroxysmal AF has been investigated.

**Cardiac Rhythm Ambulatory Monitoring Devices**

A Holter monitor is worn continuously and records cardiac electrical output continuously throughout the recording period. Holter monitors are capable of recording activity for up to about 24 to 72 hours. Traditionally, most Holter monitors had 3 channels based on 3 ECG leads. However, some currently available Holter monitors have up to 12 channels. Holter monitors are an accepted intervention in a variety of settings where a short period (24-48 hours) of comprehensive cardiac rhythm assessment is needed (eg, suspected arrhythmias when symptom, such as syncope and palpitations are occurring daily). These devices are not the focus of this policy.

Various classes of devices are available for situations where longer monitoring than can be obtained with a traditional Holter monitor is needed. Because there may be many devices within each category, a comprehensive description of each device is beyond the scope of this policy. Specific devices may vary in how data are transmitted to the location where the ECG output is interpreted. Data may be transmitted via cellular phone or landline, or by direct download from the device after its return to the monitoring center. The device classes are described in Table 1.

<table>
<thead>
<tr>
<th>Table 1: Ambulatory Cardiac Rhythm Monitoring Devices</th>
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<tbody>
<tr>
<td><strong>Device Class</strong></td>
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| Noncontinuous devices with memory (event recorder) | Devices not worn continuously but rather activated by patient and applied to skin in the precordial area when symptoms develop | • Zio® Event Card (iRhythm Technologies, San Francisco, CA)  
• REKA E100™ (REKA Health, Bridgewater, NJ) |
## Ambulatory Event Monitors

<table>
<thead>
<tr>
<th>Continuous recording devices with longer recording periods</th>
<th>Devices continuously worn and continuously record via ≥1 cardiac leads and store data for a longer period than traditional Holter (14 d)</th>
<th>• Zio® Patch system (iRhythm Technologies, San Francisco, CA)</th>
</tr>
</thead>
</table>
| External memory loop devices (patient- or autotriggered) | Devices continuously worn and continuously store a single channel of ECG data in a refreshed memory. If device is activated, the ECG is then recorded from the memory loop for the preceding 30-90 s and for next minute or so. These devices may be activated by a patient when symptoms occur (patient-triggered) or by an automated algorithm when changes suggestive of an arrhythmia are detected (autotriggered). | • Patient-triggered: Explorer™ Looping Monitor (LifeWatch Services, Switzerland)  
• Autotriggered: LifeStar AF Express™ Auto-Detect Looping Monitor (LifeWatch Services, Switzerland)  
• Autotriggered or patient-triggered: King of Hearts Express® AF (CardGuard Scientific Survival, Rehovot, Israel) |
| Implantable memory loop devices (patient- or autotriggered) | Devices similar in design to external memory loop devices but implanted under the skin in the precordial region | • Autotriggered: Reveal® XT ICM (Medtronic, Minneapolis, MN)  
• Autotriggered: BioMonitor, Biotronik SE (Berlin, Germany) |
| Mobile cardiac outpatient telemetry | Continuously recording or autotriggered memory loop devices that transmit data to a central recording station with real-time monitoring and analysis | • CardioNet MCOT (BioTelemetry, Malvern, PA)  
• LifeStar Mobile Cardiac Telemetry (LifeWatch Services, Switzerland)  
• SEEQ Mobile Cardiac Telemetry (Medtronic, Minneapolis, MN) |

There are also devices that combine features of multiple classes. For example, the LifeStar ACT Ex Holter (LifeWatch Services, Switzerland) is a 3-channel Holter monitor, but is converted to a mobile cardiac telemetry system if a diagnosis is inconclusive after 24 to 48 hours of monitoring. The BodyGuardian® Heart Remote Monitoring System (Preventice Services, Houston, TX) is an external autotriggered memory loop device that can be converted to a real-time monitoring system. The eCardio Verité™ system (eCardio, Houston, TX) can be changed between a patient-activated event monitor and a continuous telemetry monitor. The Spiderflash-T (LivaNova, London, England) is an example of an external autotriggered or patient-triggered loop recorder, but, like the ZioPatch, can record 2 channels for 14 to 40 days.

***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

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.
Ambulatory Event Monitors

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

Benefits Application

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

The use of patient-activated or auto-activated external ambulatory event monitors and long-term ambulatory monitoring may be considered medically necessary as a diagnostic alternative to Holter monitoring in the following situations:

- Patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope)
- Patients with atrial fibrillation who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered
- Patients treated for atrial fibrillation to monitor for asymptomatic episodes in order to evaluate treatment response
- Patients with cryptogenic stroke who have a negative standard work-up for atrial fibrillation including a 24-hour Holter monitor.

The use of implantable ambulatory event monitors, either patient-activated or auto-activated, may be considered medically necessary in the following situations:

- The small subset of patients who experience recurrent symptoms so infrequently that a prior trial of other external ambulatory event monitors has been unsuccessful.
- Patients who require long-term monitoring for atrial fibrillation or possible atrial fibrillation.

The use of continuous ambulatory monitors that record and store information for periods longer than 48 hours may be considered medically necessary as a diagnostic alternative to Holter monitoring or patient-activated or auto-activated external ambulatory event monitors in the following situations:

- Patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope).
- Patients with atrial fibrillation who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered.
- Patients with cryptogenic stroke who have a negative standard work-up for atrial fibrillation including a 24-hour Holter monitor.

When Ambulatory Event Monitors are not covered

Outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry or MCOT) is considered investigational 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.
Policy Guidelines

For the use of patient- or auto-activated external ambulatory event monitors or continuous ambulatory monitoring for storing information more than 48 hours, in patients with signs and/or symptoms suggestive of arrhythmia(s), the evidence include prospective and retrospective studies reporting on the diagnostic yield. Relevant outcomes include overall survival and morbid events. Studies show that continuous monitors with longer recorded periods clearly detect more arrhythmias than 24- or 48-hour Holter monitoring. Particularly for patients who would, without the more prolonged monitoring, only undergo shorter term monitoring, the diagnostic yield is likely to identify arrhythmias that may have therapeutic implications. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For the use of long term ambulatory cardiac monitoring for patients with atrial fibrillation following ablation or with cryptogenic stroke with a negative standard workup for AF, the evidence includes RCTs comparing ambulatory event monitoring with standard care. Relevant outcomes include overall survival, morbid events, medication use, and treatment-related morbidity. RCTs evaluating a long term monitoring strategy post-stroke or after catheter ablation for AF report significantly higher rates of AF detection with longer term ambulatory monitoring. The available evidence suggests that long-term monitoring for atrial fibrillation after cryptogenic stroke or postablation is associated with improved outcomes, but the specific type of monitoring associated with the best outcomes is not well-defined. Trials that have demonstrated improved outcomes have used either event monitors or implantable monitors. In addition, there are individual patient considerations that may make one type of monitor preferable over another. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Evidence for patients who are asymptomatic with risk factors for atrial fibrillation who receive long term ambulatory cardiac monitoring, includes 1 noncomparative study. Relevant outcomes include overall survival, morbid events, medication use, and treatment-related morbidity. A single study was identified that evaluated the use of a continuously recording device with a longer recording period in individuals at risk for AF. This study suggests that such monitoring is feasible. However, the use of population-based screening for asymptomatic patients is not well-established. Studies reporting on improved outcomes with such monitoring are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For the evaluation of patients with signs and/or symptoms suggestive of arrhythmia with infrequent symptoms who receive patient- or autoactivated implantable ambulatory event monitors, the evidence includes RCTs comparing implantable loop recorders (ILRs) with shorter term monitoring, usually 24-48 hour Holter monitoring. Relevant outcomes include overall survival, morbid events, medication use, and treatment-related morbidity. Studies of prolonged ILRs in patients report high rates of arrhythmia detection, compared with external event monitoring or Holter monitoring. These studies support the use of a progression in diagnostics from an external event monitor to ILR in cases where longer monitoring is needed. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Evidence for the use of outpatient cardiac telemetry for patients with signs and/or symptoms of arrhythmia, includes 1 RCT and nonrandomized studies evaluating the rate of arrhythmia detection with outpatient cardiac telemetry. Relevant outcomes are overall survival and morbid events. The available evidence suggests that outpatient cardiac telemetry is at least as good at detecting arrhythmias as ambulatory event monitoring. However, studies have not evaluated whether the real-time monitoring feature of outpatient cardiac telemetry leads to reduced cardiac events and mortality. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information
Ambulatory Event Monitors

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. 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.

Scientific Background and Reference Sources

Specialty Matched Consultant Advisory Panel, 9/00
Medical Policy Advisory Group - 10/00
BCBSA Medical Policy Reference Manual, 2.02.08, 7/12/02
BCBSA Medical Policy Reference Manual [Electronic Version], 2.02.08, 04/29/03
BCBSA Medical Policy Reference Manual [Electronic Version], 2.02.08, 9/18/07


BCBSA Medical Policy Reference Manual [Electronic Version], 2.02.08, 5/14/09
BCBSA Medical Policy Reference Manual [Electronic Version], 2.02.08, 9/16/10


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.

Medical Director review 12/2011
Specialty Matched Consultant Advisory Panel review 4/2012
Ambulatory Event Monitors

Medical Director review 8/2012


Medical Director review 12/2012

Specialty Matched Consultant Advisory Panel review 4/2013

Medical Director review 4/2013


Medical Director review 11/2013


Medical Director review 8/2014


Specialty Matched Consultant Advisory Panel review 4/2015

Medical Director review 4/2015

Ambulatory Event Monitors


Medical Director review 4/2016


Medical Director review 5/2016

Specialty Matched Consultant Advisory Panel review 4/2017

Medical Director review 4/2017


Medical Director review 5/2017

Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>9/00</td>
<td>Specialty Matched Consultant Advisory Panel. Revised section, &quot;When Ambulatory Event Monitors are not covered&quot; to include routine monitoring for effectiveness of antiarrhythmic therapy and when used for asymptomatic patients.</td>
</tr>
</tbody>
</table>
Ambulatory Event Monitors


12/03 Benefits Application and Billing/Coding sections updated for consistency.


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 even 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.


1/4/11 CPT codes 93230, 93231, 93233, 93235, 93236 and 93237 deleted from Billing/Coding section. (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
Ambulatory Event Monitors

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 12/2011. (mco)

5/15/12 Specialty Matched Consultant Advisory Panel review 4/2012. No changes to policy statements. (mco)

10/01/12 Revised the following statement in the “When Covered” section: “The use of patient-activated or auto-activated external ambulatory event monitors and long-term ambulatory monitoring 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).” Deleted the following statement from the “When not Covered” section: “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.” Removed 0296T, 0297T and 0298T from the Billing/Coding section. Medical Director review 8/2012. (mco)

1/15/13 Description section extensively revised. “When Covered” revised to state: “The use of patient-activated or auto-activated external ambulatory event monitors and long-term ambulatory monitoring 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),  Patients with atrial fibrillation who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered;  Patients treated for atrial fibrillation to monitor for asymptomatic episodes in order to evaluate treatment response.” “When not Covered” section revised to state: “Other uses of ambulatory event monitors, including outpatient cardiac telemetry, are considered investigational, including but not limited to monitoring effectiveness of antiarrhythmic therapy, for patients with cryptogenic stroke, and detection of myocardial ischemia by detecting ST segment changes.” References updated. Medical Director review 12/2012. (mco)


12/10/13 Description section updated. References updated. Policy Guidelines updated. Medical Director review 11/2013. (mco)


8/26/14 Description section updated. Added following coverage criterion to “When Covered” section: “Patients with cryptogenic stroke who have a negative standard work-up for atrial fibrillation including a 24-hour Holter monitor.” Policy Guidelines updated. References updated. Medical Director review 8/2014. (mco)

12/30/14 References updated. Billing/Coding section updated to include codes: 0296T, 0297T, 0298T Policy Guidelines section updated. When Covered section updated to indicate that continuous monitors with longer recording periods may be considered medically necessary with criteria. Policy statement unchanged. (td)

Ambulatory Event Monitors

9/1/15  Description section updated. Policy Statement and When Covered section updated to reflect change in MCOT coverage statement from not medically necessary to investigational. Policy Guidelines section updated. References updated. (td)


7/26/16  Description section extensively revised with addition of the Ambulatory Cardiac Rhythm Monitoring Devices Table 1. Policy Statement updated to include “Patients who require long-term monitoring for atrial fibrillation or possible atrial fibrillation”. Policy Guidelines extensively updated. References updated. Medical Director review 5/2016. (jd)


6/30/17  Table 1: Ambulatory Cardiac Rhythm Monitoring Devices updated under Description section. References updated. Medical Director review 5/2017. (jd)

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.