Protocol

Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

(20208)

Medical Benefit		**Effective Date**: 07/01/17	**Next Review Date**: 05/19
Preauthorization	No	**Review Dates**: 05/07, 07/08, 09/09, 09/10, 01/11, 01/12, 01/13, 01/14, 09/14, 05/15, 05/16, 05/17, 05/18	

This protocol considers mobile cardiac outpatient telemetry investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With signs and/or symptoms suggestive of arrhythmia	Interventions of interest are: • Patient- or autoactivated external ambulatory event monitoring • Continuous ambulatory monitoring storing information > 48 hours	Comparators of interest are: • Electrocardiogram only or 24- to 48-hour Holter monitoring	Relevant outcomes include: • Overall survival • Morbid events
Individuals: • With atrial fibrillation following ablation	Interventions of interest are: • Long-term ambulatory cardiac monitoring	Comparators of interest are: • Electrocardiogram only or 24- to 48-hour Holter monitoring	Relevant outcomes include: • Overall survival • Morbid events • Medication use • Treatment-related morbidity
Individuals: • With cryptogenic stroke with negative standard workup for atrial fibrillation	Interventions of interest are: • Long-term ambulatory cardiac monitoring	Comparators of interest are: • Standard evaluation for stroke, including electro-cardiogram and 24-hour Holter monitoring	Relevant outcomes include: • Overall survival • Morbid events • Medication use • Treatment-related morbidity
Individuals: • Who are asymptomatic with risk factors for atrial fibrillation	Interventions of interest are: • Long-term ambulatory cardiac monitoring	Comparators of interest are: • No additional evaluation or standard care	Relevant outcomes include: • Overall survival • Morbid events • Medication use • Treatment-related morbidity
Individuals: • With signs and/or symptoms suggestive of arrhythmia with infrequent symptoms	Interventions of interest are: • Patient- or autoactivated implantable ambulatory event monitoring	Comparators of interest are: • No additional evaluation or standard care • Patient- or autoactivated external ambulatory event monitoring	Relevant outcomes include: • Overall survival • Morbid events • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With signs and/or symptoms suggestive of arrhythmia	Interventions of interest are: • Outpatient cardiac telemetry	Comparators of interest are: • Patient- or autoactivated external ambulatory event monitoring	Relevant outcomes include: • Overall survival • Morbid events

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 (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.

SUMMARY OF EVIDENCE

For individuals who have AF following ablation or who have cryptogenic stroke with a negative standard workup for AF 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 post-stroke or after catheter ablation for AF 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 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 one 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 one noncomparative study. Relevant outcomes are overall survival, morbid events, medication use, and treatment-related morbidity. A single study was identified. It 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 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 (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 assessing prolonged ILRs in patients have reported high rates of arrhythmia detection compared with external event 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 that the technology results in a meaningful improvement in the net health outcome.

For individuals who have signs and/or symptoms suggestive of arrhythmia who receive outpatient cardiac telemetry, the evidence includes one 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. 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.

POLICY

The use of patient activated or autoactivated external ambulatory event monitors 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 (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 (see Policy Guidelines).

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 (see Policy Guidelines).

The use of outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry) as a diagnostic alternative to ambulatory event monitors in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope) is considered **investigational.**

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

POLICY GUIDELINES

The available evidence suggests that long-term monitoring for atrial fibrillation after cryptogenic stroke or post-ablation 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.

Therefore, for the evaluation of patients with cryptogenic stroke who have had a negative standard work-up 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**.**

MEDICARE ADVANTAGE

Except for this additional medically necessary statement, the above policy statements and guidelines apply for Medicare Advantage.

Telephonic EKG transmissions are considered **medically necessary** as a diagnostic service for the indications below:

1. Detect, characterize, and document symptomatic transient arrhythmias;
2. Initiate, revise, or discontinue arrhythmic drug therapy; or,
3. Carry-out early post-hospital monitoring of patients discharged after myocardial infarction (MI); (only if 24-hour coverage is provided).

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.

BACKGROUND

AMBULATORY CARDIAC RHYTHM MONITORING

Ambulatory cardiac monitoring with a variety of devices permits 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 to detect 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).

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, for patients in whom an ECG is not diagnostic, longer monitoring may be indicated. The 2009 joint guidelines from the European Society of Cardiology and three other specialty societies suggested that, in individuals with clinical or ECG features suggesting an arrhythmic syncope, ECG monitoring is indicated; the guidelines also stated 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, have recommended 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 indicated 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 (e.g., 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 was recommended by American Heart Association, American College of Cardiology, and Heart Rhythm Society in 2014 joint guidelines on 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 24 to 72 hours. Traditionally, most Holter monitors had three channels based on three 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 (e.g., 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

Device Class	Description	Device Examples
Noncontinuous devices with memory (event	Devices not worn continuously but rather activated by patient and applied to skin in the	• Zio® Event Card (iRhythm Technologies, San Francisco, CA)

Device Class	Description	Device Examples
recorder)	precordial area when symptoms develop	• REKA E100™ (REKA Health, Bridgewater, NJ)
Continuous recording devices with longer recording periods	Devices continuously worn and continuously record via one or more cardiac leads and store data for a longer period 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. If device is activated, the ECG is then recorded from the memory loop for the *preceding* 30-90s 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) • Autotriggered or patient-triggered: King of Hearts Express® AF (Card Guard 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) • 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) is a three-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 Zio® Patch, can record two channels for 14 to 40 days.

REGULATORY STATUS

Some of the newer devices are described in the Background section for informational purposes. However, because there may be many devices within each category, a comprehensive description of individual devices is beyond the scope of this review. FDA product codes include: DSH, DXH, DQK, DSI, MXD, MHX.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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