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: October 2, 2018
Next Review Date: October 2019

Related policies:
None.

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of continuous ambulatory electrocardiography patch monitoring to be investigational/experimental and, therefore, not medically necessary.

Limitations:
None.

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 (hazard ratio 2.50, \( P < .0001 \)), for mortality (1.47, \( P < .001 \)), for stroke or heart failure (2.21, \( P < .001 \)), and for cardiac interventions (3.00, \( P < 0.001 \)) (Bouchardy, 2009). Because the highest rates occur in elderly populations, 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 multisensor 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

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on August 2, 2018. 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

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 24–48-hour Holter Monitoring for quantitative ECG 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).

No systematic reviews or meta-analyses addressing the efficacy of continuously-work ambulatory electrocardiography patches have been published in the medical literature.

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 = 1364) or four months after enrollment (n = 1291). 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 non-comparative study of 75 elderly males prospectively screened with the ZIO Patch documented that atrial tachycardia was present in 67 percent (more than four beats) and 44 percent (more than eight beats). The study received in-kind support from iRhythm (Turakhia, 2015).

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 ZioTM 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).

A randomized controlled trial testing the ZIO ability to detect paroxysmal atrial fibrillation in two United Kingdom medical centers aimed to enroll 120 patients. Interim results from August 2016 showed paroxysmal atrial fibrillation detection in four of 17 cases in the active arm versus zero of 17 cases in the control arm. No manufacturers are involved with this ongoing study (Teo, 2017).

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 three peer-reviewed references were added to, and one removed from, this policy in August, 2018.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
<th>Key points:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steinhubl (2018)</td>
<td>Ambulatory patches detecting atrial fibrillation in high-risk individuals</td>
<td>Randomized controlled trial of 2655 individuals at high risk for atrial fibrillation. Subjects all wore a self-applied continuous electrocardiography monitoring patch at home for up to four weeks. Group initiated monitor immediately after enrolling (n = 1364) or four months after enrollment (n = 1291). 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 (%), 95 percent confidence interval (CI) 1.8%-4.1%). The active monitoring group had more subjects with anticoagulant initiation (5.7 versus 3.7 per 100 person-years, 95% CI, 1.9-2.2); outpatient cardiology visits (33.5 versus 26.0 per 100 person-years, 95% CI, 7.2-7.9); and primary care visits (83.5 versus 82.6 per 100 person-years, 95% CI, 0.4-1.5).</td>
</tr>
</tbody>
</table>
Median days of monitoring were 1.0 for Holter monitors and 11.1 for ZIO adhesive patches, respectively.

ZIO found significantly more total arrhythmia events than the Holter (96 versus 61, \( P < .001 \)).

In the first 24 hours, Holter monitors detected 61 arrhythmias versus 52 for the ZIO (\( P < .01 \)).

Significantly more patients found the ZIO comfortable (93.7\% versus 51.7\%), significantly fewer stated that ZIO affected activities of daily living (10.5\% versus 76.2\%), and 81\% preferred ZIO overall.

Partial funding was from iRhythm Technologies, developer of ZIO.

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Citation | Content, Methods, Recommendations
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**Cheung (2014)**
Observations of improvements and concerns about ZIO Patch

Key points:
- Response to the Barrett study by members of a Canadian arrhythmia service.
- Authors state that patches "represent the changing face of ambulatory ECG monitoring."
- Concerns that need to be addressed include loss of quality, automated rhythm analysis, and inability to detect myocardial ischemia.

**Schreiber (2014)**

Key points:
- Review of 174 patients with symptoms of possible cardiac arrhythmia, discharged with ZIO Patch, which were worn for an average of 6.9 days.
- 47.7\% (\( \% \)) had one or more arrhythmia, and 9.8\% were symptomatic at first arrhythmia.
- Median times to first arrhythmia or first symptomatic arrhythmia were 1.0 and 1.5 days.
- Overall diagnostic yield (number of triggered events without arrhythmias) was 63.2\%, much higher than yields from Holter monitors.
- No manufacturer played any role in the review.

**Turakhia (2013)**

Key points:
- Study of 26,751 patients using ZIO for the first time.
- Mean wearing time of 7.6 days; only 16\% wore the device for the full two-week capacity.
- 29.9\% of first arrhythmias occurred and 51.1\% of symptom-triggered arrhythmias occurred after 48 hours (maximum time wearing Holter monitor).
- One of the authors was a founder and Chief Medical Officer of iRhythm, inventor of ZIO.

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**References**

Professional society guidelines/other:


**Peer-reviewed references:**


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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</thead>
<tbody>
<tr>
<td>33282</td>
<td>Implantation of patient-activated cardiac event recorder</td>
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<tr>
<td>33284</td>
<td>Removal of an implantable, patient-activated cardiac event recorder</td>
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<tr>
<td>93224-93227</td>
<td>Electrocardiographic monitoring [Holter monitors and other event recording]</td>
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<tr>
<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>
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<tr>
<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</td>
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<tr>
<td>CPT Code</td>
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<td>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>
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<tr>
<td>93268</td>
<td>External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download 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>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>
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<tr>
<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; 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 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</td>
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<tr>
<td>93291</td>
<td>Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable loop recorder system, including heart rhythm derived data analysis</td>
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<tr>
<td>93298</td>
<td>Interrogation device evaluation(s), (remote) up to 30 days; implantable loop recorder system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional</td>
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<tr>
<td>93299</td>
<td>Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results</td>
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<tr>
<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>
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<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>
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<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>
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<tr>
<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>
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<tr>
<td>I44.0 - I45.9</td>
<td>Atrioventricular and left bundle-branch block and other conduction disorders</td>
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<tr>
<td>I47.0 - I49.9</td>
<td>Paroxysmal tachycardia, atrial fibrillation and flutter, and other cardiac arrhythmias</td>
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<tr>
<td>I63.00 - I63.9</td>
<td>Cerebral infarction</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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<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>C1764</td>
<td>Event recorder, cardiac (implantable)</td>
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<tr>
<td>E0616</td>
<td>Implantable cardiac event recorder with memory, activator, and programmer</td>
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