Medical Policy

Ambulatory Cardiac Event Monitors (Excluding Holter Monitors)

Policy Number: OCA 3.35
Version Number: 13
Version Effective Date: 01/01/16

Product Applicability

- All Plan+ Products

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</table>

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 event monitors (also known as ambulatory electrocardiography [AECG] monitors) to be medically necessary as a diagnostic tool to evaluate eligible members with symptoms suggestive of cardiac arrhythmias. Ambulatory cardiac event monitors require prior authorization.

It will be determined during the Plan’s prior authorization process if the service is considered medically necessary for the requested use. See the Plan’s policy, Medically Necessary (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment.

Ambulatory Cardiac Event 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.
Description of Item or Service

**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 while a patient is engaged in daily activities, including sleep. These devices are worn externally by patients or subcutaneously inserted into patients to evaluate symptoms that are suggestive of cardiac arrhythmias such as palpitations, dizziness, chest pain, shortness of breath, near syncope, or syncope.

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.

Ambulatory cardiac event monitoring is 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. See Plan policy, *Mobile Cardiac Outpatient Telemetry* (policy number OCA 3.356), for additional information. 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 MCOT, single-use ambulatory electrocardiographic (ECG) monitors, and other types of emerging technology to be experimental and investigational. See Plan policy, *Experimental and Investigational Treatment* (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment.

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Medical Policy Statement

The Plan considers the use of ambulatory cardiac event monitors 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 1 for pre-symptom external recorders and post-symptom external recorders or item 2 for implantable loop recorders:

1. Criteria for 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 BOTH of the following criteria are met, as specified below in item (a) and item (b):

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

(b) 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 near syncope 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 (c):

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

(c) 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:

** 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 Recorder:**

Both of the following criteria are met for an implantable loop recorder, as specified below in item a and item b:

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. Near syncope, 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).

**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 Plan considers mobile cardiac outpatient telemetry (MCOT), single-use ambulatory electrocardiographic (ECG) monitors (e.g., Zio Patch), and other types of emerging technology.
to be experimental and investigational. See Plan policy, *Experimental and Investigational Treatment* (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment.

**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.

**Near Syncope:** An episode in which an individual feels s/he might lose consciousness but does not.

**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 Stated 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

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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>
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<tbody>
<tr>
<td>33282</td>
<td>Implantation of patient-activated cardiac event recorder</td>
</tr>
<tr>
<td>33284</td>
<td>Removal of an implantable, patient-activated cardiac event recorder</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>
<tr>
<td>93270</td>
<td>External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)</td>
</tr>
<tr>
<td>93271</td>
<td>External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis</td>
</tr>
<tr>
<td>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>
</tr>
<tr>
<td>E0616</td>
<td>Implantable cardiac event recorder with memory, activator and programmer</td>
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<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Considered Experimental and Investigational</th>
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<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>
<tr>
<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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<tr>
<td>0297T</td>
<td>External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report</td>
</tr>
<tr>
<td>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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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 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.

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.
The Zio Patch is a new technology that competes with Holter monitoring, event monitoring, and mobile cardiac outpatient telemetry (MCOT). As the first commercially available, single-use, ambulatory electrocardiographic (ECG) monitor, the Zio Patch provides 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. Continuous 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. Currently, there is insufficient scientific evidence in the peer reviewed medical literature to support the effectiveness of Zio Patch.

**References**


Strickberger SA, Benson DW, Biaggioni I, et al. AHA/ACCF Scientific Statement on the evaluation of syncope: from the American Heart Association Councils on Clinical Cardiology, Cardiovascular Nursing, Ambulatory Cardiac Event Monitors (Excluding Holter Monitors)

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Cardiovascular Disease in the Young, and Stroke, and the Quality of Care and Outcomes Research Interdisciplinary Working Group; and the American College of Cardiology Foundation: in collaboration with the Heart Rhythm Society: endorsed by the American Autonomic Society. Circulation 2006; 113:316.


<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
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<tr>
<td>04/24/07</td>
<td>Added coding and references.</td>
<td>Version 2</td>
<td>04/24/07: UMC</td>
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<td>05/03/07: QIC</td>
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<td>04/08/08</td>
<td>No changes.</td>
<td>Version 3</td>
<td>04/08/08: MPCTAC</td>
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<td>04/22/08: UMC</td>
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<td>04/25/08: QIC</td>
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<tr>
<td>04/15/09</td>
<td>Clarified prior authorization for ambulatory event monitors.</td>
<td>Version 4</td>
<td>05/26/09: MPCTAC</td>
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<td>06/24/09: QIC</td>
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<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</td>
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<td>06/23/10: QIC</td>
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<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</td>
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<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</td>
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<td>06/27/12: QIC</td>
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<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</td>
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<td>09/13/12: QIC</td>
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<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 to new technology. Changed name of policy category from “Clinical Coverage Guidelines” to “Medical Policy.”</td>
<td>Version 9</td>
<td>12/19/12: MPCTAC</td>
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<td>01/31/13: QIC</td>
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<td>12/01/13</td>
<td>Review of effective date 02/01/14. Referenced near syncope in the</td>
<td>02/01/14</td>
<td>12/18/13: MPCTAC</td>
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<td>Version 10</td>
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**Policy Revisions History**

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<th>Description</th>
<th>Effective Date</th>
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<tr>
<td>12/01/14</td>
<td>Revised criteria in the Medical Policy Statement and Limitations sections.</td>
<td>05/01/15</td>
<td>05/01/15: MPCTAC</td>
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<td></td>
<td>Updated Definitions and References sections.</td>
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<td>01/14/15: QIC</td>
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<tr>
<td>10/01/15</td>
<td>Updated list of applicable products and corresponding notes. Clarified text</td>
<td>12/01/15</td>
<td>10/21/15: MPCTAC</td>
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<td>in the Description of Item or Service section.</td>
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<td>11/11/15: QIC</td>
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<tr>
<td>11/25/15</td>
<td>Revised language in the Applicable Coding section.</td>
<td>01/01/16</td>
<td>11/25/15: MPCTAC</td>
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<td>(electronic vote)</td>
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**Last Review Date**

11/25/15

**Next Review Date**

10/01/16

**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
Medical Policy - *Mobile Cardiac Outpatient Telemetry*, policy number OCA 3.356
Reimbursement Guidelines - *General Billing and Coding Guidelines*, policy number SCO 4.31
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 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.