Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

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Policy Number: 347
BCBSA Reference Number: 2.02.08
NCD/LCD: National Coverage Determination (NCD) for Electrocardiographic Services (20.15)

Related Policies
NA

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

The use of patient-activated or auto-activated external ambulatory event monitors OR continuous ambulatory monitors that record and store information for periods longer than 48 hours may be 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 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:

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

For the evaluation of patients with cryptogenic stroke who have had a negative standard work-up for atrial fibrillation including 24-hour Holter monitoring, 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.
The use of outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry or MCOT) as a diagnostic alternative to ambulatory event monitors in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (ie, palpitations, dizziness, presyncope, or syncope) may be considered MEDICALLY NECESSARY.

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

Transtelephonic transmission of post-symptom electrocardiograms and cardiac event monitors may be MEDICALLY NECESSARY for the following indications, when used to evaluate patients in remote areas or long distances (such as 100 miles) from physicians capable of interpreting ECG: ¹

- To detect, characterize, and document symptomatic transient arrhythmias
- To assess anti-arrhythmic drug efficiency, and
- To carry out early post-hospital monitoring of patients discharged after a myocardial infarction, if 24 hour coverage is provided. Such coverage must be performed by an experienced electrocardiogram technician receiving the calls (tapes and facsimiles do not count). These technicians must have immediate access to a physician, and have been instructed when and how to contact available facilities to assist the patient in case of emergencies.
- This policy statement applies to plain EKGs (ECGs, electrocardiograms) only, transmitted electronically for the purposes of interpretation, and
- Transmitting devices must be capable of transmitting ECG leads I, II, and III, and transmissions must be comparable to readings obtained by conventional ECGs, to permit proper interpretation of abnormal cardiac rhythms.

NOTE: Facsimiles and tapes are not reimbursed.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Indications and Limitations of Coverage
B. Nationally Covered Indications
The following indications are covered nationally unless otherwise indicated:
1. Computer analysis of EKGs when furnished in a setting and under the circumstances required for coverage of other EKG services.
2. EKG services rendered by an IDTF, including physician review and interpretation. Separate physician services are not covered unless he/she is the patient's attending or consulting physician.
3. Emergency EKGs (i.e., when the patient is or may be experiencing a life-threatening event) performed as a laboratory or diagnostic service by a portable x-ray supplier only when a physician is in attendance at the time the service is performed or immediately thereafter.
4. Home EKG services with documentation of medical necessity.
5. Transtelephonic EKG transmissions (effective March 1, 1980) as a diagnostic service for the indications described below, when performed with equipment meeting the standards described below, subject to the limitations and conditions specified below. Coverage is further limited to the amounts payable with respect to the physician's service in interpreting the results of such transmissions, including charges for rental of the equipment. The device used by the beneficiary is part of a total diagnostic system and is not considered DME separately. Covered use is to:
   a. Detect, characterize, and document symptomatic transient arrhythmias;
   b. Initiate, revise, or discontinue arrhythmic drug therapy; or,
   c. Carry out early post-hospital monitoring of patients discharged after myocardial infarction (MI); (only if 24-hour coverage is provided, see C.5. below).

Certain uses other than those specified above may be covered if, in the judgment of the local Medicare Administrative Contractor (MAC), such use is medically necessary.
Additionally, the transmitting devices must meet at least the following criteria:

a. They must be capable of transmitting EKG Leads, I, II, or III; and,

b. The tracing must be sufficiently comparable to a conventional EKG.

24-hour attended coverage used as early post-hospital monitoring of patients discharged after MI is only covered if provision is made for such 24-hour attended coverage in the manner described below:

24-hour attended coverage means there must be, at a monitoring site or central data center, an EKG technician or other non-physician, receiving calls and/or EKG data; tape recording devices do not meet this requirement. Further, such technicians should have immediate, 24-hour access to a physician to review transmitted data and make clinical decisions regarding the patient. The technician should also be instructed as to when and how to contact available facilities to assist the patient in case of emergencies.

C. Nationally Non-Covered Indications
The following indications are non-covered nationally unless otherwise specified below:
1. The time-sampling mode of operation of ambulatory EKG cardiac event monitoring/recording.
2. Separate physician services other than those rendered by an IDTF unless rendered by the patient’s attending or consulting physician.
3. Home EKG services without documentation of medical necessity.
4. Emergency EKG services by a portable x-ray supplier without a physician in attendance at the time of service or immediately thereafter.
5. 24-hour attended coverage used as early post-hospital monitoring of patients discharged after MI unless provision is made for such 24-hour attended coverage in the manner described in section B.5. above.
6. Any marketed Food and Drug Administration (FDA)-approved ambulatory cardiac monitoring device or service that cannot be categorized according to the framework below.

D. Other
Ambulatory cardiac monitoring performed with a marketed, FDA-approved device, is eligible for coverage if it can be categorized according to the framework below. Unless there is a specific NCD for that device or service, determination as to whether a device or service that fits into the framework is reasonable and necessary is according to local MAC discretion.

Electrocardiographic Services Framework

<table>
<thead>
<tr>
<th>Patient/Event-Activated</th>
<th>Pre-symptom memory loop</th>
<th>Attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermittent Recorders</td>
<td>Insertable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non Insertable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post-symptom (no memory loop)</td>
<td>Non-attended</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-Activated</th>
<th>Dynamic Electrocardiography</th>
<th>Non-attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous</td>
<td>(e.g., Holter. Monitor)</td>
<td></td>
</tr>
</tbody>
</table>
National Coverage Determination (NCD) for Electrocardiographic Services (20.15)


Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th></th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>No</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>No</td>
</tr>
<tr>
<td>Medicare HMO BlueSM</td>
<td>No</td>
</tr>
<tr>
<td>Medicare PPO BlueSM</td>
<td>No</td>
</tr>
</tbody>
</table>

Other Information:
- Interpretation of the transmitted telephonic electrocardiogram must be performed by a Blue Cross Blue Shield of Massachusetts contracted Cardiologist when referred for interpretation by a physician.
- Transmission of a telephonic electrocardiogram, when performed by an independent physiological/diagnostic laboratory, must be rendered by a Blue Cross Blue Shield contracted Independent Physiological/Diagnostic Lab.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO and Indemnity:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33282</td>
<td>Implantation of patient-activated cardiac event monitor</td>
</tr>
<tr>
<td>93228</td>
<td>Wearable mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; physician review and interpretation with report</td>
</tr>
<tr>
<td>93229</td>
<td>Wearable mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and physician prescribed transmission of daily and emergent data reports</td>
</tr>
<tr>
<td>93268</td>
<td>External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download</td>
</tr>
</tbody>
</table>
### Description

#### Indications for Ambulatory Cardiac Rhythm Monitoring

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 a 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.”¹ 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.²

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 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.3

**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.4

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.5,6 Paroxysmal AF confers an elevated risk of stroke, just as persistent and permanent AF do. 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 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 device 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>
<thead>
<tr>
<th>Device Class</th>
<th>Description</th>
<th>Example Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noncontinuous devices with memory (event recorder)</td>
<td>Devices not worn continuously but rather activated by patient and applied to skin in the precordial area when symptoms develop</td>
<td>Zio® Event Card (iRhythm Technologies, San Francisco, CA)</td>
</tr>
<tr>
<td>Continuous recording devices with longer recording periods</td>
<td>Devices continuously worn and continuously record via ≥1 cardiac leads and store data for a longer period than traditional Holter (14 d)</td>
<td>• Zio® Patch system (iRhythm Technologies, San Francisco, CA)</td>
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<tr>
<td>----------------------------------------------------------</td>
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<td>---------------------------------------------------------------</td>
</tr>
</tbody>
</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) |
| 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) |
| 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) |

ECG: electrocardiogram.

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.

Summary
There are a wide variety of devices available for outpatient cardiac rhythm monitoring. The primary purpose of these devices is to evaluate 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 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. For individuals with signs and/or symptoms suggestive of arrhythmia(s) who receive patient- or auto-activated 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 detect more arrhythmias than 24- or 48-hour Holter monitoring. Particularly for patients in 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 individuals with AF following ablation or with cryptogenic stroke who receive long-term ambulatory cardiac monitoring, the evidence includes randomized controlled trials (RCTs) comparing ambulatory event monitoring to standard care. Relevant outcomes are overall survival, morbid events, medication use, and treatment-related morbidity. RCTs evaluating a long-term monitoring strategy poststroke 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 AF 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 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 qualitatively 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 noncomparative study. Relevant outcomes are 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 suggested 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 individuals with 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 (ILRs) 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 of prolonged ILRs in patients have reported high rates of arrhythmia detection compared with external event monitoring or Holter monitoring. These studies support use of a progression in diagnostics from an external event monitor to ILR when longer monitoring is needed. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals with signs and/or symptoms suggestive of arrhythmia who receive outpatient cardiac telemetry, the evidence includes 1 RCT and nonrandomized studies evaluating rates of arrhythmia detection with 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.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>6/2017</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>Date</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
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</tr>
<tr>
<td>7/2016</td>
<td>BCBSA National medical policy review. 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.” 7/1/2016</td>
</tr>
<tr>
<td>9/2015</td>
<td>BCBSA National medical policy review. Policy revised with clarification of policy statements to indicate that the use of EITHER an external long term monitor OR an implantable monitor (but not both) is medically necessary for the evaluation of cryptogenic stroke. Effective 9/1/2015.</td>
</tr>
<tr>
<td>1/2015</td>
<td>BCBSA National medical policy review. The phrase “for patients with cryptogenic stroke” removed from the investigational policy statement. Effective 1/1/2015.</td>
</tr>
<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>6/2014</td>
<td>Language on MCOT clarified.</td>
</tr>
<tr>
<td>4/2014</td>
<td>BCBSA National medical policy review. Revisied to change “loop monitors” to “ambulatory event monitors” and add “The policy statement on outpatient cardiac telemetry was reworded and language was added that the least costly alternative may be considered medically necessary.” Effective 4/1/2014.</td>
</tr>
<tr>
<td>3/2014</td>
<td>BCBSA National medical policy review. 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.” Effective 3/1/2014.</td>
</tr>
<tr>
<td>1/2014</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>6/1/2013</td>
<td>BCBSA National medical policy review. Changes to policy statements.</td>
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</tbody>
</table>
### Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
- [Medical Policy Terms of Use](#)
- [Managed Care Guidelines](#)
- [Indemnity/PPO Guidelines](#)
- [Clinical Exception Process](#)
- [Medical Technology Assessment Guidelines](#)

### References


64. 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


Endnotes

1 Based on expert opinion