Medical Policy

Ambulatory Cardiac Monitors (Excluding Holter Monitors)

Policy Number: OCA 3.35
Version Number: 14
Version Effective Date: 02/01/17

Product Applicability

- All Plan* Products

Well Sense Health Plan
- New Hampshire Medicaid
- NH Health Protection Program

Boston Medical Center HealthNet Plan
- MassHealth
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options ◊

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers the use of ambulatory cardiac monitors in the outpatient setting to be medically necessary when applicable Plan criteria are met, as specified in the Medical Policy Statement and Limitations sections of this policy. **Holter monitoring does NOT require Plan prior authorization when conducted in an outpatient setting.** The Plan considers the use of ambulatory cardiac event monitors (also known as ambulatory electrocardiography [AECG] monitors) as a diagnostic tool using non-continuous monitoring to evaluate eligible members with symptoms suggestive of cardiac arrhythmias to be medically necessary when applicable medical criteria are met. The Plan considers the use of mobile cardiac outpatient telemetry (MCOT) to provide continuous, real-time ambulatory electrographic monitoring and analysis to be medically necessary as a diagnostic alternative to ambulatory event...
monitors only when service-specific criteria are met. The use of single-use ambulatory electrocardiographic (ECG) monitors, self-monitoring ECG technologies, and/or other types of emerging and unproven technology is considered experimental and investigational when used as a diagnostic tool to evaluate symptoms suggestive of a cardiac etiology or for any other indication. It will be determined during the Plan’s prior authorization process if the service is considered medically necessary, experimental and investigational, or not medically necessary for the requested indication. See the Plan’s policy, *Medically Necessary* (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. Review the Plan’s policy, *Experimental and Investigational Treatment* (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment.

All inpatient admissions require Plan prior authorization, as stated in the Prior Authorization/Notification Requirements matrix available at [www.bmchp.org](http://www.bmchp.org) for BMC HealthNet Plan members and [www.wellsense.org](http://www.wellsense.org) for Well Sense Health Plan members. Cardiac monitoring conducted during an authorized inpatient stay does NOT require a separate Plan authorization.

**Description of Item or Service**

There are a wide variety of devices available to conduct outpatient cardiac rhythm monitoring with ambulatory patients and may combine features of multiple classes of devices; variations include the types of monitoring leads used, the duration and continuity of monitoring (i.e., continuous or intermittent monitoring), the ability to detect arrhythmias with or without patient intervention (i.e., automatically activated or patient activated), and/or the mechanism of delivering the information from patient to clinician. Ambulatory cardiac event monitors/ambulatory electrocardiography (AECG) monitors are similar to mobile cardiac outpatient telemetry (MCOT) but with these important differences: (1) Unlike the AECG monitors (with non-continuous monitoring), the MCOT device is completely automatic, continuous, and requires no patient intervention to capture electrocardiographic data when an arrhythmia occurs; and (2) MCOT electrocardiographic data are automatically transmitted to a central service center for immediate interpretation when an arrhythmia is detected. Like a MCOT, the duration of an AECG study is typically up to 30 days. Unlike Holter monitors, event monitors (including pre-symptom recorders, post-symptom recorders, and implantable loop recorders) do not continuously record the heart's electrical activity. The Plan considers single-use ambulatory electrocardiographic (ECG) monitors, self-monitoring ECG technologies, and/or other types of emerging and unproven technology to be experimental and investigational as a diagnostic alternative to AEG monitors and/or MCOT in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias or for any other indication.

**Ambulatory Cardiac Event Monitors:** Also known as ambulatory electrocardiography (AECG) monitors, these are portable, external devices or implantable devices that are used to detect, store, and record electrocardiogram (ECG) data using non-continuous monitoring while a patient is engaged in daily activities, including sleep. These devices are worn externally by patients or subcutaneously inserted

---

*Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.*
into patients to evaluate symptoms that are suggestive of cardiac arrhythmias such as palpitations, dizziness, chest pain, shortness of breath, presyncope, or syncope.

Ambulatory cardiac event monitors document cardiac rhythm on an intermittent basis and devices may be worn externally or implanted. An ambulatory cardiac event monitor with an external loop recorder is activated by the patient when a symptom occurs (pre-symptom continuous loop and post-symptom recorders) or the device is equipped with an auto-trigger external loop recorder to document an asymptomatic event (but still requires that the patient transmit documentation of the event after the asymptomatic episode). An ambulatory cardiac event monitor with an implantable loop recorder performs the same function as an external loop recorder but the inserted device is implanted subcutaneously in the chest region and can be used for longer periods of time. The Plan considers the use of ambulatory cardiac event monitors (also known as ambulatory electrocardiography [AECG] monitors) to be medically necessary as a diagnostic tool to intermittently evaluate eligible members with symptoms suggestive of cardiac arrhythmias.

Examples of ambulatory cardiac event monitors (or AECG monitors) include:

1. **Pre-symptom Memory Loop Recorder**: The patient, upon detecting symptoms, activates the external device, or the device can be activated automatically by sensing the event which triggers the recording. These devices are typically worn at all times for up to 30 days.

2. **Post-symptom Recorder**: The patient temporarily places this external device against his/her chest when symptoms occur and activates the device by pressing a button. The data can be transmitted telephonically in real time or may have a memory loop to store data. These devices are typically worn for up to 30 days.

3. **Implantable Loop Recorder (ILR)**: Also known as an insertable loop recorder, this device is a subcutaneous monitoring recorder for the detection of cardiac arrhythmias. The device is typically implanted in the left pectoral region and stores events when the device is activated automatically according to programmed criteria. The device can also record data when manually activated with a magnet. Insertion is a simple outpatient procedure performed under local anesthesia. These devices may remain implanted for several months.

**Mobile Cardiac Outpatient Telemetry (MCOT)**: Also known as an automatic outpatient cardiac monitoring device, MCOT is a mobile device that provides continuous, real-time ambulatory electrographic monitoring and analysis that is automatically activated and used as a diagnostic alternative to ambulatory event monitors in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias. MCOT is a completely automatic and continuous cardiac monitoring device that requires no patient intervention to capture electrocardiographic data when an arrhythmia occurs; also known as real-time cardiac monitoring or real-time continuous attended cardiac monitoring system. MCOT overcomes limitations of Holter monitors and patient-activated event recorders by providing continuous outpatient electrocardiographic monitoring for periods ranging up to several weeks, if necessary. The device consists of a three
(3)-electrode and a two (2)-channel sensor; the sensor transmits wirelessly to a small portable monitor which can be clipped to the waist or worn on a strap around the neck. Rhythm strips are recorded continuously and analyzed by an automated arrhythmia analysis algorithm. When an arrhythmia is detected, the monitor can transmit the ECG data to the monitoring center utilizing a cellular modem or telephone data line. The patient’s physician is made aware of arrhythmias based on pre-determined notification criteria, tailored to the patient by the physician. Certified cardiovascular technicians analyze the transmissions 24 hours a day, 7 days a week. The prescribing physician selects individualized monitoring thresholds and response parameters. Routine daily telemetry reports are issued to the physician by email, fax, internet or phone. MCOT is similar to ambulatory cardiac event monitoring but with these important differences: (1) Unlike the ambulatory cardiac event monitors (with non-continuous monitoring), the MCOT device is completely automatic and continuous; and (2) with MCOT the electrocardiographic data are automatically transmitted to a central service center for immediate interpretation when an arrhythmia is detected. Like ambulatory cardiac event monitoring, the duration of an MCOT study is typically up to 30 days.

**Self-monitoring Electrocardiogram (ECG) Technologies:** Health monitoring devices (wireless or non-wireless which may be attached to a finger, ear lobe or other body part) or software applications for smartphones and other electronic devices used to monitor ECG, heart rate, oxygen saturation, respiratory rate, and other non-cardiac indications and may be obtained without physician prescription. An example of such a device includes Kardia Mobile (developed by AliveCor and formerly marketed as AliveCor Mobile); Kardia Mobile is a single-channel cardiac event recorder, captures a medical-grade ECG in 30 seconds. The device converts electrical impulses from the user’s fingertips into ultrasound signals that are transmitted to a mobile device’s microphone. Kardia uses FDA-cleared algorithms to instantly analyze the ECG tracing and, in consultation with board-certified cardiologists, can assist in determining the presence of atrial fibrillation or normal sinus rhythm. The device allows users to easily track palpitations, shortness of breath, and dietary, sleep, and exercise patterns. Currently, Kardia Mobile works with iPhone, iPad, and iPod Touch devices, and most Android operating systems, enabling users to capture heart activity data and relay these to their doctor for diagnosis and treatment planning. The Kardia monitors are intended for use in adult patients and are cleared through the FDA 510(k) process as class II devices. Kardia devices have not been tested and are not intended for pediatric use. Kardia is a new technology that competes with Holter monitoring, event monitoring, and mobile cardiac outpatient telemetry (MCOT). Currently, there is insufficient scientific evidence in the peer reviewed medical literature to support the effectiveness of Kardia devices or other self-monitoring ECG technologies, with user difficulties also documented in clinical studies.

**Single-use Ambulatory Electrocardiographic (ECG) Monitors:** Ambulatory ECG monitoring device designed for single use. Zio Patch (developed by iRhythm Technologies Inc.) is the first commercially available, single-use and waterproof ambulatory ECG monitor; the Zio Patch provides non-continuous or continuous monitoring for up to 14 days for patients with suspected cardiac arrhythmia(s). The device is configured with a single lead, monitor, and data storage in an adhesive patch that is approximately 2 x 5 inches. ECG data are stored in an internal flash drive and a patch is applied to the patient’s left pectoral area, and the patient is instructed to wear the patch until it no longer adheres to their skin, or up to 14 days. Patients can press a button on the Zio Patch when they recognize a
symptomatic episode. The patient mails the monitor to a central diagnostic testing facility for evaluation. Zio Patch is waterproof, small, and wire free, which may improve patient compliance with use of the device. The Zio ECG Utilization Service (ZEUS) system is a comprehensive system that processes and analyzes received ECG data captured by long-duration, single-lead, continuous recording diagnostic devices (e.g., the Zio Patch and Zio Event Card). The Zio Patch/Zio Event Card is a new technology that competes with Holter monitoring, event monitoring, and mobile cardiac outpatient telemetry (MCOT). Currently, there is insufficient scientific evidence in the peer reviewed medical literature to support the effectiveness of Zio Patch or single-use ambulatory ECG monitoring with adult and/or pediatric patients.

**Medical Policy Statement**

The Plan considers the use of ambulatory cardiac event monitors and/or mobile cardiac outpatient telemetry (MCOT) to be medically necessary when the following applicable criteria are met for the specified service and documented in the member’s medical record, as listed below in item A for ambulatory cardiac event monitors or item B for mobile cardiac outpatient telemetry (MCOT):

**A. Ambulatory Cardiac Event Monitors:**

Ambulatory cardiac event monitors are considered medically necessary when ordered by the member’s treating provider (with treating provider defined as a physician board certified in a cardiology specialty or the member’s primary care provider in consultation with a physician specialist who is board certified in a cardiology specialty) and the following applicable criteria are met for a Plan member, as listed below in item 1 (for pre-symptom external recorders and post-symptom external recorders) or item 2 (for implantable loop recorders):

1. **Criteria for External Ambulatory Electrocardiography Pre-Symptom External Recorders or Post-Symptom External Recorders:**

   The applicable criteria are met for initial testing (as specified below in item a) or repeat testing (as specified below in item b):

   a. Initial Testing (Up to Twice in a Calendar Year):

      At least ONE (1) of the following criteria is met for initial testing, as specified below in item (1) or item (2) for initial testing:

      (1) Ambulatory ECG (AECG) pre-symptom recorders and/or post symptom recorders are used as a diagnostic alternative to Holter monitoring when ALL of the following criteria are met, as specified below in items (a) through (c):

         (a) The member experiences infrequent symptoms (i.e., symptom less frequently than every 48 hours); AND

         Ambulatory Cardiac Monitors (Excluding Holter Monitors)

*Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.*
(b) The member is age 18 or older on the date of service; AND

(c) The member’s symptoms are suggestive of an arrhythmia that include but are not limited to ANY of the following, as specified below in items I through iv:

i. Member with presyncope or episodic dizziness without obvious cause; OR

ii. Member with unexplained recurrent palpitations; OR

iii. Member with unexplained syncope; OR

iv. Other symptom suggestive of arrhythmia; OR

(2) Member has had a cryptogenic stroke and ALL of the following criteria are met, as specified below in items (a) through (d):

(a) The member is age 18 or older on the date of service; AND

(b) Initial AECG testing will be conducted within ONE (1) month from the time the stroke was diagnosed (which only applies to the initial testing); AND

(c) AECG monitoring will be used to detect suspected paroxysmal atrial fibrillation when prior testing with Holter monitoring has yielded inconclusive results; AND

(d) The results of AECG monitoring will be used to guide medical management with anticoagulants; OR

b. Repeat Testing (More Than Twice in a Calendar Year):

BOTH of the following criteria are met for repeating testing, as specified below in item (1) and item (2):

(1) Repeat testing must meet applicable criteria for initial testing (as specified above in item a); AND

(2) At least ONE (1) of the following criteria is met, as specified below in item (a) or item (b) for repeat testing: ***

(a) Testing with AECG pre-symptom recorders and/or post-symptom recorders has not been performed more than twice in the past one (1)-year period for the member’s current symptom; OR
(b) Testing with AECG pre-symptom recorders and/or post-symptom recorders has been performed more than twice in the past one-year period, but the repeat test will be used to evaluate a new or recurrent, undiagnosed symptom that meets Plan criteria for the AECG pre-symptom recorders and post-symptom recorders; OR

Notes for Ambulatory AECG Pre-symptom Records and Post-symptom Records+: 

** Ambulatory ECG pre-symptom recorders and/or post symptom recorders may be authorized for a total of 30 days for the purpose of documenting the diagnosis of arrhythmias; however, the testing may be discontinued once the symptom-producing arrhythmia has been documented. The average duration of service is 14 days or more.

*** The Plan requires Medical Director review to determine the medical necessity of a request for a repeat study that does not meet Plan criteria, as specified in this policy.

2. Criteria for Implantable Loop Recorders:

ALL of the following criteria are met for an implantable loop recorder, as specified below in items a through c:

a. An implantable loop recorder is used when conventional diagnostic testing (such as electrocardiogram, Holter monitoring, external pre-symptom loop recorder and/or post-symptom loop record) is inconclusive in the evaluation of at least ONE (1) of the following conditions, as specified below in items (1) through (4):

(1) Apparent life threatening event (ALTE); OR

(2) Cryptogenic stroke with testing used to detect suspected paroxysmal atrial fibrillation to guide medical management with anticoagulants; OR

(3) Presyncope, OR

(4) Recurrent unexplained episodes of syncope; AND

b. When a cardiac arrhythmia is the suspected cause of symptoms in a member (with or without structural heart disease); AND

c. The member is age 18 or older on the date of service; OR
B. Mobile Cardiac Outpatient Telemetry (MCOT):

The Plan considers MCOT to be medically necessary when ordered by the member’s treating provider (with treating provider defined as a physician board certified in a cardiology specialty or the member’s primary care provider in consultation with a physician specialist who is board certified in a cardiology specialty) and the following applicable criteria are met, as specified below in items 1 through 4:

1. The member is age 18 or older on the date of service; AND

2. The treating provider has determined that the member has a low likelihood of a potentially life-threatening cardiac event; AND

3. The member has received other diagnostic cardiac monitoring (i.e., hospital inpatient telemetry, Holter monitoring, or ambulatory cardiac event monitoring) with inconclusive results; AND

4. MCOT will be used for ONE (1) of the following indications, as specified below in items a through d:

   a. The member is experiencing infrequent symptoms (less frequently than every 48 hours) suggestive of a cardiac arrhythmias which include at least ONE (1) of the following, as specified below in items (1) through (4):

      (1) Member with presyncope or episodic dizziness without obvious cause; OR

      (2) Member with unexplained recurrent palpitations; OR

      (3) Member with unexplained syncope; OR

      (4) Other symptom suggestive of arrhythmia as determined by the treating provider (e.g., chest pain, shortness of breath); OR

   b. Evaluation of an arrhythmia during initiation, revision, or discontinuation of anti-arrhythmic drug therapy; OR

   c. Evaluation of an arrhythmia during recovery from surgical or ablative procedure for arrhythmia or myocardial infarction; OR

   d. Evaluation of atrial fibrillation as possible etiology after cryptogenic stroke.
Notes Related to MCOT:

† When Plan criteria are met, the Plan will authorize one (1) medically necessary MCOT monitoring session as a diagnostic tool to evaluate the member’s condition/symptoms (with an average duration of 10 to 14 days and not to exceed 30 days per session).

† MCOT may be authorized for a total of 30 days for the purpose of documenting the diagnosis of arrhythmias; however, the testing may be discontinued once the symptom-producing arrhythmia has been documented.

† MCOT monitoring beyond 30 days or subsequent sessions within 12 calendar months of an approved MCOT session requires Plan Medical Director review.

Limitations

1. Contraindications to ambulatory cardiac event monitoring include ANY of the following, as specified below in item a or item b:
   
a. Inability of the adhesive electrode patch to affix to the member’s skin; OR

b. Inability of the member to wear the monitor consistently over the monitoring period.

2. The Plan considers ANY of the following uses of ambulatory cardiac event monitors to be experimental and investigational, as specified below in item a or item b:
   
a. For monitoring the effectiveness of anti-arrhythmia therapy and detection of myocardial ischemia by detecting ST segment changes; OR

b. Following catheter or surgical ablation of atrial fibrillation when Plan criteria are not met (as specified in the Medical Policy Statement section).

3. The use of self-monitoring ECG technologies (e.g., Kardia) and other new and emerging technology used to diagnose and/or monitor cardiac arrhythmia(s) is considered experimental and investigational because the clinical utility and clinical validity of these technologies have not been consistently established; these self-monitoring and emerging technologies may include an ECG monitor combined with a cellular telephone or other personal electronic device or the use of additional software or hardware required for downloading ECG data to a device such as personal computer, smart phone, or tablet.

4. The use of single-use ambulatory ECG monitors (e.g., Zio Patch) is considered experimental and investigational because the clinical utility and clinical validity of these monitors have not been consistently demonstrated and Plan Medical Director review is required to determine the

Ambulatory Cardiac Monitors (Excluding Holter Monitors)
medical necessity of single-use ambulatory ECG monitoring as an alternative to other types of diagnostic cardiac monitoring.

5. Plan Medical Director review is required for the trans-telephonic transmission of results from ambulatory cardiac monitoring for a member who lives in remote areas or at least 100 miles from a physicians capable of interpreting the results; applicable Plan criteria must also be met and documented in the member’s medical record.

6. Plan Medical Director review is required for mobile cardiac outpatient telemetry (MCOT) monitoring in excess of 30 days per session or subsequent sessions of monitoring within 12 calendar months of an approved MCOT session.

7. Plan Medical Director review is required for MCOT monitoring when used as the first method of ambulatory monitoring for a Plan member (rather than other diagnostic cardiac monitoring such as hospital inpatient telemetry, Holter monitoring, and/or ambulatory cardiac event monitoring after inconclusive results).

8. Plan Medical Director review is required for ambulatory cardiac event monitoring (including external ambulatory electrocardiography pre-symptom external recorders, post-symptom external recorders, and/or implantable loop recorders) and/or MCOT monitoring for a member younger than age 18 on the date of service.

Definitions

Arrhythmia: Irregular heart action secondary to a physiological or pathological disturbance in the discharge of electrical impulses or in the electrical transmission that cause dysfunction of the heart pumping mechanism. Examples of arrhythmia include bradycardia and tachycardia. Serious arrhythmias include ventricular tachycardia (VT) and ventricular fibrillation (VF). Both VT and VF are the primary causes of sudden death.

Cryptogenic Stroke: A stroke of undetermined origin. Cryptogenic stroke is defined as a brain infarction that is not attributable to a source of definite cardioembolism, large artery atherosclerosis, or small artery disease despite extensive vascular, cardiac, and serologic evaluation.

Electrocardiogram (EKG or ECG): A test that measures the electrical activity of the heart and used to diagnose cardiac arrhythmias and a wide range of heart disease. Electrodes are placed on the body in predetermined locations to sense electrical activity of the heart.

Holter Monitor: A type of portable heart monitor that is a small electrocardiogram (ECG) device worn in a pouch around the neck or waist. A Holter monitor keeps a record of the heart rhythm, typically over a 24-hour period (up to 72 hours), and the patient keeps a diary of activities and symptoms while wearing the device continuously throughout the recording period. The ECG recording is then correlated
with the person's activities and symptoms. This type of test is useful for identifying heart disturbances that are sporadic and not readily identified with a resting ECG.

Presyncope: Symptoms of dizziness or lightheadedness without loss of consciousness.

Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>33282</td>
<td>Implantation of patient-activated cardiac event recorder</td>
</tr>
<tr>
<td></td>
<td>Plan note: Code used for ambulatory cardiac event monitors.</td>
</tr>
<tr>
<td>33284</td>
<td>Removal of an implantable, patient-activated cardiac event recorder</td>
</tr>
</tbody>
</table>

*Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.*
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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>
</tr>
<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 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>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>
</tbody>
</table>

Plan notes:
1. Only CPT code 93228 or 93229 should be used when billing the Plan for mobile cardiac outpatient telemetry (MCOT) for a Plan member when it is a covered service.
2. This code is NOT covered (with MCOT listed as a benefit exclusion) for the Well Sense Health Plan products (i.e., New Hampshire Medicaid and NH Health Protection Program).
<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description: Code Covered When Medically Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0616</td>
<td>Implantable cardiac event recorder with memory, activator and programmer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Considered Experimental and Investigational</th>
</tr>
</thead>
<tbody>
<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>
</tr>
</tbody>
</table>

Plan notes:
1. Only CPT codes 0295T through 0298T should be used when billing the Plan for single-use ambulatory electrocardiographic (ECG) monitors (e.g., Zio Patch).
2. The Plan considers the use of single-use ambulatory ECG monitors to be experimental and investigational.
### Clinical Background Information

Palpitations are sensations of a rapid or irregular heartbeat and can result from many arrhythmias, including bradycardia, tachycardia, premature ventricular and atrial contractions, sick sinus syndrome, advanced arteriovenous block, or ventricular tachycardia. Episodes of arrhythmias perceived as palpitations can be asymptomatic or lead to syncope. Palpitations that are associated with dizziness, near-syncope, or syncope suggest tachyarrhythmia and are potentially more serious. Certain cardiac conditions can predispose the patient to arrhythmia and palpitations such as cardiomyopathy, congenital heart disease, congestive heart failure, valvular disease, and pericarditis. Non-cardiac causes of palpitations can include hyperthyroidism, vasovagal syncope, hypoglycemia, stimulant drugs, over-the-counter drugs, and prescription medications. The cause of palpitations can often be determined by history and physical examination. A 12-lead ECG evaluation is appropriate in all patients who complain of palpitations. High-risk patients who require ECG monitoring include those

---

**0296T**

External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial recording)

**Plan notes:**
1. Only CPT codes 0295T through 0298T should be used when billing the Plan for single-use ambulatory electrocardiographic (ECG) monitors (e.g., Zio Patch).
2. The Plan considers the use of single-use ambulatory ECG monitors to be experimental and investigational.

**0297T**

External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report

**Plan notes:**
1. Only CPT codes 0295T through 0298T should be used when billing the Plan for single-use ambulatory electrocardiographic (ECG) monitors (e.g., Zio Patch).
2. The Plan considers the use of single-use ambulatory ECG monitors to be experimental and investigational.

**0298T**

External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; review and interpretation

**Plan notes:**
1. Only CPT codes 0295T through 0298T should be used when billing the Plan for single-use ambulatory electrocardiographic (ECG) monitors (e.g., Zio Patch).
2. The Plan considers the use of single-use ambulatory ECG monitors to be experimental and investigational.
with organic heart disease or any heart abnormality that could predispose the patient to arrhythmias. Patients with a family history of arrhythmia, syncope, or sudden death may be at higher risk.

Cardiac arrhythmias occur when there is abnormal impulse formation or disordered conduction of electrical impulses within the myocardium. Depending on the type and severity, arrhythmias can cause palpitations, weakness, dizziness, syncope, hemodynamic complications, or death. Arrhythmias are classified as bradyarrhythmias when the heart rate falls below 60 b.p.m. (beats per minute) and as tachycardia when the rate exceeds 200 b.p.m. The most dangerous type of tachycardia is ventricular tachycardia; it can evolve into ventricular fibrillation, an arrhythmia that is fatal unless corrected immediately. Supraventricular tachycardia originates in the atria and disrupts the normal electrical conduction pathways in the heart. Atrial fibrillation, a relatively common form of supraventricular tachycardia, occurs due to chaotic, uncoordinated electrical activity that causes the atria to quiver. Although atrial fibrillation is not usually life threatening, it can cause transient weakness and distress that, if prolonged, may lead to stroke or cardiac muscle damage.

A variety of treatments have been developed for arrhythmias including anti-arrhythmic drugs, artificial pacemakers, implanted cardiac defibrillators, and ablation of damaged or malfunctioning cardiac tissue. Selection of the appropriate treatment requires an accurate diagnosis, which may be difficult when arrhythmias occur infrequently, unpredictably, or are asymptomatic. To detect infrequent arrhythmias, patients can undergo 24 to 48 hours of continuous outpatient electrocardiographic (ECG) recording with a Holter monitor. Repeated monitoring sessions may be necessary if an arrhythmia does not occur during the first 1 or 2 days. Another method for detecting infrequent arrhythmias is the use of an event recorder, which stores 1 to 2 minutes of ECG data as soon as the patient experiences symptoms and presses a button to activate the device; although this technique enables a much longer period of monitoring, some arrhythmias are asymptomatic or some symptomatic patients may fail to activate the event recorder at the appropriate time.

Ambulatory cardiac event monitors, also known as ambulatory electrocardiography (AECG) monitoring, is usually indicated if the patient’s history, physical examination, and resting ECG cannot determine the etiology of palpitations. AECG is used to characterize, detect, and document abnormal cardiac events that occur during daily activities. Because specific abnormalities may occur only during sleep, exercise, and mental or emotional stress, an ECG may need to be recorded over longer periods of time.

There are two (2) categories of AECG examinations: (1) Continuous recordings that are generally used for 24-48 hours; and (2) intermittent recordings over longer periods of time. Some intermittent event recorders have a memory loop that permits capture of fleeting symptoms, tachycardia onset, and in some cases syncope of infrequent occurrence. When monitoring is performed to evaluate the cause of intermittent symptoms, the frequency of symptoms should dictate the type of recording. Continuous recordings are indicated for the assessment of symptoms that occur frequently, at least once daily, for the assessment of syncope or near syncope and for patients with unexplained palpitations. Holter monitoring for 24-48 hours may be appropriate in patients with daily palpitations. When palpitations occur unpredictably, or do not occur daily, an initial two (2)-week course of continuous loop event recording may be indicated. Continuous monitoring may also be indicated for patients receiving anti-
arrhythmic therapy to assess medication response, to monitor the rate of atrial fibrillation, to analyze the rhythm of patients with pacemakers, implantable cardioverter defibrillators (ICDs) and for the assessment of silent ischemia.

Implanted loop recorders (ILRs) are used to determine if the patient’s symptoms are related to the cardiac rate and can be used on patients with infrequent symptoms when other diagnostic tests are inconclusive. Some ILRs are able to record the ECG continuously with a battery life of 12 to 24 months. The device is typically inserted in the left pectoral region and is done under local anesthesia in an outpatient setting.

If an individual has undergone cardiac monitoring (i.e., hospital inpatient telemetry, Holter monitoring, and/or ambulatory cardiac event monitoring) with inconclusive results or when symptoms occur infrequently (less frequently than every 48 hours), mobile cardiac outpatient telemetry (MCOT) may be medically appropriate for the evaluation of recurrent and explained symptoms and/or for medical management. MCOT is a mobile device that provides continuous, real-time ambulatory electrographic monitoring and analysis that is automatically activated and therefore requires no patient intervention. Examples of MCOT include but are not limited to the following: Cardiac Telecom and Health Monitoring Services of America’s Telemetry @ Home Service, CardioNet Mobile Cardiac Outpatient Telemetry (MCOT) Service, Heartbreak ECAT (External Cardiac Ambulatory Telemetry) (Med net Healthcare Technologies), Heart 2005A, HEARTLink™ II ECG Arrhythmia Detector and Alarm System (Cardiac Telecom Corporation), LifeStar ACT (LifeWatch®, Inc.), SEEQ, Telemetry™ (Scott Care Cardiovascular Solutions) TeleSence 3-in 1 remote cardiac rhythm monitor, and Trove® (Biomedical Systems). At the current time the overall quality of the peer reviewed published evidence is low to verify the clinical utility of self-monitoring ECG technologies and single-use ambulatory ECG monitors (including Zio Patch).

At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) 20.15 includes medically necessary indications for ambulatory electrocardiographic services. NCD 20.15 states that ambulatory cardiac monitoring is eligible for coverage by CMS if it is performed with a marketed, FDA-approved cardiac event device with “pre-event” or “post-event” recorders categorized as a CMS-covered device (e.g., ambulatory cardiac event monitors or Holter monitors) based on their memory capabilities and is used for at least one (1) of the following indications: Detect, characterize, and document symptomatic transient arrhythmias; initiate, revise, or discontinue arrhythmic drug therapy; or carry-out early post-hospital monitoring of patients discharged after myocardial infarction if 24-hour coverage is provided according to applicable CMS coverage guidelines. Unless there is an NCD for the specified device or service, determination as to whether a cardiac monitoring device or service that fits into the framework is reasonable and necessary is according to local Medicare Administrative Contractor (MAC) discretion, and CMS has issued a Decision Memo for Electrocardiographic Services (CAG-00158N) as a framework to aid local contractors in making reasonable and necessary determinations for specific technologies. Verify CMS criteria in the applicable NCD or local coverage determination (LCD) and coverage guidelines in effect on the date of the prior authorization request for a Senior Care Options member.
No clinical guidelines were found from CMS in an NCD or local coverage determination (LCD) specifically for automatic and continuous outpatient cardiac monitoring devices (including mobile cardiac outpatient telemetry [MCOT]), single-use ambulatory electrocardiographic (ECG) monitors (e.g., Zio Patch), and/or self-monitoring ECG technologies (e.g., Kardia). Determine if applicable CMS criteria are in effect for the cardiac monitoring device in an NCD or LCD on the date of the prior authorization request for a Senior Care Options member by evaluating the device’s memory capabilities and indications for use.

**References**


---

Ambulatory Cardiac Monitors (Excluding Holter Monitors)

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.


*Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.*


Hayes Medical Technology Directory. Implantable Cardiac Loop Recorders for Diagnosis and Management of Syncope in Adults. Winifred Hayes, Inc. March 10, 2016.


Ambulatory Cardiac Monitors (Excluding Holter Monitors)


Ambulatory Cardiac Monitors (Excluding Holter Monitors)

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.


Tung CE, Su D, Turakhia MP, Lansberg MG. Diagnostic yield of extended cardiac patch monitoring in patients with stroke or TIA. Front Neurol. 2015;5:266.


<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Approval: N/A Internal Approval: 05/09/06</td>
<td>05/09/06 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>Quality and Clinical Management Committee (Q&amp;CMC)</td>
</tr>
</tbody>
</table>

*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for the Senior Care Options Product(s): 01/01/16
Policy title was Ambulatory Cardiac Event Monitors (Excluding Holter Monitors) from 05/09/06 to 01/31/17. Policy title changed to Ambulatory Cardiac Monitors (Excluding Holter Monitors) as of 02/01/17; as of 02/01/17 this policy includes mobile cardiac outpatient telemetry (after retiring the Mobile Cardiac Outpatient Telemetry medical policy, policy number OCA 3.356, as of 01/31/17).

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/24/07</td>
<td>Added coding and references.</td>
<td>Version 2</td>
<td>04/24/07: UMC 05/03/07: QIC</td>
</tr>
<tr>
<td>04/08/08</td>
<td>No changes.</td>
<td>Version 3</td>
<td>04/08/08: MPCTAC 04/22/08: UMC 04/25/08: QIC</td>
</tr>
<tr>
<td>04/15/09</td>
<td>Clarified prior authorization for ambulatory event monitors.</td>
<td>Version 4</td>
<td>05/26/09: MPCTAC 05/26/09: UMC 06/24/09: QIC</td>
</tr>
<tr>
<td>05/01/10</td>
<td>Updated clinical criteria and coding, clinical information and references.</td>
<td>Version 5</td>
<td>05/25/10: MPCTAC 06/23/10: QIC</td>
</tr>
<tr>
<td>05/01/11</td>
<td>Updated references and coding, added specific limitations that are considered investigational and updated the title.</td>
<td>Version 6</td>
<td>05/18/11: MPCTAC 06/22/11: QIC</td>
</tr>
<tr>
<td>05/01/12</td>
<td>Annual review, no changes made to clinical criteria, CPT code definitions and references updated.</td>
<td>Version 7</td>
<td>05/16/12: MPCTAC 06/27/12: QIC</td>
</tr>
<tr>
<td>07/30/12</td>
<td>Off cycle review for Well Sense Health Plan, deleted reference to ‘eligible’ members, revised the introductory paragraph in Applicable Coding section, revised code list headings, updated code list.</td>
<td>Version 8</td>
<td>08/13/12: MPCTAC 09/13/12: QIC</td>
</tr>
<tr>
<td>12/01/12</td>
<td>Revised applicable code list, updated references, revised language in Description of Item or Service section. Referenced Plan’s Experimental and Investigational Treatment policy, Mobile Cardiac Outpatient Telemetry policy, and Medically Necessary policy. Reformatted criteria in Medical Policy Statement section. Added limitations for repeat studies within one year and for new and emerging technology. Added documentation in Clinical Background Information section related.</td>
<td>Version 9</td>
<td>12/19/12: MPCTAC 01/31/13: QIC</td>
</tr>
</tbody>
</table>

*Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
<table>
<thead>
<tr>
<th>Date</th>
<th>Change Description</th>
<th>Effective Date</th>
<th>Reviewers</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/01/13</td>
<td>Review of effective date 02/01/14. Referenced near syncope in the Description of Item or Service and Definitions sections. Clarified external vs. implantable devices in Description of Item or Service section and Medical Policy Statement section without changing criteria. Updated References and Summary sections. Revised text in Limitations section without changing criteria.</td>
<td>02/01/14</td>
<td>02/18/13: MPCTAC 01/21/14: QIC</td>
</tr>
<tr>
<td>12/01/14</td>
<td>Review for effective date 05/01/15. Revised criteria in the Medical Policy Statement and Limitations sections. Updated Definitions and References sections.</td>
<td>05/01/15</td>
<td>05/17/14: MPCTAC 01/14/15: QIC</td>
</tr>
<tr>
<td>10/01/15</td>
<td>Review for effective date 12/01/15. Updated list of applicable products and corresponding notes. Clarified text in the Description of Item or Service section. Updated references.</td>
<td>12/01/15</td>
<td>10/21/15: MPCTAC 11/11/15: QIC</td>
</tr>
<tr>
<td>11/25/15</td>
<td>Review for effective date 01/01/16. Revised language in the Applicable Coding section.</td>
<td>01/01/16</td>
<td>11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
</tr>
<tr>
<td>10/01/16</td>
<td>Review for effective date 02/01/17. Revised policy title. Included mobile cardiac outpatient telemetry (MCOT), single-use ambulatory ECG monitors, and self-monitoring ECG technologies in the policy (retiring the Mobile Cardiac Outpatient Telemetry medical policy, policy number OCA 3.356 as of 01/31/17). Revised Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections. Revised criteria in the Medical Policy Statement and Limitations sections, adding criteria for medically necessary indications for</td>
<td>02/01/17</td>
<td>10/19/16: MPCTAC 11/09/16: QIC</td>
</tr>
</tbody>
</table>

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCOT</td>
<td>Revised the applicable code list to include additional services. Added Plan notes to the coding section.</td>
</tr>
</tbody>
</table>

Last Review Date

10/01/16

Next Review Date

10/01/17

Authorizing Entity

QIC

Other Applicable Policies

Medical Policy - Experimental and Investigational Treatment, policy number OCA 3.12
Medical Policy - Medically Necessary, policy number OCA 3.14
Reimbursement Policy - General Billing and Coding Guidelines, policy number 4.31
Reimbursement Policy - General Billing and Coding Guidelines, policy number SCO 4.31
Reimbursement Policy - General Billing and Coding Guidelines, policy number WS 4.31

Reference to Applicable Laws and Regulations


Disclaimer Information:

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these

Ambulatory Cardiac Monitors (Excluding Holter Monitors)

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.