**Policy Statement**

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 any of 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 workup for atrial fibrillation including a 24-hour Holter monitor (see Policy Guidelines section)

The use of implantable ambulatory event monitors, either patient-activated or autoactivated, may be considered medically necessary in either of 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 section)

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, syncope) is considered investigational.

Other uses of ambulatory event monitors, including outpatient cardiac telemetry, are considered investigational, including but not limited to either of the following:

- Monitoring the effectiveness of antiarrhythmic medications
- Detection of myocardial ischemia by detecting ST-segment changes

**Policy Guidelines**

The available evidence suggested 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 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.

**Effective January 1, 2018**, the following CPT codes are specific to the KardiaMobile device (AliveCor, Inc.) and is considered mobile cardiac outpatient telemetry:

- **0497T**: External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recorder without 24 hour attended monitoring; in-office connection
• **0498T**: External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recording without 24 hour attended monitoring; review and interpretation by a physician or other qualified health care professional per 30 days with at least one patient-generated triggered event

**Examples of Cardiac Monitoring Devices and Procedural Coding (not all inclusive):**
For a complete description of the codes, see the Coding section of the Medical Policy.

<table>
<thead>
<tr>
<th>Cardiac Event Monitoring Device</th>
<th>Product Name</th>
<th>CPT Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>External Ambulatory Event Monitors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Noncontinuous devices with memory</td>
<td>Zio® Event Card (iRhythm Technologies, Inc., San Francisco, CA)</td>
<td>93268, 93270, 93271, 93272</td>
</tr>
<tr>
<td>Autoactivated or patient-activated</td>
<td>REKA E100™ (REKA Health, San Diego, CA)</td>
<td>(See *Note below)</td>
</tr>
<tr>
<td><strong>Implantable Ambulatory Event Monitors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuous “memory loop” devices</td>
<td>Reveal® Insertable Loop Recorder (Medtronic Inc., Minneapolis, MN)</td>
<td>33282</td>
</tr>
<tr>
<td></td>
<td>Reveal LINQ™ (Medtronic Inc., Minneapolis, MN)</td>
<td></td>
</tr>
<tr>
<td><strong>Mobile Outpatient Cardiac Telemetry (MCOT)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>CardioNet Mobile Cardiac Outpatient Telemetry™ (MCOT™) (CardioNet, Inc., Conshohocken, PA)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HEARTLink™ II system (Cardiac Telecom Corporation, Greensburg, PA)</td>
<td>93228, 93229</td>
</tr>
<tr>
<td></td>
<td>Vital Signs Transmitter (VST™) Monitor (Biowatch Medical, Columbia, SC)</td>
<td>(See **Note below)</td>
</tr>
<tr>
<td></td>
<td>Lifestar Ambulatory Cardiac Telemetry (ACT) system (LifeWatch Technologies, Ltd., Rehovot, Israel)</td>
<td></td>
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<tr>
<td><strong>Continuous Monitoring Devices with Longer Recording Periods</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Zio® Patch (iRhythm Technologies, Inc., San Francisco, CA)</td>
<td>0295T, 0296T, 0297T, 0298T</td>
</tr>
<tr>
<td></td>
<td>BodyGuardian® Remote Monitoring System (Preventice®, Inc., Minneapolis, MN)</td>
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</tbody>
</table>

*Note*: CPT code (93268) represents a bundled CPT code including all components of AEM monitoring, including ECG analysis of all the recorded strips during a 30-day period. CPT codes (93270, 93271, and 93272) represent unbundling of CPT code 93268.

Ambulatory event monitoring services may supply the monitoring, receipt of transmissions and analysis of the ECGs (i.e., CPT codes 93271 and 93272), but the provider supplies the hook-up and disconnection of the device (i.e., CPT code 93270). If this is the case, the unbundled codes may be used. It should also be noted that CPT code 93272 (physician review and interpretation) applies to all ECGs transmitted during a 30-day period; therefore, billing for each individual transmitted strip is not warranted.

**Note**: CPT codes (93228 and 93229) can only be reported once per 30 days of service.

**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 to the patient or 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.
2.02.08 Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry
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Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of the FDA-approved technologies on the basis of medical necessity alone.

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, and MHX.

Rationale

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 3 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.” 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.⁵⁶ 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 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 (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**

<table>
<thead>
<tr>
<th>Device Class</th>
<th>Description</th>
<th>Device Examples</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></td>
<td></td>
<td>• REKA E100™ (REKA Health, Bridgewater, NJ)</td>
</tr>
<tr>
<td>Continuous recording devices with longer recording periods</td>
<td>Devices continuously worn and store data for a longer period than traditional Holter (14 d)</td>
<td>• Zio® Patch system (iRhythm Technologies)</td>
</tr>
<tr>
<td>External memory loop devices (patient- or autotriggered)</td>
<td>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 30-90 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).</td>
<td>• Patient-triggered: Explorer™ Looping Monitor (LifeWatch Services, Switzerland)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Autotriggered: LifeStar AF Express™ Auto-Detect Looping Monitor (LifeWatch Services)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Autotriggered or patient-triggered: King of Hearts Express® AF (Card Guard Scientific Survival, Rehovot, Israel)</td>
</tr>
<tr>
<td>Implantable memory loop devices (patient- or autotriggered)</td>
<td>Devices similar in design to external memory loop devices but implanted under the skin in the precordial region</td>
<td>• Autotriggered: Reveal® XTICM (Medtronic, Minneapolis, MN)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Autotriggered: BioMonitor, Biotronik SE (Berlin, Germany)</td>
</tr>
<tr>
<td>Mobile cardiac outpatient telemetry</td>
<td>Continuously recording or autotriggered memory loop devices that transmit data to a central recording station with real-time monitoring and analysis</td>
<td>• CardioNet MCOT (BioTelemetry, Malvern, PA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• LifeStar Mobile Cardiac Telemetry (LifeWatch Services)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• SEEQ Mobile Cardiac Telemetry (Medtronic, Minneapolis, MN)</td>
</tr>
</tbody>
</table>

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, 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 2 channels for 14 to 40 days.

**Literature Review**

This review is structured around 3 questions: First, in what clinical situations, and with what classes of ambulatory event monitors (AEMs), do AEMs improve health outcomes? Second, under what circumstances are implantable AEMs associated with improved outcomes? Third, under what circumstances is real-time monitoring associated with improved outcomes?

For some of AEMs discussed herein, including monitors that include real-time monitoring and analysis, the technologies represent an enhancement to existing technology and are intended to improve outcomes compared with event monitors. As such, to demonstrate an improvement in health outcomes, there must be a clinically significant incremental benefit when the additional technology, such as real-time monitoring, is added. The following is a summary of the key literature to date.

**AEMs in the detection of Arrhythmias**

The following section focuses on the clinical situations for which the use of AEMs is associated with improved health outcomes. Two clinical situations are considered. First, the use of AEMs in
the diagnosis of cardiac rhythm abnormalities in individuals with signs and/or symptoms of arrhythmias (e.g., dizziness, syncope or near syncope, palpitations) is discussed. Specific arrhythmias may be relatively nonspecific in terms of the symptoms they cause. However, the diagnosis of some arrhythmias has well-defined management implications that are known to improve outcomes, such as the use of an implantable cardioverter defibrillator (ICD) in individuals with potentially lethal arrhythmias, or antiarrhythmic drugs or pulmonary vein isolation for the treatment of atrial fibrillation (AF). Therefore, identification of an arrhythmia is considered a reasonable end point in this case.

The second clinical situation relates to the use of AEMs in the detection of AF in clinical situations potentially associated with the presence of AF, which may not be associated with symptoms (e.g., dizziness, syncope), but for which management may be changed as a result. This circumstance may occur in the identification of AF following catheter ablation, if management changes may occur if AF can reliably be excluded (e.g., discontinuing antiarrhythmic drugs). The second situation is in the identification of AF following cryptogenic stroke.

Diagnosis of Suspected Arrhythmias in Symptomatic Patients

The diagnostic yield of monitoring with external event monitors depends on the underlying population, the inherent sensitivity of the device, and the duration of monitoring. External loop recorders have an established role in current clinical practice in evaluating suspected arrhythmias. A few pieces of evidence suggested that autotriggered event monitors have an inherently higher yield than patient-activated AEMs. Several studies, including an analysis of a database of 100,000 patients, have compared the diagnostic yield of automatic and patient-activated arrhythmia recordings and reported an improved yield with autotriggering devices.7-9 Hoefman et al (2010) published a systematic review on diagnostic tools for detecting cardiac arrhythmias.10 This analysis included studies of patients presenting with palpitations and compared the yield of remote monitoring for several classes of devices: Holter monitors, patient-activated event recorders, autotriggered event recorders, and implantable loop recorders (ILRs). The yield varied among devices, with the autotrigger devices offering the highest range of detection (72%-80%), followed by the patient-activated devices (17%-75%), and Holter monitors (33%-35%).

Continuous Monitors with Longer Recording Periods

Newer devices are available that record cardiac rhythms continuously, but for longer periods of time than traditional Holter monitors. For example, the Zio Patch continuously records and stores information for up to 2 weeks. In addition to recording information for longer periods of time, this device uses “near-field” recording electrodes that differ from most other devices.

Several studies have evaluated the diagnostic yield of continuous monitoring for more than 48 hours, either directly through comparison to Holter monitoring or indirectly through determination of the proportion of arrhythmias detected in the first 48 hours of monitoring.

Turakhia et al (2013) published a study evaluating the diagnostic yield of the Zio Patch.11 Data from the manufacturer was used to identify 26,751 first-time users of the device. The most common clinical indications were palpitations (40.3%), AF (24.3%), and syncope (15.1%). Mean duration of use was 7.6 days, and 95.9% of patients wore the device for more than 48 hours. At least 1 episode of an arrhythmia was detected in 16,142 (60.3%) patients. The authors compared the detection rate in the first 48 hours to the detection rate over the entire time the device was worn, with 70.1% of patients having their arrhythmia detected within the first 48 hours and 29.9% having their first arrhythmia detected after the first 48 hours. The overall yield was significantly higher when comparing the total monitored period (62.2%) with the first 48 hours (43.9%; p<0.001). These data confirmed previous studies that had showed a substantial proportion of arrhythmias in symptomatic patients can be detected with a 48-hour period of monitoring and that longer monitoring periods increase the detection rate.
Barrett et al (2014) published a comparison of arrhythmia detection rates in 146 patients who underwent simultaneous monitoring with a 24-hour Holter monitor and a 14-day Zio Patch monitor. Included were patients referred for evaluation of a suspected cardiac arrhythmia at a single institution. For the detection of atrioventricular (AV) block, sinus pause, polymorphic ventricular tachycardia, supraventricular tachycardia (SVT), or AF, Holter monitoring detected 61 arrhythmias, while the Zio Patch detected 96 ($p<0.001$). Over the monitoring period, the same 60 arrhythmia events were detected by both devices, with 36 only detected by the Zio Patch and 1 only detected by the Holter. The investigators conducted within-subject comparisons of arrhythmia detection for the 24-hour period during which both devices were worn. Holter monitoring detected 61 arrhythmia events compared with 52 detected by the Zio Patch ($p=0.013$). This study also suggested that extended monitoring may increase the diagnostic yield of cardiac monitoring. However, a relatively large number of missed events occurred with the Zio Patch during the period of simultaneous monitoring, which may have clinical significance if its performance is similar in nonresearch settings.

In 2016, Solomon et al evaluated the diagnostic yield for potentially high-risk arrhythmias during 14 days of continuous recording with the Zio Patch among 122,454 patients (122,815 recordings) included in a manufacturer registry. Patients included in the series all underwent monitoring with the device from November 2011 to December 2013. Mean wear time was 9.6 days. Overall, there were 22,443 (18%) patients with sustained ventricular tachycardia, 1766 (1.4%) patients with sinus pauses of 3 seconds or more, 521 (0.4%) patients with AF pauses of 3 seconds or more, 249 (0.2%) patients with symptomatic pauses, and 1468 (0.4%) with high-grade heart block, which were considered potentially high-risk arrhythmias. After 24 and 48 hours of monitoring, 52.5% and 65.5%, respectively, of potentially high-risk arrhythmias were detected. Seven days of monitoring identified 92.9% of potentially high-risk arrhythmias.

In 2015, Bolourchi et al evaluated the diagnostic yield of 14 days of monitoring with the Zio Patch in a series of 3209 children included in a manufacturer registry. Patient age ranged from 1 month to 17 years. Indications for monitoring included palpitations ($n=1138$ [95.5%]), syncope ($n=450$ [14.0%]), unspecified tachycardia ($n=291$ [9.1%]), paroxysmal SVT ($n=264$ [8.2%]), and chest pain ($n=261$ [8.1%]). The overall prevalence of any arrhythmia was 12.1%, with 44.1% of arrhythmias occurring after the first 48 hours of monitoring. Arrhythmias were detected in 10.0% of patients referred for palpitations, 6.7% referred for syncope, 14.8% referred for tachycardia, 22.7% referred for paroxysmal SVT, and 6.5% referred for chest pain.

Single-center studies, summarized in Table 2, have reported on the diagnostic yield and timing of detection of arrhythmias in patients monitored with the Zio Patch for a variety of arrhythmias. These studies generally have reported high rates of arrhythmia detection.

Health Quality Ontario published a health technology assessment comparing long-term continuous AEMs to external cardiac loop recorders for detecting arrhythmias in 2017. The assessment included a systematic review of the literature on the effectiveness of both devices for detecting arrhythmias. No studies directly comparing long-term continuous AEMs to external loop recorders were found so indirect comparisons were constructed using 24-hour Holter monitors as the common comparator. Twelve cohort studies were included; 7 addressed long-term AEMs and 5 addressed external loop recorder. Using a meta-regression model to control for variation in device-wearing time and baseline syncope rate, the estimated difference between the long-term continuous AEMs and external loop recorders in their ability to detect arrhythmias was small (risk difference, 0.01; 95% confidence interval [CI], -0.18 to 0.20). Both devices were more effective than a 24-hour Holter. However, the quality of the body of evidence was evaluated as poor using GRADE criteria.

### Table 2: Single-Center Studies Reporting on Zio Patch Yield

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Monitoring Indication</th>
<th>Main Findings</th>
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### Section Summary: Continuous Monitors with Longer Recording Periods

The available evidence on continuously worn cardiac monitors that can store data for longer periods of time than standard Holter monitors indicates that such devices typically detect greater numbers of arrhythmias during extended follow-up than 24- or 48-hour Holter monitoring. The evidence to suggest that long-term continuous monitors are superior to external loop recorders in detecting arrhythmias is not strong.

### AEMS for the detection of AF

AF can be diagnosed using an electrocardiogram (ECG) or on Holter monitoring in individuals with suspected AF; however, a single ECG or short-term Holter monitor may not reliably exclude paroxysmal AF. In some cases where identifying paroxysmal AF is associated with potential changes in management, longer term monitoring may be considered. There are well-defined management changes that occur in patients with AF. However, until relatively recently the specific role of long-term (i.e., >48 hours) monitoring in AF was not well-described.

### Patients with AF Treated with Catheter Ablation

Many patients with AF treated with catheter ablation are on long-term anticoagulation, and all patients treated with ablation are given anticoagulation for up to 3 months postprocedure. In patients with an apparently successful ablation who do not show signs or symptoms of recurrent AF at time periods longer than 3 months postablation, a decision whether to continue treatment with anticoagulants needs to be made. Studies have demonstrated that late recurrences are not uncommon after ablation and that these recurrent episodes are often asymptomatic. In addition, the presence of recurrent episodes of AF is a predictor of future thromboembolic events. In a larger observational study of 565 patients postablation, the 2 major predictors of thromboembolism were the CHADS\textsubscript{2} score and the presence of recurrent episodes of AF. In a prospective, randomized study, Kapa et al (2013) compared implantable loop monitors with conventional transtelephonic recorders in the assessment of arrhythmia burden after catheter ablation of AF. Forty-four patients were enrolled and randomized; all patients received the ILR postablation. Six patients were excluded due to requests for device removal or loss to follow-up. During the first 6 months after ablation, all subjects underwent conventional monitoring that...
consisted of twice daily 1-minute pulse rate assessments by the patient and three 30-day transtelephonic monitoring periods. At 6 months postablation, patients were allocated to the randomization arm (on a 1:1 basis at initial enrollment) of either the ILR (transmission of data every 31 days) or conventional monitoring (twice daily 1-minute pulse-rate assessment, 1 transtelephonic recording for 30 days at month 11). Over the first 6 months after ablation, conventional monitoring revealed AF in 7 (18%) of 38 patients and the ILR confirmed AF in all of these patients. In an additional 11 (29%) patients, AF was detected on ILR. During the subsequent 6-month period, 5 of 18 patients in the conventional monitoring arm refused ongoing monitoring due to discomfort and lifestyle restrictions; of the remaining 13, 5 (38%) had a recurrence of AF. In the ILR group, 5 of 20 patients had recurrence of AF. In the ILR arm, 71% patients had their antiarrhythmic drugs discontinued compared with 44% in the conventional monitoring group over the randomization period (p=0.04).

A 2013 prospective study, which evaluated the incidence of asymptomatic AF episodes for 18 months postablation (using an implantable cardiac monitoring), followed 50 patients using cardiac monitoring. Based on symptoms alone, 29 (58%) of 50 patients were arrhythmia-free after ablation; based on occurrence of symptoms or the detection of AF on intermittent (every 3 month) ECG or Holter monitor, 28 (56%) patients were arrhythmia-free postablation. Six (12%) patients had arrhythmias detected on implantable monitoring alone.

Several other observational studies have followed patients who stopped anticoagulation after an evaluation that included ambulatory monitoring was negative for recurrent episodes. These patients appear to have a low subsequent rate of thromboembolic events. In 1 such study (2010) of 3355 patients from 5 clinical centers, 2692 discontinued anticoagulation at 3 to 6 months postablation. During a mean follow-up of 28 months, 2 (0.07%) patients who discontinued anticoagulation experienced an ischemic stroke. This rate did not differ significantly from the stroke rate in patients who continued anticoagulation (0.45%). The rate of major hemorrhage was lower for patients who discontinued anticoagulation (2%) than from those who continued (0.04% p<0.001).

Section Summary: Patients with AF Treated With Catheter Ablation
This evidence makes a strong indirect argument that long-term monitoring for asymptomatic episodes of AF with AEMs will lead to changes in management of long-term anticoagulation. These changes in management based on ambulatory monitoring are likely to improve outcomes.

Patients with Cryptogenic Stroke
Approximately 5% of patients with cryptogenic stroke will have AF diagnosed on ECG and/or telemetry monitoring in the hospital. The use of continuous telemetry monitoring has been compared with Holter monitoring for patients hospitalized for stroke or transient ischemic attack (TIA); these results are inconclusive as to which is the preferred method. Longer term ambulatory event monitoring will identify additional patients with asymptomatic episodes, with rates of detection estimated at 6% to 26% of patients.

Systematic Reviews
In 2015, Sposato et al reported results of a systematic review and meta-analysis of studies assessing rates of newly diagnosed AF after cryptogenic stroke or TIA based on cardiac monitoring, stratified into 4 sequential screening phases: phase 1 (emergency department) consisted of admission ECG; phase 2 (in hospital) comprised serial ECG, continuous inpatient ECG monitoring, continuous inpatient cardiac telemetry, and in-hospital Holter monitoring; phase 3 (first ambulatory period) consisted of ambulatory Holter monitoring; and phase 4 (second ambulatory period) consisted of mobile cardiac outpatient telemetry (MCOT), external loop recording, and implantable loop recording. In total, 50 studies with 11,658 patients met the inclusion criteria. Studies were mixed in their patient composition: 22 (28%) included only cryptogenic stroke cases, 4 (5%) stratified events into cryptogenic and noncryptogenic, and 53 (67%) included unselected patient populations. The summary proportion of patients diagnosed
with poststroke AF was 7.7% (95% CI, 5.0% to 10.8%) in phase 1, 5.1% (95% CI, 3.8% to 6.5%) in phase 2, 10.7% (95% CI, 5.6% to 17.2%) in phase 3, and 16.9% (95% CI, 13.0% to 21.2%) in phase 4. The overall AF detection yield after all phases of sequential cardiac monitoring was 23.7% (95% CI, 17.2% to 31.0%). In phase 4, there were no differences between the proportion of patients diagnosed with poststroke AF by MCOT (15.3% 95% CI, 5.3% to 29.3%), external loop recording (16.2% 95% CI, 0.3% to 24.6%), or ILR (16.9% 95% CI, 10.3% to 24.9%; p=0.97).

Kishore et al (2014) conducted a systematic review and meta-analysis of prospective observational studies and RCTs that have reported detection rates of newly diagnosed AF in patients with ischemic stroke or TIA who had had any cardiac monitoring for at least 12 hours. 29 Thirty-two studies were selected: 18 studies that included patients with ischemic stroke only, 1 study included TIA only, and 13 studies included both ischemic stroke and TIA. Reviewers reported significant study heterogeneity. Among unselected patients (i.e., selected on the basis of stroke pathogenesis, age, or prescreening for AF), the detection rate of any new AF was 6.2% (95% CI, 4.4% to 8.3%); among selected patients, it was 13.4% (95% CI, 9.0% to 18.4%). In cryptogenic strokes, new AF was detected in 15.9% of patients (95% CI, 10.9% to 21.6%). Among selected patients, the AF detection rate during 24-hour Holter monitoring was 10.7% (95% CI, 3.4% to 21.5%), while the detection rate during monitoring beyond 24 hours (including more prolonged Holter monitoring, implantable and nonimplantable loop recording, and MCOT) was 14.7% (95% CI, 10.7% to 19.3%).

The Kishore study and others have suggested that longer periods of cardiac monitoring increase the likelihood of AF detection. However, many of these asymptomatic episodes of AF are brief and their relation to the preceding stroke uncertain, because there are other potential causes of asymptomatic stroke. The ideal study to evaluate the role of cardiac monitoring in the management of patients with cryptogenic stroke would be trials that randomize patients to a strategy involving event monitoring or routine care with evaluation of rates of detection of AF and stroke-related outcomes.

Randomized Controlled Trials
Four RCTs were identified that evaluated ambulatory monitoring in patients with cryptogenic stroke. Two were small pilot trials. One small RCT published in 2013 randomized 40 patients with cryptogenic ischemic stroke or high-risk TIA to usual care or to 21 days of MCOT.30 There were no cases of AF detected in either group. Two patients in the MCOT group had nonsustained ventricular tachycardia detected, which was of uncertain clinical significance in relation to their strokes.

A second small pilot trial published in 2013 by Higgins et al randomized 100 patients with ischemic stroke and no history of AF presenting within 7 days of a cryptogenic ischemic stroke to standard practice investigations, which may have included 12-lead ECG, 24-hour Holter monitoring, and/or echocardiography, at the discretion of the treating practitioner, or to standard practice plus cardiac event monitoring with Novacor R-test Evolution 3 device.31 At 90-day follow-up, any-duration paroxysmal AF was more commonly detected in the event monitoring group (48% vs 10%; risk difference, 38%; 95% CI, 21.8% to 54.1%; p<0.001).

Two larger RCTs have also been published. Sanna et al (2014) reported results from the CRYSTAL-AF trial, an RCT that evaluated whether long-term monitoring with implantable cardiac monitors (ICMs) in patients who had cryptogenic stroke would lead to changes in anticoagulant management and/or improved outcomes.32 The trial randomized 441 patients to continuous monitoring with the Reveal XT ICM or routine care. Eligibility criteria included no known history of AF, cryptogenic stroke, or TIA with infarct, and no mechanism determined after a workup that included 12-lead ECG, 24-hour Holter monitoring, transthoracic echocardiography, CT or magnetic resonance angiography of the head and neck, and hypercoagulability screening (for patients <55 years old). Analysis was intention-to-treat. Of the 441 patients randomized, 416 (94.3%) completed 6 months of follow-up, 2 were lost to follow-up, 5 died, and 18 exited the trial before 6 months. Crossover occurred in 12 patients in the ICM group and 6 in the control group.
AF was detected in 8.9% of the ICM group compared with 1.4% of the control group (hazard ratio [HR], 6.43; 95% CI, 1.90 to 21.74). Median time from randomization to detection of AF was 41 days (interquartile range [IQR], 14-84 days) in the ICM group and 32 days (IQR, 2-73 days) in the control group. Most AF episodes in the ICM group were asymptomatic (74%) compared with 33% in the control group. The rate of AF detection was similarly greater in the ICM group at the 12-month follow-up (12.4% vs 2.0%; HR=7.3; 95% CI, 2.6 to 20.8; p<0.001). Use of oral anticoagulants was 10.1% in the ICM group and 4.6% in the control group at 6 months (p=0.04) and 14.7% and 6.0% at 12 months (p=0.007), respectively. Five (2.4%) of the 208 ICMs inserted were removed due to infection or erosion of the device pocket.

Brachmann et al reported on 3-year follow-up from the CRYSTAL-AF trial in 2016.34 At trial closure, 48 subjects had completed 3 years of follow-up (n=24 in each treatment group). By 3 years, the hazard ratio for detecting AF for ICM-monitored versus control patients was 8.8 (95% CI, 3.5 to 22.2; p<0.001).

Also, in 2014, Gladstone et al reported results from the EMBRACE study, an RCT that compared 30-day autotriggered cardiac event monitors with conventional 24-hour monitors for the detection of AF in patients with cryptogenic stroke.35 Included patients were ages 55 years or older, with no known history of AF, and an ischemic stroke or TIA of undetermined cause within the prior 6 months. All patients underwent standard screening for AF with 1 or more ECGs and 1 or more 24-hour Holter monitors. Five hundred seventy-two patients were randomized to an external loop recorder (ER910AF Cardiac Event Monitor, Braemar) or to a 24-hour Holter monitor. Among intervention group subjects, 82% completed at least 3 weeks of monitoring. AF was detected in 45 (16.1%) of 280 patients in the intervention group compared with 9 (3.2%) of 277 patients in the control group (risk difference, 12.9 percentage points; 95% CI, 8.0 to 17.6; p<0.001). At 90-day follow-up, patients in the intervention group (18.6%) were more likely to be treated with anticoagulants than those in the control group (11.1%; absolute treatment difference, 7.5 percentage points; 95% CI, 1.6 to 13.3; p=0.01).

Other Studies
Nonrandomized and noncomparative studies published before the RCTs described above have reported on AF detection rates after cryptogenic stroke and long-term monitoring with various devices, including ILRs,6,36,37 and continuous monitors with longer recording periods,38 along with a pilot study evaluating the Zio Patch for AF detection poststroke.39

Section Summary: Patients with Cryptogenic Stroke
Randomized studies have demonstrated that ILRs are associated with higher rates of AF detection than Holter monitors among patients with cryptogenic stroke, including 2 larger RCTs. Because most patients with a history of stroke who have AF detected will be treated with anticoagulation, and because anticoagulation is an effective treatment for stroke prevention, it can be concluded that longer term monitoring of patients with cryptogenic stroke will improve outcomes.

AF Detection in Asymptomatic Patients
Screening for AF in asymptomatic patients has been proposed to reduce burden of stroke. Evaluating the net benefits of screening for AF in unselected patients requires considering the potential risk of stroke in absence of screening, the incremental benefit of earlier versus later treatment for stroke resulting from earlier detection of AF, and the potential harms of overdiagnosis.

Assessing the prevalence of asymptomatic AF is difficult because of the lack of symptoms. Those who are asymptomatic have been estimated to constitute approximately a third of all patients with AF.40 Studies have suggested that most paroxysmal episodes of AF are asymptomatic.41,42 It is uncertain whether patients with paroxysmal AF have a stroke risk comparable to those with persistent or permanent AF; some studies have suggested the risk of stroke is similar43,44 while a 2016 systematic review of 12 studies (total N=99,996 patients) suggested the risks of

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thromboembolism and all-cause mortality were higher with nonparoxysmal compared to paroxysmal AF. The clinical management of symptomatic and asymptomatic AF is the same. Anticoagulation should be initiated if reduction in risk of embolization exceeds complications due to increase bleeding risk regardless of AF symptoms.

Screening for AF in asymptomatic patients could be either systematic or targeted to high-risk populations. European guidelines for screening for AF are based on a 2007 large-cluster RCT of opportunistic pulse taking versus systematic screening with 12-lead ECG or standard care in general practice. This RCT showed that systematic and opportunistic screening detected similar rates of AF and both were superior to standard care. The mechanisms of how and when to screen for AF in unselected populations have not been well-studied.

In 2015, Turakhia et al reported results for a single-center noncomparative study evaluating the feasibility and diagnostic yield of a continuous recording device with longer recording period (Zio Patch) for patients with risk factors for AF. The study included 75 patients older than age 55 with at least 2 of risk factors for AF (coronary disease, heart failure, hypertension, diabetes, or sleep apnea), without a history of prior AF, stroke, TIA, implantable pacemaker or defibrillator, or palpitations or syncope in the prior year. Of the 75 subjects, 32% had a history of significant valvular disease and 9.3% had prior valve replacement. Most subjects were considered at moderate to high risk of stroke (CHA2DS2-VASc scores ≥2 in 97% of subjects). AF was detected in 4 (5.3%) subjects, all of whom had CHA2DS2-VASc scores of 2 or greater. All patients with AF detected had an initial episode within the first 48 hours of monitoring. Five patients had detected episodes of atrial tachyarrhythmias lasting at least 60 seconds.

**Section Summary: AF Detection in Asymptomatic Patients**

For the use of ambulatory monitoring in the diagnosis of AF in asymptomatic but higher risk patients, a small noncomparative study have demonstrated that 14-day monitoring with the Zio Patch is feasible. The use of population-based screening for asymptomatic patients is not well-established, and several studies are underway to evaluate population-based screening and may influence the standard of care for AF detection in those without symptoms or a history of stroke or TIA. To determine whether outcomes are improved for ambulatory monitoring for AF in patients without a history of stroke or TIA or treated AF, studies comparing the outcomes for various outpatient diagnostic screening strategies for AF would be needed.

**Implantable Loop Recorders**

This section discusses the use of ILRs, with a focus on clinical situations when use of an ILR at the beginning of a diagnostic pathway is indicated. It is expected that a longer period of monitoring with any device category is associated with a higher diagnostic yield. A progression in diagnostics, from an external event monitor to ILR, in cases where longer monitoring is needed is considered appropriate. However, there may be situations where it is sufficiently likely that long-term monitoring will be needed that an ILR as an initial strategy may be reasonable.

**ILR Use in Individuals with Signs and/or Symptoms of Arrhythmia**

In 2016, Burkowitz et al reported on a systematic review and meta-analysis of ILRs in the diagnosis of syncope and the detection of AF. These indications are discussed separately in this review. For syncope diagnosis, the review identified 3 RCTs comparing ILRs with a conventional diagnosis strategy (Holter monitoring) in all 3 studies. In pooled analysis, an ILR diagnosis strategy was associated with a higher likelihood of the end point of diagnostic yield (relative risk, 4.17; 95% CI, 2.57 to 6.77; I²=14%).

In 2014, Podoleanu et al reported results of an open-label RCT comparing 2 strategies for evaluating syncope - an experimental strategy involving the early use of an ILR and a conventional strategy. The trial included patients who had a single syncope (if severe and recent) or at least 2 syncope in the past 12 months. The syncope had to be unexplained at the end of clinical examination and a workup including 12-lead ECG, echocardiography, and head-up tilt-test. The 78 selected patients were randomized to an ILR (the Reveal or Reveal Plus...
devices, MN; n=39) immediately or to assessment using the conventional evaluation strategy (n=39), excluding the use of an ILR. After 14 months of follow-up, a definitive cause of syncope was established in 18 (46.2%) of patients in the ILR group and in 2 (5%) in the conventionally managed group (p<0.001). Arrhythmic causes of syncope in the ILR group included 2 (5%) cases of AV block, 4 (10%) cases of sinus node disease, 1 (2.5%) case of AF, 1 (2.5%) case of ventricular fibrillation, and 3 (8%) other tachycardias. In the conventionally managed group, 8 patients had a diagnosis of presumed reflex syncope.

A small 2013 RCT compared use of an ILR to a conventional follow-up strategy in 78 patients with a first episode of syncope.50 A significant number of patients had cardiomyopathy (23%), AF (15.4%), and/or bundle branch block (58%) on ECG. Mean follow-up time was 27 months. Twenty-one (27%) patients had at least 1 arrhythmia detected, with a significant difference in the detection rate for the ILR group (36.6%) compared with the conventional follow-up group (10.8%; p=0.02).

Giada et al (2007) conducted an RCT assessing 2 diagnostic strategies in 50 patients with infrequent (≤1 episode per month) unexplained palpitations—an ILR strategy (n=26) and a conventional strategy (n=24) including 24-hour Holter, 4 weeks of ambulatory ECG monitoring with an external recorder, and an electrophysiologic study if the 2 prior evaluations were negative).51 Prior cardiac evaluation in eligible patients included standard ECG and echocardiography. Rhythm monitoring was considered diagnostic when a symptom-rhythm correlation was demonstrated during spontaneous palpitations that resembled pre-enrollment symptoms. In the conventional strategy group, a diagnosis was made in 5 (21%) subjects, after a mean time to diagnosis of 36 days, based on external ECG monitoring in 2 subjects and electrophysiologic studies in 3 subjects. In the ILR group, a diagnosis was made in 19 subjects (73%; vs conventional group, p<0.001) after a mean time to diagnosis of 279 days.

In 2004, Farwell et al reported on results of an RCT comparing the diagnostic yield of an ILR (Reveal Plus) with a conventional diagnostic strategy in 201 patients with unexplained syncope.52 Eligible patients were evaluated at a single institution for recurrent syncope and had no definitive diagnosis after a basic initial workup (including 12-lead ECG, Holter monitoring in patients with suspected cardiac syncope, upright cardiac sinus massage, and tilt-table testing). At last follow-up, more loop recorder patients (33%) had an ECG diagnosis than control patients (4%; HR for ECG diagnosis 8.93; 95% CI, 3.17 to 25.19; p<0.001). Seven of the loop recorder patients had a diagnosis made with the device’s autotrigger feature. In the loop recorder group, 34 patients had an ECG-directed therapy initiated (vs 4 in the control group; HR=7.9; 95% CI, 2.8 to 22.3). No device-related adverse events were reported.

An earlier (2001) RCT reported by Krahn et al with a similar design compared a conventional monitoring strategy (ELR monitoring for 2-4 weeks, followed by tilt-table and electrophysiologic testing) with at least 1 year of monitoring to an ILR in 60 subjects with unexplained syncope (n=30 per group).53 Eligible patients had previously had clinical assessment, at least 24 hours of continuous ambulatory monitoring or inpatient telemetry, and a transthoracic echocardiogram. A diagnosis was made in 20% of those in the conventional monitoring arm and in 52% of those in the ILR arm (p=0.012).

In a report from an observational registry of patients who received or were about to receive an ILR (the Reveal Plus, DX, or XT device) because of unexplained syncope, Edwardsson et al (2014) described the monitoring yield in 570 patients implanted and followed for at least a year or until diagnosis.54 Most (97.5%) patients had a standard ECG before initiation of the ILR, 11.8% had prior ELR, and 54.6% had in-hospital ECG monitoring. During the monitoring period, 218 (38%) patients had recurrent syncope. The proportion of specific diagnoses based on the ILR is not reported, but of subjects who had a recurrence, 42.2% had a pacemaker implanted, 4.6% had an ICD placed, 4.1% received antiarrhythmic drug therapy, and 3.7% underwent catheter ablation.
Other observational studies have reported on the yield of arrhythmia diagnosis in patients with symptoms monitored with ILRs. Bhangu et al (2016) reported on the diagnostic yield of ILRs in a series of 70 elderly patients with unexplained falls.

**ILRs in the Detection of AF**

As noted in the preceding section (AEMs for the Detection of AF), some trials have demonstrated improved outcomes with monitoring strategies (i.e., the CRYSTAL AF) that used ILRs. Autotrigger ILRs have also been developed specifically to detect AF through the use of detection algorithms. Several nonrandomized studies have evaluated the accuracy of autotriggered ILRs for the diagnosis of AF.

Hindricks et al (2010) evaluated the accuracy of an autotriggered ILRs in 247 patients at high risk for paroxysmal AF. All patients underwent simultaneous 46-hour continuous Holter monitoring, and the authors calculated the performance characteristics of the loop recorder using physician-interpreted Holter monitoring as the criterion standard. The sensitivity of the loop recorder for detecting AF episodes of 2 minutes or more in duration was 88.2%, increasing to 92.1% for episodes of 6 minutes or more. AF was falsely identified by the loop recorder in 19 of 130 patients who did not have AF while on a Holter monitor, for a false-positive rate of 15%. AF burden was accurately measured by the loop recorder, with the mean absolute difference between the loop recorder and Holter monitor of 1.4% (SD=6.4%).

Hanke et al (2009) compared an autotrigger ILR with 24-hour Holter monitoring done at 3-month intervals in 45 patients who had undergone surgical ablation for AF. After a mean follow-up of 8.3 months, the ILR identified AF in 19 (42%) patients in whom Holter monitoring recorded sinus rhythm.

In 2015, Afzal et al reported on a systematic review and meta-analysis of studies comparing ILRs with wearable AEMs for prolonged outpatient rhythm monitoring after cryptogenic stroke. Reviewers included 16 studies (total N=1770 patients) - 3 RCTs and 13 observational studies. For ILR-monitored patients, the median monitoring duration was 365 days (range, 50-569 days), while for wearable device-monitored patients, the median monitoring duration was 14 days (range, 4-30 days). Compared with wearable AEMs, ILRs were associated with significantly higher rates of AF detection (23.3% vs 13.6%; odds ratio, 4.54; 95% CI, 2.92 to 7.06; p<0.05).

In the 2016 Burkowitz systematic review (described above), for the indication of cryptogenic stroke, 1 RCT and 5 noncomparative studies met inclusion criteria. The sole RCT identified was that by Sanna et al (described above).

In 2015, Ziegler et al reported on a large (N=1247) set of patients identified from the manufacturer’s registry undergoing ILR monitoring for AF detection after a cryptogenic stroke. Over a median follow-up of 182 days, 1521 episodes of AF were detected in 147 patients. Overall, 42 (29%) patients had a single episode of AF and 105 (71%) patients had multiple episodes. The overall detection rate (12.2% at 182 days) was somewhat higher than that reported in the CRYSTAL AF trial.

Sanders et al (2016) reported on the diagnostic yield for AF with the Reveal Linq device, a miniaturized ILR with a detection algorithm designed to detect AF. This nonrandomized, prospective trial included 151 patients, most of whom (81.5%) were undergoing monitoring for AF ablation or AF management. Compared with Holter-detected AF, the ILR had a diagnostic sensitivity and specificity for AF of 97.4% and 97.0%.

**Safety of ILRs**

In 2015, Mittal et al reported on safety outcomes related to the use of an ILR, the Reveal LINQ device, based on data from 2 studies, the Reveal LINQ Usability study and the Reveal LINQ Registry. The Usability study enrolled 151 patients at 16 European and Australian centers; adverse events were reported for the first month of follow-up. The Registry is a multicenter
postmarketing surveillance registry, with a planned enrollment of at least 1200. At the time of analysis, 161 patients had been enrolled. For Registry patients, all adverse events were recorded when they occurred. The device is inserted with a preloaded insertion tool via a small skin incision. In the Usability study, 1 serious adverse event was recorded (insertion site pain); in the Registry study, 2 serious adverse events were recorded (1 case each of insertion site pain and insertion site infection). The rates of infection and procedure-related serious adverse events in the Usability study were 1.3% and 0.7%, respectively, and were 1.6% and 1.6%, respectively, in the Registry study.

Section Summary: Implantable Loop Recorders
Studies of prolonged use of ILRs in patients have reported 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 when longer monitoring is needed. Some available trials evaluating the detection of AF after ablation procedures or in patients with cryptogenic stroke used ILRs as an initial ambulatory monitoring strategy, after a negative Holter monitor.

Mobile Cardiac Outpatient Telemetry
This section addresses whether the addition of real-time monitoring to ambulatory cardiac monitoring (MCOT) is associated with improved outcomes. Two factors must be addressed in evaluating MCOT: (1) the inherent detection capability of the monitoring devices and (2) whether the real-time transmission and interpretation of data confers an incremental health benefit. The proposed addition of real-time monitoring suggests that there may be a subset of individuals who require immediate intervention when an arrhythmia is detected. Because it is not clear which patients comprise that subset, or whether identification of those patients in the outpatient setting leads to improved outcomes (e.g., reduced risks of sudden cardiac death), the evaluation of the second factor requires studies that directly assess outcomes, not just arrhythmia detection rates.

One RCT was identified that compared MCOT with standard event monitors.62 This 2007 trial involved 305 patients randomized to the LOOP recorder or to MCOT and monitored for up to 30 days. The unblinded study enrolled patients at 17 centers; those enrolled were patients for whom the investigators had a strong suspicion of an arrhythmic cause of symptoms, including those with symptoms of syncope, presyncope, or severe palpitations occurring less frequently than once per 24 hours and a nondiagnostic 24-hour Holter or telemetry monitor within the prior 45 days. Test results were read in a blinded fashion by an electrophysiologist. Most patients in the control group had a patient-triggered event monitor. Only a subset of patients (n=50) had autotrigger devices, thus precluding comparison between MCOT and autotrigger devices.

A diagnostic end point (confirmation or exclusion of arrhythmic cause of symptoms) was found in 88% of MCOT patients and in 75% of LOOP patients (p =0.008). The difference in rates was primarily due to detection of asymptomatic (not associated with simultaneous symptoms) arrhythmias in the MCOT group; symptoms consisting of rapid AF and/or flutter (15 patients vs 1 patient), and ventricular tachycardia defined as more than 3 beats and rate greater than 100 (14 patients vs 2 patients). These differences were thought to be clinically significant rhythm disturbances and the likely causes of the patients' symptoms. The trialists did not comment on the clinical impact (changes in management) of these findings in patients for whom the rhythm disturbance did not occur simultaneously with symptoms. In this trial, median time to diagnosis in the total study population was 7 days in the MCOT group and 9 days in the LOOP group.

Kadish et al (2010) evaluated the frequency with which events transmitted by MCOT represented emergent arrhythmias, thereby indirectly assessing the clinical utility of real-time outpatient monitoring.63 A total of 26,438 patients who had undergone MCOT during a 9-month period were retrospectively examined. Of these patients, 21% (5459) had an arrhythmic event requiring physician notification, and 1% (260) had an event that could be considered potentially emergent. These potentially emergent events included 120 patients with wide-complex
tachycardia, 100 patients with sinus pauses 6 seconds or longer, and 42 with sustained bradycardia at less than 30 beats per minute.

A number of uncontrolled case series have reported on arrhythmia detection rates of MCOT.64-67 One such published study (2005) described the outcomes of a consecutive case series of 100 patients.64 Patients with a variety of symptoms were included, most commonly, palpitations (47%), dizziness (24%), or syncope (19%), as well as those being evaluated for efficacy of drug treatment (25%). Clinically significant arrhythmias were detected in 51% of patients, but half of these patients were asymptomatic. The authors commented that the automatic detection resulted in an increased diagnostic yield, but there was no discussion of its unique feature (i.e., the real-time analysis, transmission, and notification of arrhythmia).

Studies have evaluated MCOT for detecting AF. In the largest study evaluating the diagnostic yield of MCOT for AF, Favilla et al (2015) reported on results of a retrospective cohort of 227 patients with cryptogenic stroke or TIA who underwent 28 days of monitoring with MCOT.68 AF was detected in 14% (31/227) of patients, of whom 3 reported symptoms at the time of AF. Oral anticoagulation was initiated in 26 (84%) patients diagnosed with AF. Of the remaining 5 (16%) not on anticoagulation therapy, 1 had a prior history of gastrointestinal bleeding, 3 were unwilling to accept the risk of bleeding, and 1 failed to follow up.

In an uncontrolled case series, Tayal et al (2008) retrospectively analyzed patients with cryptogenic stroke who had not been diagnosed with AF by standard monitoring.67 In this study, 13 (23%) of 56 patients with cryptogenic stroke had AF using MCOT. Twenty-seven asymptomatic AF episodes were detected in the 13 patients; 23 of these were less than 30 seconds in duration. In contrast, Kalani et al (2015) reported a diagnostic yield for AF of 4.7% (95% CI, 1.5% to 11.9%) in a series of 85 patients with cryptogenic stroke.69 In this series, 82.4% of patients had completed transesophageal echocardiography, cardiac magnetic resonance imaging, or both, with negative results. Three devices were used and described as MCOT devices: 34% received LifeStar ACT ambulatory cardiac telemetry, 41% received the LifeStar AF Express autodetect looping monitor, and 25% received the Cardiomedix cardiac event monitor. While the authors reported that there was a system in place to transmit the data for review, it is unclear whether data were sent in “real-time.”

In an earlier retrospective cohort study, Miller et al (2013) retrospectively analyzed paroxysmal AF detection rates among 156 patients evaluated with MCOT within 6 months of a cryptogenic stroke or TIA.27 Over a median 21-day period of MCOT monitoring (range, 1-30 days), AF was detected in 17.3% of patients. Mean time to first occurrence of AF was 8.8 days (range, 1-21 days).

**Section Summary: Mobile Cardiac Outpatient Telemetry**

The available evidence has suggested that MCOT is likely to be at least as good at detecting arrhythmias as ambulatory event monitoring. Compared with ambulatory event monitoring, MCOT is associated with the theoretical advantage of real-time monitoring, permitting for emergent intervention for potentially life-threatening arrhythmias. One study reported that 1% of arrhythmic events detected on MCOT over a 9-month period could be considered potentially emergent. However, no studies were identified that addressed whether the use of MCOT is associated with differences in the management of or outcomes after these potentially emergent events. The addition of real-time monitoring to outpatient ambulatory monitoring is considered an enhancement to existing technology. Currently, the evidence does not demonstrate a clinically significant incremental benefit for MCOT.

**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 poststroke 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 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 1 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 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. 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
Clinical Input from Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input
In response to requests from Blue Cross Blue Shield Association, input was received from 3 physician specialty societies and 4 academic medical centers (3 reviews) in 2014. Input was obtained to provide information on mobile cardiac outpatient telemetry (MCOT) and new devices. There was no consensus whether MCOT is medically necessary. While reviewers agreed that MCOT is comparable to event monitors for arrhythmia detection, they did not agree on whether the real-time monitoring provides incremental benefit over external event monitors or is associated with improved health outcomes compared with external event monitors. There was consensus on the medical necessity of externally worn event monitors with longer continuous recording periods as an alternative to Holter monitors or event monitors. For implantable memory loop devices that are smaller than older-generation devices, there was consensus that
these devices improve the likelihood of obtaining clinically useful information due to improved ease of use, but there was no consensus that such devices improve clinical outcomes and are medically necessary.

2009 Input
In response to requests from Blue Cross Blue Shield Association, input was received from 1 physician specialty society and 4 academic medical centers (5 reviews) in 2009. There were differences among reviewers on outpatient cardiac telemetry, with some reviewers concluding it had a role in certain subsets of patients (e.g., in those with sporadic atrial fibrillation). Other reviewers commented that the value of this technology should be considered in both providing a diagnosis and in making treatment decisions. At times, excluding arrhythmia as a cause of a patient’s symptoms is an important finding.

Practice Guidelines and Position Statements
American College of Cardiology, American Heart Association, et al
In 2014, the American College of Cardiology (ACC), the American Heart Association (AHA), and Heart Rhythm Society (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.

In 1999, ACC and AHA published guidelines for the use of ambulatory electrocardiography. These guidelines did not explicitly distinguish between continuous (i.e., Holter monitoring) and intermittent (i.e., 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, European Heart Rhythm Association, et al
A consensus document on catheter and surgical ablation for AF was published in 2012 by HRS, the European Heart Rhythm Association (EHRA), and the European Cardiac Arrhythmia Society. This document did not contain formal practice guidelines, but provided general recommendations based on literature review and expert consensus. Use of AEMs 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 systemic anticoagulation is being considered should consider undergoing continuous ECG [electrocardiographic] monitoring to screen for asymptomatic AF/AFL/AT [atrial fibrillation/atrial flutter/atrial tachycardia].”

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

“ECGs should be obtained at all follow-up visits. More intense monitoring should be mainly driven by the clinical impact of AF detection with strict monitoring being necessary (e.g., in patients with thromboembolic risk factors for determining the adequate anticoagulation approach). Frequent ECG recording using a manually activated event recorder and counseling patients to take their pulse to monitor for irregularity may serve as initial screening tools for asymptomatic AF episodes. A one to seven day Holter monitor is an effective way to identify frequent asymptomatic recurrences of AF. A four-week autotrigger event monitor, mobile cardiac outpatient telemetry system, or implantable subcutaneous monitor may identify less frequent AF.”
European Heart Rhythm Association
In 2009, EHRA published guidelines on the use of diagnostic implantable and external loop recorders. For the indications that EHRA considered established at the time of publication, the guidelines made the following statements about indications for implantable and external recorders (see Table 3).

Table 3. Guidelines on Use of Diagnostic Implantable and External Loop Recorders

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“ILR [implantable loop recorder] is indicated:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• “In an early phase of evaluation of patients with recurrent syncope of uncertain origin who have:”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• “absence of high-risk criteria that require immediate hospitalization or intensive evaluation...”; and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• “a likely recurrence within battery longevity of the device.”</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>“ELRs are indicated in patients with recurrent palpitations, undocumented by conventional ECG techniques, who have: inter-symptom interval &lt;4 weeks and absence of high-risk criteria...which require immediate hospitalization or intensive evaluation.”</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>“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.”</td>
<td>Ila</td>
<td>B</td>
</tr>
<tr>
<td>“ILRs may be indicated in selected cases with severe infrequent symptoms when ELRs and other ECG monitoring systems fail to document the underlying cause.”</td>
<td>Ila</td>
<td>B</td>
</tr>
<tr>
<td>“ELRs [external loop recorder] may be indicated in patients with recurrent (pre)syncope who have:”</td>
<td>Ila</td>
<td>B</td>
</tr>
<tr>
<td>• “inter-symptom interval of ≤4 weeks, and”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• “suspicion of arrhythmic origin and”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• “absence of high-risk criteria that require immediate hospitalization or intensive evaluation...”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

COR: Class of Recommendations; ECG: Electrocardiogram; ELR: External Loop Recorder; LOE: Level of Evidence.

American Academy of Neurology
Also in 2014, the American Academy of Neurology updated its guidelines on the prevention of stroke in patients with nonvalvular atrial fibrillation (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).”
A2. “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
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCTNo.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>Detection of Silent Atrial Fibrillation after Ischemic Stroke (SAFFO)</td>
<td>424</td>
<td>Jun 2019</td>
</tr>
</tbody>
</table>
### 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


**Documentation for Clinical Review**

**Please provide the following documentation (if/when requested):**
- History and physical and/or cardiology consultation report including:
  - Clinical justification for device
  - Description of symptoms present and frequency
  - Name and type of device including vendor name
  - Documentation of prior trial of Holter monitor or external ambulatory event monitor
  - History of atrial fibrillation including (if applicable):
    - Past catheter ablation history
    - Anticoagulation status and plan for discontinuation

**Post Service**
- Ambulatory monitor report

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>0295T</td>
<td>External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation</td>
</tr>
<tr>
<td></td>
<td>0296T</td>
<td>External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial recording)</td>
</tr>
<tr>
<td>Type</td>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
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<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>0297T</td>
<td>External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report</td>
</tr>
<tr>
<td></td>
<td>0298T</td>
<td>External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; review and interpretation</td>
</tr>
<tr>
<td></td>
<td>0497T</td>
<td>External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recorder without 24 hour attended monitoring; in-office connection <em>(Code effective 1/1/2018)</em></td>
</tr>
<tr>
<td></td>
<td>0498T</td>
<td>External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recording without 24 hour attended monitoring; review and interpretation by a physician or other qualified health care professional per 30 days with at least one patient-generated triggered event <em>(Code effective 1/1/2018)</em></td>
</tr>
<tr>
<td></td>
<td>33282</td>
<td>Implantation of patient-activated cardiac event recorder</td>
</tr>
<tr>
<td></td>
<td>33284</td>
<td>Removal of an implantable, patient-activated cardiac event recorder</td>
</tr>
<tr>
<td></td>
<td>93228</td>
<td>External 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; review and interpretation with report by a physician or other qualified health care professional</td>
</tr>
<tr>
<td></td>
<td>93229</td>
<td>External 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 transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional</td>
</tr>
<tr>
<td></td>
<td>93268</td>
<td>External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; includes transmission, review and interpretation by a physician or other qualified health care professional</td>
</tr>
<tr>
<td></td>
<td>93270</td>
<td>External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)</td>
</tr>
<tr>
<td></td>
<td>93271</td>
<td>External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis</td>
</tr>
<tr>
<td></td>
<td>93272</td>
<td>External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis</td>
</tr>
</tbody>
</table>
### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.
Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.