Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

Description
Various devices are available for outpatient cardiac rhythm 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 delivering the information from patient to clinician. These devices may be used to evaluate symptoms suggestive of arrhythmias (eg, 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.

OBJECTIVE
The objective of this evidence review is to determine whether outpatient cardiac rhythm monitoring improves the net health outcome in individuals being monitored for arrhythmia or atrial fibrillation.

POLICY STATEMENT
The use of patient-activated or autoactivated external ambulatory event monitors (AEMs) OR 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 in the following situations:

• Patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (ie, palpitations, dizziness, presyncope, or syncope).
• Patients with atrial fibrillation (AF) 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 workup for AF including a 24-hour Holter monitor (see Policy Guidelines section).

The use of implantable AEMs, either patient-activated or autoactivated, may be considered medically necessary in the following situations:

• In the small subset of patients who experience recurrent symptoms so infrequently that a prior trial of other external AEMs has been unsuccessful.
• In patients who require long-term monitoring for AF or possible AF (see Policy Guidelines section).
The use of outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry) as a diagnostic alternative to AEMs in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (ie, palpitations, dizziness, presyncope, syncpe) is considered \textbf{not medically necessary}.

Other uses of AEMs, including outpatient cardiac telemetry and mobile applications, are considered \textbf{not medically necessary}, including but not limited to monitoring asymptomatic patients with risk factors for arrhythmia, monitoring the effectiveness of antiarrhythmic medications, and detection of myocardial ischemia by detecting ST-segment changes.

**POLICY GUIDELINES**

The available evidence has suggested that long-term monitoring for atrial fibrillation postablation or after cryptogenic stroke is associated with improved outcomes, but the specific type of monitoring associated with the best outcomes is not well-defined. Trials demonstrating improved outcomes have used either event monitors or implantable monitors. In addition, there are individual patient considerations that may make 1 type of monitor preferable over another.

Therefore, for the evaluation of patients with cryptogenic stroke who have had a negative standard workup for atrial fibrillation including 24-hour Holter monitoring, or for the evaluation of atrial fibrillation after an ablation procedure, the use of long-term monitoring with an external event monitor, OR a continuous ambulatory monitor that records and stores information for periods longer than 48 hours, OR an implantable ambulatory monitor may be considered medically necessary for patients who meet the criteria outlined above.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA REGULATORY STATUS**

Ambulatory cardiac monitoring with a variety of devices permits the evaluation of cardiac electrical activity over time, in contrast to a static ECG, which only permits the detection of abnormalities in cardiac electrical activity at a single point in time.

A Holter monitor is worn continuously and records cardiac electrical output continuously throughout the recording period. Holter monitors are capable of recording activity for 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 symptoms [syncope, palpitations] are occurring daily). These devices are not the focus of this review.

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 is beyond our scope. 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 1. Ambulatory Cardiac Rhythm Monitoring Devices

<table>
<thead>
<tr>
<th>Device Class</th>
<th>Description</th>
<th>Device Examples</th>
</tr>
</thead>
</table>
| 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)  
• REKA E100™ (REKA Health) |
| Continuous recording devices with longer recording periods | Devices continuously worn and continuously record via ≥1 cardiac leads and store data longer than traditional Holter (14 d) | • Zio® Patch system (iRhythm Technologies) |
| External memory loop devices (patient- or autotriggered) | Devices continuously worn and store a single channel of ECG data in a refreshed memory. When the device is activated, the ECG is then recorded from the memory loop for the preceding 30-90 s and for next 60 s or so. 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)  
• Autotriggered: LifeStar AF Express™ Auto-Detect Looping Monitor (LifeWatch Services)  
• Autotriggered or patient-triggered: King of Hearts Express® AF (Card Guard Scientific Survival) |
| 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 or patient-triggered: Reveal® XT ICM (Medtronic)  
• Autotriggered: BioMonitor, Biotronik) |
| 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)  
• LifeStar Mobile Cardiac Telemetry (LifeWatch Services)  
• SEEQ Mobile Cardiac Telemetry (Medtronic) |

ECG: electrocardiogram.

There are also devices that combine features of multiple classes. For example, the LifeStar ACT Ex Holter (LifeWatch Services) 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) is an external autotriggered memory loop device that can be converted to a real-time monitoring system. The eCardio Verté™ system (eCardio) can switch between a patient-activated event monitor and a continuous telemetry monitor. The Spiderflash-T (LivaNova) is an example of an external autotriggered or patient-triggered loop recorder, but, like the Zio® Patch, can record 2 channels for 14 to 40 days.

Because there may be many devices within each category, a comprehensive description of individual devices is beyond the scope of this review. U.S. Food and Drug Administration product codes include: DSH, DXH, DQK, DSI, MXD, MHX.

RATIONALE

Summary of Evidence

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

For individuals who have AF following ablation who receive long-term ambulatory cardiac monitoring, the evidence includes an RCT comparing ambulatory event monitoring with standard care and several observational studies. Relevant outcomes are overall survival, morbid events, medication use, and
treatment-related morbidity. The RCT evaluating a long-term monitoring strategy after catheter ablation for AF reported significantly higher rates of AF detection. The available evidence has suggested that long-term monitoring for AF postablation is associated with improved outcomes. However, the specific type of monitoring associated with the best outcomes is not established, because different long-term monitoring devices were used across the studies. Trials demonstrating improved outcomes have used event monitors or implantable monitors. In addition, there are individual patient considerations that may make 1 type of monitor preferable over another. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cryptogenic stroke with a negative standard workup for AF who receive long-term ambulatory cardiac monitoring, the evidence includes systematic reviews of RCTs comparing ambulatory event monitoring with standard care. Relevant outcomes are overall survival, morbid events, medication use, and treatment-related morbidity. RCTs evaluating a long-term AF monitoring strategy poststroke have reported significantly higher rates of AF detection with longer term ambulatory monitoring. The available evidence has suggested that long-term monitoring for AF after cryptogenic stroke is associated with improved outcomes, but the specific type of monitoring associated with the best outcomes is not established, because different long-term monitoring devices were used across the studies. Trials demonstrating improved outcomes have used event monitors or implantable monitors. In addition, there are individual patient considerations that may make 1 type of monitor preferable over another. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are asymptomatic with risk factors for AF who receive long-term ambulatory cardiac monitoring, the evidence includes an RCT and 2 nonrandomized studies. Relevant outcomes are overall survival, morbid events, medication use, and treatment-related morbidity. The studies showed use of the ambulatory monitors would result in higher AF detection compared with routine care. However, the RCT followed patients for 1 year and did not detect a difference in stroke occurrence between the monitored group and the standard of care group. The other studies did not discuss changes in patient management or health outcomes based on monitoring. Studies reporting on improved outcomes with longer follow-up are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Implantable Loop Recording
For individuals who have signs and/or symptoms suggestive of arrhythmia with infrequent symptoms who receive patient- or autoactivated implantable ambulatory event monitoring, the evidence includes RCTs comparing implantable loop recorders with shorter term monitoring, usually 24- to 48-hour Holter monitoring. Relevant outcomes are overall survival, morbid events, medication use, and treatment-related morbidity. Studies assessing prolonged implantable loop recorders in patients have reported high rates of arrhythmia detection compared with shorter external event or Holter monitoring. These studies have supported use of a progression in diagnostics from an external event monitor to implantable loop recorder when longer monitoring is needed. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Outpatient Cardiac Telemetry
For individuals who have signs and/or symptoms suggestive of arrhythmia who receive outpatient cardiac telemetry, the evidence includes an RCT and nonrandomized studies evaluating rates of arrhythmia detection using outpatient cardiac telemetry. Relevant outcomes are overall survival and morbid events. The available evidence has suggested 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.
SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

International Society for Holter and Noninvasive Electrocardiology et al
In 2017, the International Society for Holter and Noninvasive Electrocardiology and the Heart Rhythm Society (HRS) issued a consensus statement on ambulatory electrocardiogram and external monitoring and telemetry. Below are 2 summary tables from the consensus statement, detailing advantages and limitations of ambulatory electrocardiogram techniques (see Table 2) and recommendations for the devices that are relevant to this evidence review (see Table 3).

Table 2. Advantages and Limitations of Ambulatory ECG Techniques

<table>
<thead>
<tr>
<th>ECG Monitoring Technique</th>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holter monitoring</td>
<td>• Records and documents continuous 3- to 32-lead ECG signal simultaneously with biologic signals during normal daily activities • Physicians familiar with analysis software and scanning services</td>
<td>• Frequent noncompliance with symptom logs and event markers • Frequent electrode detachments • Signal quality issues due to skin adherence, tangled wires, dermatitis • Absence of real-time data analysis • Poor patient acceptance of electrodes • Limited ECG from closely spaced electrodes, lacking localization of arrhythmia origin • Inconsistent ECG quality due to body type variations</td>
</tr>
<tr>
<td>Patch ECG monitors</td>
<td>• Long-term recording of ≥14 d • Excellent patient acceptance</td>
<td></td>
</tr>
<tr>
<td>External loop recorders</td>
<td>• Records only selected ECG segments marked as events either automatically or manually by patient • Immediate alarm generation on event detection</td>
<td>• Single-lead ECG, lacking localization of arrhythmia origin • Cannot continuously document cardiac rhythm • Requires patient to wear electrodes continuously</td>
</tr>
<tr>
<td>Event recorders</td>
<td>• Records only selected ECG segments after an event is detected by patient • Immediate alarm generation at event detected by patient • Well-tolerated by patient</td>
<td>• Single-lead ECG, lacking localization of arrhythmia origin • Cannot continuously document cardiac rhythm • Diagnostic yield dependent on patient ability to recognize correct symptom</td>
</tr>
<tr>
<td>Mobile cardiac telemetry</td>
<td>• Multilead, so higher sensitivity and specificity of arrhythmia detection • Streams data continuously; can be programmed to autodetect and autosend events at prescribed time intervals • Immediate alarm generation on event without patient interaction</td>
<td>• Long-term patient acceptance is reduced due to requirement of daily electrode changes</td>
</tr>
</tbody>
</table>

ECG: electrocardiogram.
Table 3. Select Recommendations for Ambulatory ECG and External Monitoring or Telemetry

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection of ambulatory ECG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Holter monitoring when symptomatic events anticipated within 48 h</td>
<td>I</td>
<td>B-NR</td>
</tr>
<tr>
<td>Extended ambulatory ECG (15-30 d) when symptomatic events are not daily or are uncertain</td>
<td>I</td>
<td>B-R</td>
</tr>
<tr>
<td>Continuous monitoring (1-14 d) to quantify arrhythmia burden and patterns</td>
<td>I</td>
<td>B-NR</td>
</tr>
<tr>
<td>Specific conditions for use of ambulatory ECG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexplained syncope, when tachycardia suspected</td>
<td>I</td>
<td>B-R</td>
</tr>
<tr>
<td>Unexplained palpitation</td>
<td>I</td>
<td>B-R</td>
</tr>
<tr>
<td>Detection of atrial fibrillation, triggering arrhythmias, and postconversion pauses</td>
<td>IIa</td>
<td>B-NR</td>
</tr>
<tr>
<td>Cryptogenic stroke, to detect undiagnosed atrial fibrillation</td>
<td>I</td>
<td>B-R</td>
</tr>
</tbody>
</table>

ECG: electrocardiogram; COR: class of recommendation; LOE: level of evidence.

a COR definitions: I: strong recommendation; IIa: benefit probably exceeds risk.
b LOE definitions: B-NR: moderate level based on well-executed nonrandomized studies; B-R: moderate level based on randomized trials.

American College of Cardiology et al
In 2014, the American College of Cardiology, the American Heart Association, and HRS issued guidelines on the management of patients with atrial fibrillation (AF). These guidelines recommended the use of Holter or event monitoring if the diagnosis of the type of arrhythmia is in question or as a means of evaluating rate control.

The same associations collaborated on guidelines in 2017 on the evaluation and management of patients with syncope. Cardiac monitoring recommendations are summarized below in Tables 4 and 5.

Table 4. Cardiac Monitoring Recommendations for Patients With Syncope

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Choice of a specific cardiac monitor should be determined on the basis of frequency and nature of syncope events.</td>
<td>I</td>
<td>C-EO</td>
</tr>
<tr>
<td>To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, the following external cardiac monitoring approaches can be useful: Holter monitor, transtelephonic monitor, external loop recorder, patch recorder, and mobile cardiac outpatient telemetry.</td>
<td>IIa</td>
<td>B-NR</td>
</tr>
<tr>
<td>To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an implantable cardiac monitor can be useful.</td>
<td>IIa</td>
<td>B-R</td>
</tr>
</tbody>
</table>

COR: class of recommendation; LOE: level of evidence.
a COR definitions: I: strong recommendation; IIa: benefit probably exceeds risk.
b LOE definitions: B-NR: moderate level based on well-executed nonrandomized studies; B-R: moderate level based on randomized trials; C-EO: consensus of expert opinion based on clinical experience.

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Table 5. Patient Selection Recommendations by Cardiac Rhythm Monitor

<table>
<thead>
<tr>
<th>Type of Monitor</th>
<th>Patient Selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holter monitor</td>
<td>Symptoms frequent enough to be detected within 24 to 72 h</td>
</tr>
<tr>
<td>Patient-activated event monitor</td>
<td>• Frequent spontaneous symptoms likely within 2 to 6 wk</td>
</tr>
<tr>
<td></td>
<td>• Limited use when syncope associated with sudden incapacitation</td>
</tr>
<tr>
<td>External loop recorder (patient or auto-triggered)</td>
<td>Frequent spontaneous symptoms likely to occur within 2 to 6 wk</td>
</tr>
<tr>
<td>External patch recorder</td>
<td>• Alternative to external loop recorder</td>
</tr>
<tr>
<td></td>
<td>• Leadless, so more comfortable, resulting in improved compliance</td>
</tr>
<tr>
<td></td>
<td>• Offers only 1-lead recording</td>
</tr>
<tr>
<td>Mobile cardiac outpatient telemetry</td>
<td>• Spontaneous symptoms related to syncope and rhythm correlation</td>
</tr>
<tr>
<td></td>
<td>• High-risk patients needing real-time monitoring</td>
</tr>
<tr>
<td>Implantable cardiac monitor</td>
<td>Recurrent, infrequent, unexplained syncope</td>
</tr>
</tbody>
</table>

The American College of Cardiology and the American Heart Association (1999) published guidelines for the use of ambulatory electrocardiography. The guidelines recommended ambulatory electrocardiography for 2 indications, unexplained syncope and unexplained recurrent palpitations, but did not explicitly distinguish between continuous (ie, Holter monitoring) and intermittent (ie, ambulatory event monitoring) monitoring. Regarding the effectiveness of antiarrhythmic therapy, the guidelines listed 1 class I indication: “To assess antiarrhythmic drug response in individuals in whom baseline frequency of arrhythmia has been well characterized as reproducible and of sufficient frequency to permit analysis.”

The guidelines did not specify whether Holter monitoring or ambulatory event monitors (AEMs) are most likely to be used. However, accompanying text noted that intermittent monitoring may be used to confirm the presence of an arrhythmia during symptoms. There were no class I indications for detection of myocardial ischemia. In addition, there were no class I indications for ambulatory monitoring to assess risk for future cardiac events in patients without symptoms of arrhythmia.

Heart Rhythm Society et al
A consensus document on catheter and surgical ablation for AF was published in 2012 by HRS, the European Heart Rhythm Association, and the European Cardiac Arrhythmia Society and updated in 2017. This document did not contain formal practice guidelines, but provided general recommendations based on literature review and expert consensus. Use of ambulatory event monitors postablation was addressed in 2 sections of the document. First, in the section discussing use of anticoagulation following ablation, the following statement was made:

“Patients in whom discontinuation of systematic anticoagulation is being considered based on patient values and preferences should consider undergoing continuous or frequent ECG [electrocardiogram] monitoring to screen for AF recurrence.”

In the section on postoperative rhythm monitoring of patients who are postablation, the following statements were made:

“The success of AF ablation is based in large part on freedom from AF recurrence based on ECG monitoring. Arrhythmia monitoring can be performed with the use of noncontinuous or continuous ECG monitoring tools.”

The statement referenced a table of ambulatory cardiac monitoring devices (Holter, patch, external loop, implantable loop, wearable multisensors, Smartphone monitors), describing unique features of each. The table did not evaluate the safety or efficacy of these devices, nor recommend one over another.

European Heart Rhythm Association
In 2009, the European Heart Rhythm Association published guidelines on the use of diagnostic implantable and external loop recorders. For the indications that the Association considered established...
at the time of publication, the guidelines made the following statements about indications for implantable and external recorders (see Table 6).

Table 6. Guidelines on Use of Diagnostic ILRs and ELRs

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
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</table>
| "ILR [implantable loop recorder] is indicated:  
• "In an early phase of evaluation of patients with recurrent syncope of uncertain origin who have:  
• "absence of high-risk criteria that require immediate hospitalization or intensive evaluation...and  
• "a likely recurrence within battery longevity of the device."  
"ELRs are indicated in patients with recurrent palpitations, undocumented by conventional ECG techniques, who have: inter-symptom interval <4 weeks and absence of high-risk criteria...which require immediate hospitalization or intensive evaluation."  
"ILR may be indicated to assess the contribution of bradycardia before embarking on cardiac pacing in patients with suspected or certain neurally mediated syncope presenting with frequent or traumatic syncopal episodes."  
"ILRs may be indicated in selected cases with severe infrequent symptoms when ELRs and other ECG monitoring systems fail to document the underlying cause."  
"ELRs [external loop recorder] may be indicated in patients with recurrent (pre)syncopes who have:  
• "inter-symptom interval of ≤4 weeks, and  
• "suspicion of arrhythmic origin and  
• "absence of high-risk criteria that require immediate hospitalization or intensive evaluation..."  
| I   | A   |
|     | I   | B   |
|     | Ila | B   |
|     | Ila | B   |

COR: class of recommendations; ECG: electrocardiogram; ELR: external loop recorder; ILR: implantable loop recorder; LOE: level of evidence.

American Academy of Neurology

In 2014, the American Academy of Neurology updated its guidelines on the prevention of stroke in patients with nonvalvular AF (NVAF). These guidelines made the following recommendations on the identification of patients with occult NVAF:

A1. "Clinicians might obtain outpatient cardiac rhythm studies in patients with cryptogenic stroke without known NVAF, to identify patients with occult NVAF (Level C). Clinicians might obtain cardiac rhythm studies for prolonged periods (e.g., for 1 or more weeks) instead of shorter periods (e.g., 24 hours) in patients with cryptogenic stroke without known NVAF, to increase the yield of identification of patients with occult NVAF (Level C)."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services implemented a national coverage determination in 2004 for electrocardiographic services. This national coverage determination includes descriptions of the Holter monitor and event recorders (both external loop recorders and implantable loop recorders). Ambulatory cardiac monitors are covered when there is documentation of medical necessity. Indications for use include detection of symptomatic transient arrhythmias and determination of arrhythmic drug therapy (to either initiate, revise, or discontinue the therapy).
REFERENCES


20. Chao TF, Lin YJ, Tsao HM, et al. CHADS(2) and CHA(2)DS(2)-VASc scores in the prediction of clinical outcomes in patients with atrial fibrillation after catheter ablation. *J Am Coll Cardiol.* Nov 29 2011;58(23):2380-2385. PMID 22115643


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70. Joshi AK, Kowey PR, Prystowsky EN, et al. First experience with a Mobile Cardiac Outpatient Telemetry (MCOT) system for the diagnosis and management of cardiac arrhythmia. *Am J Cardiol.* Apr 1 2005;95(7):878-881. PMID 15781022


<table>
<thead>
<tr>
<th>Date</th>
<th>Update/Policy Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2013</td>
<td>Policy updated with literature search, reference numbers 17-24, 25 added. Medically necessary indication for use of event monitors in patients with atrial fibrillation treated with catheter ablation revised for clarity and for working to be consistent with recent guidelines. Not medically necessary indication for MCOT changed to reflect revised language for not medically necessary technologies. Additional investigational indications added for use of continuous monitor that record for periods longer than 72 hours, and for monitoring patients with cryptogenic stroke.</td>
</tr>
<tr>
<td>March 2014</td>
<td>Policy updated with literature review. References 3, 10, 28 and 29 added. Medically necessary criteria for implantable loop monitors revised from “a prior trial of Holter monitor and other external ambulatory event monitors has been unsuccessful” to “...a prior trial of other external ambulatory event monitors has been unsuccessful.” Investigational indications have been changed to not medically necessary to align with FDA approved status.</td>
</tr>
<tr>
<td>March 2015</td>
<td>Policy updated with results of clinical input. Policy statements changed to indicated that continuous monitors with longer recording periods may be medically necessary with conditions.</td>
</tr>
<tr>
<td>September 2016</td>
<td>Policy updated with literature review through March 29, 2016; references 1-3, 13, 15-16, 21, 33, 43-53, 61, and 65 added. Rationale revised and rewritten. Policy statements edited for simplicity to group continuous ambulatory monitors with longer recording periods with external event monitors, and to move language regarding the use of long-term outpatient monitoring for AF to “Policy Guidelines.”</td>
</tr>
<tr>
<td>September 2018</td>
<td>Policy updated with literature review through March 5, 2018; references 17, 40-46, 47, 49-50, 60-61, 68, 75, 77, and 83 added. The last policy statement was edited (1) to include the use of mobile apps as an example of an ambulatory event monitor and (2) to include the monitoring of patients who are asymptomatic as an example of an “other use,” which is still considered not medically necessary.</td>
</tr>
</tbody>
</table>