Clinical Policy Title: Continuous ambulatory electrocardiography patch monitoring

Clinical Policy Number: CCP.1337

Effective Date: October 1, 2017
Initial Review Date: September 21, 2017
Most Recent Review Date: November 5, 2019
Next Review Date: March 2021

Coverage policy

Continuous ambulatory electrocardiography patch monitoring is investigational/not clinically proven and therefore, not medically necessary.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

Alternative covered services:

- External memory loop devices.
- Holter monitors.
- Implantable memory loop devices.
• Mobile cardiac telemetry systems (Schreiber, 2014).

Background

Arrhythmia, or irregular heartbeat, is a condition that may lead to stroke or heart failure. The most common form of arrhythmia is atrial fibrillation, which affects 2.7 to 6.1 million Americans. At age 40, the lifetime risk of atrial fibrillation is 26 percent for men and 23 percent for women (Lloyd-Jones, 2004). In a comparison of persons with congenital heart disease with versus without atrial arrhythmia, risk was significantly higher for those with the condition for any adverse event ($P < .0001$), for mortality ($P < .001$), for stroke or heart failure ($P < .001$), and for cardiac interventions ($P < .001$) (Bouchardy, 2009).

The highest arrhythmia rates occur in elderly populations, and the growing proportion of elderly means overall prevalence is projected to increase substantially in the future (U.S. Centers for Disease Control and Prevention, 2017).

Electrocardiography has long been an effective means to monitor heart rhythm. The introduction of the Holter monitor in the 1960s enabled providers to collect helpful data outside the institutional setting, as these devices can capture continuous data on heartbeat for 24 hours. However, an under-use of this service exists in at-risk populations. In 17,398 patients treated at Ontario stroke centers from 2003 to 2013 with a first acute ischemic stroke or transient ischemic attack in sinus rhythm without known atrial fibrillation, only 30.6 percent received a Holter monitor for at least 24 hours (less than one percent at least 48 hours) within 30 days of a stroke or transient ischemic attack (Edwards, 2016).

Electrocardiography is useful for patients who are asymptomatic, or who suffer from symptoms such as anxiety, dizziness, fatigue, light-headedness, palpitations, pre-syncope, shortness of breath, and syncope.

More than one day of monitoring may be needed to detect arrhythmias. Thus, new technologies have developed other ambulatory cardiac monitoring devices, including patch monitors, external loop recorders, external non-loop recorders, smart phone monitors, mobile cardiac telemetry, implantable loop recorders, pacemakers and implantable cardioverter defibrillators with atrial leads, and wearable multi-sensor electrocardiography monitors (Heart Rhythm Society, 2017).

One of these categories, electrocardiography patch devices, may be worn for much longer periods while collecting continuous data have been developed in recent years. The ZIO XT system (iRhythm Technologies Inc.) is small, at three inches in length and 34 grams in weight (Holter monitors are between 100 and 150 grams). It is a wireless, water resistant, adhesive patch that consists of one chip and two electrodes, and continually sticks to the chest for up to 14 days at a time. Approved for use by the U.S. Food and Drug Administration in July 2012, the ZIO uses hydrogel electrodes for clearer electrocardiography tracings. However, ZIO requires the user to mail the device to a cardiologist after use, delaying the time when results are obtained and a diagnosis made (Fung, 2015).
Another new electrocardiography patch is the NUVANT® or SEEQ mobile cardiac telemetry system (Medtronic Inc.). Like the ZIO, the SEEQ has a wireless transmitter, and also makes a continual recording of the heartbeat, but for up to 7.5 days at a time. Also approved by the Food and Drug Administration, it weighs 50 grams, and includes a battery charger. It transmits data to the Medtronic Monitoring Center for continuous monitoring (Fung, 2015).

Another federally-approved device, known as the V-patch (Vpatch CardioPty Ltd.), allows the patient to wear a small device continually for seven days, as the heartbeat is being monitored in real time.

Ambulatory wireless electrocardiography patch monitors have grown rapidly in popularity. In Ontario, Canada, the volume of such monitors increased from 638 to 37,191 between 2006 and 2014. The projection for 2020 ranges from 57,289 to 102,829, depending on the growth trend (Health Services Ontario, 2017).

Technologies other than wireless patches have recently been developed. The extended external auto-trigger loop recorder can record ambulatory heartbeat patterns for seven days. The scope of this policy, however, will be limited to wireless patches.

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- The Cochrane library.

We conducted searches on September 5, 2019. Search terms were: “ECG Patch Monitoring,” “ZIO Patch,” “SEEQ,” and “V-patch.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**
The May 2017 Heart Rhythm Society Atrial Fibrillation Consensus Statement includes patch monitors as one method of ambulatory electrocardiography monitoring (Calkins, 2017). The March 2017 American College of Cardiology/American Heart Association/Heart Rhythm Society Guideline for the Evaluation and Management of Patients with Syncope listed patch monitoring as one of five recommended approaches to electrocardiography monitoring (Shen, 2017). The July 2017 Expert Consensus Statement from the International Society for Holter and Noninvasive Electrocardiology and the Heart Rhythm Society recommends 24- to 48-hour Holter Monitoring for quantitative electrocardiography analysis, but also supports continuous monitoring for 1 to 14 days when additional data on trends are needed, without using the specific term “patch monitoring” (Steinberg, 2017). A briefing that does not recommend for or against use of Zio states there is no evidence comparing the Zio Service with other monitoring devices that have a similar monitoring period (National Institute for Health and Care Excellence, 2017).

The only known systematic review, with 22 studies, comparing electrocardiography patch monitoring (ZIO patch, worn an average of 10.4 days) with Holter monitoring was published in spring 2019. Arrhythmia detection increased with length of time the patch was worn. Supraventricular tachycardia, supraventricular ectopy, and ventricular tachycardia rates were 12.2 percent, 45.5 percent, and 17.3 percent, respectively; detection rates for chronic/sustained and paroxysmal atrial fibrillation were 5.6 percent and 23.3 percent, all greater than rates for monitoring < 48 hours (Yenikomshian, 2019).

A review of 804 elderly persons (average age 75) with no history of arrhythmia or flutter found that the ZIO device detected one or both in 4.0 percent of subjects, nearly half of which were detected during days three through 12 of monitoring (Heckbert, 2018).

A randomized controlled trial analyzed the ability of ambulatory patches to detect atrial fibrillation in high-risk individuals. Subjects wore a self-applied continuous electrocardiography monitoring patch at home for up to four weeks, initiated either immediately after enrolling (n = 1,364) or four months after enrollment (n = 1,291). By the four-month mark, new cases of atrial fibrillation was significantly greater in the group with immediate initiation (53 versus 12 cases, or 3.9 versus 0.9 percent), leading to greater rates of primary care visits and increased initiation of anticoagulants (Steinhubl, 2018).

Articles from recent conference proceedings of the Engineering in Medicine and Biology Society of the Institute of Electrical and Electronics Engineers addressed various aspects of the SEEQ device. The lead author of each study was Jonathan Engel of Corventis, a St. Paul, Minnesota, company that developed SEEQ. Findings include:

- SEEQ was a factor in improper application in 2.3 percent of patients using the device (Engel, 2011).
- In a group of 951 patients, SEEQ detected arrhythmias with significant tachycardia in 2.2 percent of patients, potential brachycardia in 19 percent, atrial fibrillation in 20 percent, and arrhythmias not likely to require treatment in another 58 percent (Engel, 2012).
In a study of 2,231 U.S. patients and 1,053 patients from India with the SEEQ device, specific arrhythmia types were similar between the two nations, except that U.S. elderly had higher prevalence of atrial fibrillation and flutter (Engel, 2014).

Varying weather conditions do not degrade SEEQ’s ability to detect event rates (Engel, 2015).

A comparative study of 146 patients referred for evaluation of cardiac arrhythmia underwent simultaneous ambulatory electrocardiography recording with a conventional Holter monitor and a ZIO adhesive patch monitor. The median days of monitoring were 1.0 and 11.1, respectively, and the median age of patients was 64. ZIO detected significantly more total arrhythmia events than did the Holter (96 versus 61, \( P < .001 \)). In the first 24 hours of monitoring, Holter monitors detected 61 arrhythmias compared to 52 for the ZIO \( (P < .01) \). The ZIO detected two events that the Holter did not; and the Holter detected 11 that the ZIO did not (10 of these later found by the ZIO). Significantly more patients found the ZIO comfortable (93.7 versus 51.7 percent), while significantly fewer stated that ZIO affected activities of daily living (10.5 percent versus 76.2 percent). Most (81 percent) preferred ZIO overall. Partial funding for this study was from iRhythm Technologies, developers of the ZIO device (Barrett, 2014).

Another comparative study of 74 patients at Beth Israel Deaconness Medical Center in Boston who were monitored simultaneously with Holter monitors (median 1.0 days) and ZIO patches (median 10.8 days) found no significant difference in atrial fibrillation burden between the two (58.4 for Holter, 54.7 for ZIO). Atrial fibrillation was identified in 18 more patients using ZIO. Authors state that the data are promising for ZIO, but they call for large efficacy studies. Support for the study came from iRhythm (Rosenberg, 2013).

A study of patients with transient ischemic attack or ischemic stroke were assigned, and had 90 days of follow-up with a Zio patch for 14 days \( (n = 43) \) or with short-term Holter monitor \( (n = 47) \). The detection rate of paroxysmal atrial fibrillation at 90 days was significantly greater in the patch-based group (16.3 percent versus 2.1 percent, \( P = .026 \)) (Kaura, 2019).

A study of pediatric patients <18 years of age that compared 406 subjects with a ZIO patch and 499 with a Holter monitor showed similar arrhythmia detection rates between groups (10 percent versus 9 percent). Of ZIO-detected arrhythmias, 57 percent were detected after 24 hours; all arrhythmias detected by Holter monitor occurred within 24 hours \( (P < .0001) \) (Pradhan, 2019).

A review of 26,751 patients using ZIO for the first time reported a mean wearing time of 7.6 days; only 16 percent wore the device for the full two-week capacity. Authors focus on rates of arrhythmia detection after the first 48 hours, which is typically the maximum wearing time for Holter monitors. Findings include 29.9 percent of first arrhythmias occurred and 51.1 percent of symptom-triggered arrhythmias occurred after 48 hours. Additional detection improved the percent (after 48 hours versus total wearing time) of any arrhythmia from 43.9 percent to 62.2 percent, and of symptomatic arrhythmias from 4.4 to 9.7 percent, both significant at \( P < .0001 \). One of the authors was the founder and Chief Medical Officer of iRhythm, inventor of ZIO (Turakhia, 2013).
A review discusses 1,171 reports of patients who were monitored using the ZIO Patch in 2012 and 2013. The median wear time was 13.0 days. The review determined atrial fibrillation was present in 5.0 percent of all patients; 14.3 percent of first paroxysmal atrial fibrillation occurred after 48 hours of wear. The study was funded by iRhythm (Tung, 2015).

A study of 3,209 children receiving the ZIO Patch for 14 days in the three-year period 2011 to 2013 showed that 390 (12.2 percent) had a detected arrhythmia, and 137 (4.3 percent) had arrhythmias deemed clinically significant to warrant urgent physician notification. The percent of first detected arrhythmias and first symptom-triggered arrhythmias after 48 hours of monitoring were 44.0 and 50.4 percent, respectively. This study was funded by the manufacturer (Bolourchi, 2015).

A total of 332 children age under 18 with a need for electrocardiography monitoring wore the Zio™ patch for up to two weeks (median five days). The device identified arrhythmias requiring new intervention or medical management in 5.1 percent of subjects, and arrhythmias requiring greater clinical surveillance in 4.0 percent. For patients requiring increased surveillance or intervention 56 percent were detected after more than 24 hours of wearing the patch (May, 2018).

A non-randomized review analyzed the care of 174 patients from three California and Texas emergency departments with symptoms of possible cardiac arrhythmia (mostly palpitations, syncope, and dizziness) discharged with ZIO, worn for an average of 6.9 days. A total of 83 patients (47.7 percent) had one or more arrhythmias, and 17 (9.8 percent) were symptomatic at the time of first arrhythmia. The median times to the first arrhythmia and first symptomatic arrhythmia were 1.0 and 1.5 days, respectively. Overall diagnostic yield was 63.2 percent, defined as the number of triggered events without arrhythmias (n = 93) and the number of significant symptomatic arrhythmias detected (n = 17); the 63.2 percent figure was higher than yields from Holter monitors. Authors concluded that ZIO was efficient characterizing symptomatic patients without significant arrhythmia. No manufacturer played any role in this review (Schreiber, 2014).

Members of the arrhythmia service in a Vancouver, British Columbia, medical center, who were not affiliated with any electrocardiography patch manufacturer, commented on the Barrett study of the ZIO Patch. Their belief that these patches “represent the changing face of ambulatory ECG monitoring” is accompanied by a list of concerns (loss of quality, automated rhythm analysis, inability to detect myocardial ischemia) that still need to be addressed (Cheung, 2014).

Policy updates:

A total of one guideline/other and four peer-reviewed references were added to, and two peer-reviewed references removed from, this policy in September, 2019.

References
Professional society guidelines/other:


Peer-reviewed references:


Edwards JD, Kapral MK, Fang J, Saposnik G, Gladstone DJ, Investigators of the Registry of the Canadian


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

No Local Coverage Determinations identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is
not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>33285</td>
<td>Insertion, subcutaneous cardiac rhythm monitor, including programming</td>
<td></td>
</tr>
<tr>
<td>33286</td>
<td>Removal, subcutaneous cardiac rhythm monitor</td>
<td></td>
</tr>
<tr>
<td>93224</td>
<td>External electrocardiographic recording up to 48 hours by continuous rhythm</td>
<td>includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional</td>
</tr>
<tr>
<td>93225</td>
<td>External electrocardiographic recording up to 48 hours by continuous rhythm</td>
<td>recording (includes connection, recording, and disconnection)</td>
</tr>
<tr>
<td>93226</td>
<td>External electrocardiographic recording up to 48 hours by continuous rhythm</td>
<td>recording and storage; scanning analysis with report</td>
</tr>
<tr>
<td>93227</td>
<td>External electrocardiographic recording up to 48 hours by continuous rhythm</td>
<td>review and interpretation by a physician or other qualified health care professional</td>
</tr>
<tr>
<td>93228</td>
<td>External mobile cardiovascular telemetry with electrocardiographic recording,</td>
<td>concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage ( retrievable with query) with ECG</td>
</tr>
<tr>
<td>93229</td>
<td>External mobile cardiovascular telemetry with electrocardiographic recording,</td>
<td>concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage ( retrievable with query) with ECG</td>
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<tr>
<td>93268</td>
<td>External patient and, when performed, auto activated electrocardiographic</td>
<td>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>
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<tr>
<td>93270</td>
<td>External patient and, when performed, auto activated electrocardiographic</td>
<td>rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; includes connection, recording, and disconnection</td>
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<td>93271</td>
<td>External patient and, when performed, auto activated electrocardiographic</td>
<td>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>
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<tr>
<td>93272</td>
<td>External patient and, when performed, auto activated electrocardiographic</td>
<td>rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; review and interpretation by a physician or other qualified health care professional</td>
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<tr>
<td>93285</td>
<td>Programming device evaluation (in person) with iterative adjustment of the</td>
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Implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable loop recorder system

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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
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<tr>
<td>I44.0 - I44.7</td>
<td>Atrioventricular and left bundle-branch block</td>
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<tr>
<td>I45.0-I45.9</td>
<td>Other conduction disorders</td>
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<tr>
<td>I47.0-I47.9</td>
<td>Paroxysmal tachycardia</td>
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<tr>
<td>I48.0-I48.92</td>
<td>Atrial fibrillation and flutter</td>
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<tr>
<td>I49.01 - I49.9</td>
<td>Other cardiac arrhythmias</td>
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<td>R00.2</td>
<td>Palpitations</td>
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<tr>
<td>R42</td>
<td>Dizziness and giddiness [light-headedness]</td>
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<tr>
<td>R55</td>
<td>Syncope and collapse</td>
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<tr>
<td>R94.31</td>
<td>Abnormal electrocardiogram [ECG] [EKG]</td>
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<tr>
<td>Z86.73</td>
<td>Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits</td>
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<table>
<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>C1764</td>
<td>Event recorder, cardiac (implantable)</td>
<td></td>
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<tr>
<td>E0616</td>
<td>Implantable cardiac event recorder with memory, activator, and programmer</td>
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Appendix
No additional information was identified for this section during the writing of this policy.